Ceramics in Orthopaedics

FRANCESCO BENA
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MARTIN DIETRICH
Editors

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Bearings in Joi

11th BIOLOX® Symp
Proceedings

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Edited by
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Bioceramics and Alternative Bearings in Joint Arthroplasty

11th BIOLOX® Symposium

Rome, June 30 - July 1, 2006
Proceedings

with 177 Figures in 206 separate Illustrations
and 40 Tables

STEINKOPFF DARMSTADT

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ISBN 3-7985-1634-0 Steinkopff Verlag, Darmstadt

Cataloging-in-Publication Data applied for
A catalog record for this book is available from the Library of Congress.
Bibliographic information published by Die Deutsche Bibliothek
Die Deutsche Bibliothek lists this publication in the Deutsche Nationalbibliografie,
detailed bibliographic data is available in the Internet at <http://dnb.ddb.de>.

Steinkopff Verlag Darmstadt
a member of Springer Science+Business Media

http://www.steinkopff.springer.de

Cover Design: TOP DESIGN, Thomas Schuster, Waiblingen

Production and Typesetting: druckerei justus kuch GmbH, Nürnberg

SPIN 11779575 105/7231-5 4 3 2 1 0 - Printed on acid-free paper.

Preface

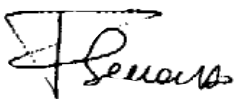
Dear Colleague and Participant in Bioceramics and Alternative Bearings in Joint Arthroplasty: 11th International BIOLOX® Symposium

We are once again very proud of the fact that we have been able to provide you with the proceedings of this Symposium as a part of your registration materials. This is a mayor achievement that could only be made possible by the excellent cooperation of all of the speakers, the publishing house and their staff and the Symposium Administrator and her support staff. Our special thanks to all of them for their hard work and dedication to meet the difficult deadlines required to make this a reality.

The proceedings for this Symposium continue the on-going tradition to provide all of us with a valuable and useful addition to our reference library. We hope that within its covers, you will find the most up to date scientific and clinical information regarding the use of ceramic solutions to address wear related problems in Orthopedic Surgery.

This is the first time that the symposium takes place in Italy. The reason we chose Italy and in particular Rome is obvious as CeramTec has had a long term and close relationship with the Italian. CeramTec is pleased that our Symposium Chairmen, Professors F. Benazzo and F. Falez have collaborated with us in the preparation and in the execution of Bioceramics and Alternative Bearings in Joint Arthroplasty - 11th International BIOLOX® Symposium.

We hope that the quality of the presentations, the openness of the discussions, the efficiency of the organization, the knowledgeable participants and the City of Rome will have all worked together to make this a very special event in the pursuit of increased recognition of the benefits of our BIOLOX® ceramic technology by the Global Orthopedic Surgical community.



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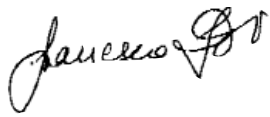

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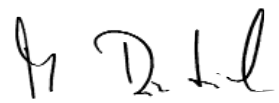

Dr. M. Dietrich
Managing Director
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In memoriam
Prof. Dr. rer. nat. Gerd Willmann

The bioceramics world mourns the loss of Professor Willmann.

On July 3rd 2005, the distinguished professor and former member of the CeramTec Medical Products Division passed away following a short and severe illness.

An internationally recognized researcher, Dr. Willmann's bioceramic and orthopedic implant research greatly contributed to the recognition of alumina ceramics as the ideal wear reduction solution for the young and active patient needs for increased durability from his joint replacement. His extensive publications and presentations are well known to scientists and orthopedic surgeons all over the world. In our opinion, Dr. Willmann's greatest contribution to the field has been the creation of this international recognized medium of exchange of the latest information on the use of ceramics and alternative bearings to the orthopaedic surgical community.

His dedication and genius will continue to be felt in the countless footsteps that might never have been taken. Or in the natural act of holding this book or picking a flower. In these simple ways the world will silently remember this extraordinary man.

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SESSION 1

Large diameter femoral and acetabular components

1.1 Head Diameter of 36mm: New alumina on alumina bearing surfaces

A. Berizzi, M. Tzemtzang and R. Aldegheri

Introduction

On a theoretical basis a larger head diameter permit e wider range of motion and enhance the stability of the implant, reducing the risk of dislocation but increasing the level of friction and the production of debris. The need for a small head diameter (22 or 28 mm) was thus storically connected to the behavior of the metal-polyethylene interface and the problem of PE debris. After the introduction of ceramics the production of debris diminished but the technology didn't permit diameter wider than 28 – 32 mm.

The development of new ceramics with improved mechanical properties permit now to obtain thinner acetabular liners and thus a larger head diameter, without increases the production of debris and the risk of breakage of the liner.

Material & methods

Starting in September 2003 we have implanted 125 consecutive uncemented alumina on alumina THR with an head diameter of 36 mm. The diagnosis was: hip fracture (72 cases), primary hip osteoarthritis (34 cases), avascular necrosis of femoral head (8 cases), dysplastic hip (6 cases), revision of failed THR (5 cases). The mean age at operation was 65 years (16 - 88). The mean follow-up time was 12 months (6-27). This paper is focused on observation about early complication. The implants was performed by all the surgeon of the department, including some residents, at their first experience in THR.

Results

All the patients at the last follow-up have regained complete autonomy during the normal daylife activity. We have had only two dislocations. The first one happened in the third post-op day, while the patient was in Intensive Care Unit, during mobilization for nursing cares. The dislocation was reduced under general anesthesia and didn't recurred. The second one happened in the third post-op week, while the patient was at his home, standing up from a low couch. The dislocation was reduced under general anesthesia, the patient was place in an Hip Spica Cast for 3 weeks and after the removal didn't recurred. One early mobilization of the cup due to poor host bone quality. One early septic loosening. No other mechanical complications due to the implant were noted.

Discussion & Conclusion

The two major problems regarding the utilization of alumina on alumina bearing surfaces in hip arthroplasty is a higher risk of dislocation of the implant and a higher theoretical risk of breakage of the liner or the head. The introduction of a new ceramic with improved mechanical properties permitting larger head size should minimize these risks. This fact, associated to the low production of debris of the alumina bearing surfaces open new prospective in performing THR and revision surgery on failed THR.

1.2 All ceramic tripolar Total Hip Arthroplasty: experimental data and clinical results

J.-Y. Lazennec, H. Sari Ali, M. A. Rousseau and S. Hansen

Introduction

Dislocation remains one of the most common complications after total hip arthroplasty (THA) especially for ceramic-on-ceramic prostheses.

The problem is of outmost importance owing to the rate of revision surgeries, and the increasing longevity of THA patients with decreasing hip girdle muscle mass and progressive changes in hip-spine relationships due to spine aging. Subluxation and microseparation also appear as an important factor for hard on hard joint surface lesions.

An innovative tripolar ceramic system has been investigated to face these problems, using the performance of delta ceramics from CeramTec. The early clinical and radiological results confirm the previous experimental data.

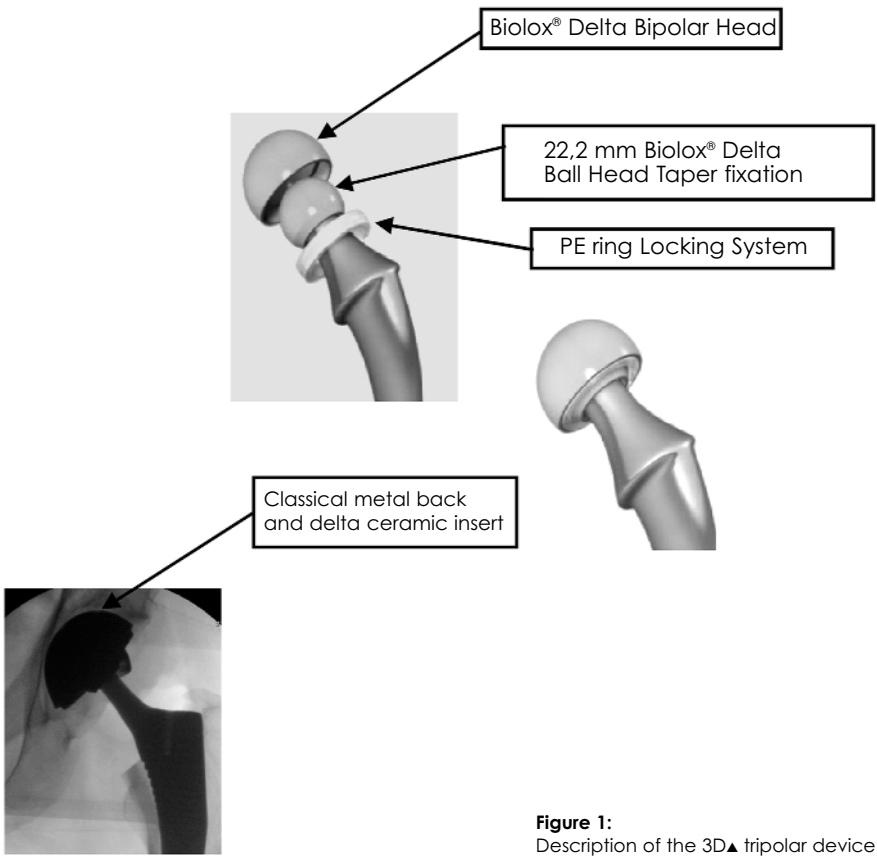

Figure 1:
Description of the 3D▲ tripolar device.

Biomechanical studies

The orientation of the cup in terms of anteversion and inclination appreciably influences the range of motion of the joint and its dislocation resistance.
The use of the 3D▲ tripolar joint seems an interesting alternative to face difficult or unexpected situations for cup adjustment and cases with hip instability.

The position of the rotation center in the cup-ball head system influences joint stability

It has been shown that a few millimeters inset of the rotation center significantly increases the peak resisting moment against dislocation. This benefit in terms of stability has a significant disadvantage due to the decrease of range of motion (ROM) with classical ball-insert systems.

The 3D▲ tripolar joint allows the location of the center of rotation much deeper inside the insert without negative impact on the ROM.

The 3D▲ tripolar joint revealed higher torques against subluxation in comparison to the classical Al-Al systems, even with 36mm head diameters. More stable situations can be obtained even in poor implant positions, while the classical systems dislocate earlier and spontaneously without previous impingement.

The "Self adaptation" of the intermediate cup has been demonstrated with computational models and experimental studies

- The additional outer-bearing surface motion creates a second "adjustable acetabulum" due to the eccentration between the rotation center of the ball head and the rotation center of the bipolar head.
- This offset creates a resultant force that rotates the bipolar component. This phenomenon has been evaluated and validated on computational models.

The system was also investigated using a series of video-based motion analysis tests in two types of loading conditions, shear-out and lever-out situations.

The relative motion of the intermediate component is closely related to the eccentricity between the intermediate component and the femoral head.

The self adjustment of the intermediate component induces significant changes in the the "sliding-rolling" phenomenon and the "jumping distance" in the acetabular cup.

Mechanical performances

The mechanical characteristics of Biolox® Delta enable the manufacturing of this special device and especially of the intermediate cup with excellent strength properties. In collaboration with CeramTec AG a qualification program has been established to evaluate the mechanical reliability of this device. Standard qualification programs have been performed on the 22,2mm Ball Head and the standard XLW fix insert 32/41mm.

Regarding the bipolar (intermediate piece) component, a new program has been set up, based on a ball head qualification program. Specifications of the bipolar component (diameter, roundness, clearance, etc.) are strictly the same as a 32mm ceramic ball head .

The bipolar part shows a particularly high resistance to fracture.

Regarding the PE ring, dislocation tests have been performed to evaluate its resistance to secure the ball head inside of the intermediate component. Results are comparable to similar PE rings that have been used for more than 18 years for classical double-mobility hip joint. The same tests have been performed using the PE ring after 5 millions cycles with micro separation in hip simulator. Results demonstrate that the locking mechanism is still efficient and intact after 5 millions cycles with micro separation, even if this test is very challenging for the components.

Tribological tests

Micro-separation is more appropriate for evaluation of ceramic bearings, as clinical wear rates, wear mechanism and wear debris are reproduced.

The 3D system was tested under standard test conditions and tests incorporating swing phase micro-separation between 200 and 500µm for a total of 5 million cycles.

Wear of the ceramic components could not be detected gravimetrically. There was no visual macroscopic evidence of wear.

In a previous study, wear of conventional Biolox Delta components under microseparation conditions in the same simulator was measurable with reported wear rates of 0.32mm^3/million cycles during bedding-in (0-1 million cycles), reducing to a steady state wear rate of 0.12 mm^3/million cycles (1-5 million cycles). Furthermore, a stripe of wear was formed on the standard Biolox Delta heads . However, no stripe wear was observed in the testing of the 3D▲ tripolar joint.

The wear of the 3D▲ tripolar all ceramic hip was less than 0.01 mm^3/ million cycles, the detection limit for wear measurement.There was no change in the surface roughness of the inserts. The 3D▲ tripolar joint showed reduced frictional torque due to articulation at the smaller diameter 22mm inner femoral head. The wear volume of the PE rings could not be accurately quantified as it was within the systematic error of the soak control ring.

The design of the 3D▲ tripolar joint with the mobile ceramic head prevented edge loading of the head on the edge of the cup, so significantly reducing wear under these severe, but clinically relevant microseperation conditions.

Clinical data

Clinical results show the the efficiency of the system regarding the dislocation rate. To date, no adverse effect has been noted regarding the function of the implanted T.H.A.

A specific radiological protocol allows to observe the adaptation of the intermediate component. Additionnal informations are collected from the the tridimensionnal radiological system EOS: this innovative technology provides accurate informations on the standing, sitting and walking conditions with direct visualization of the T.H.A. and its components.

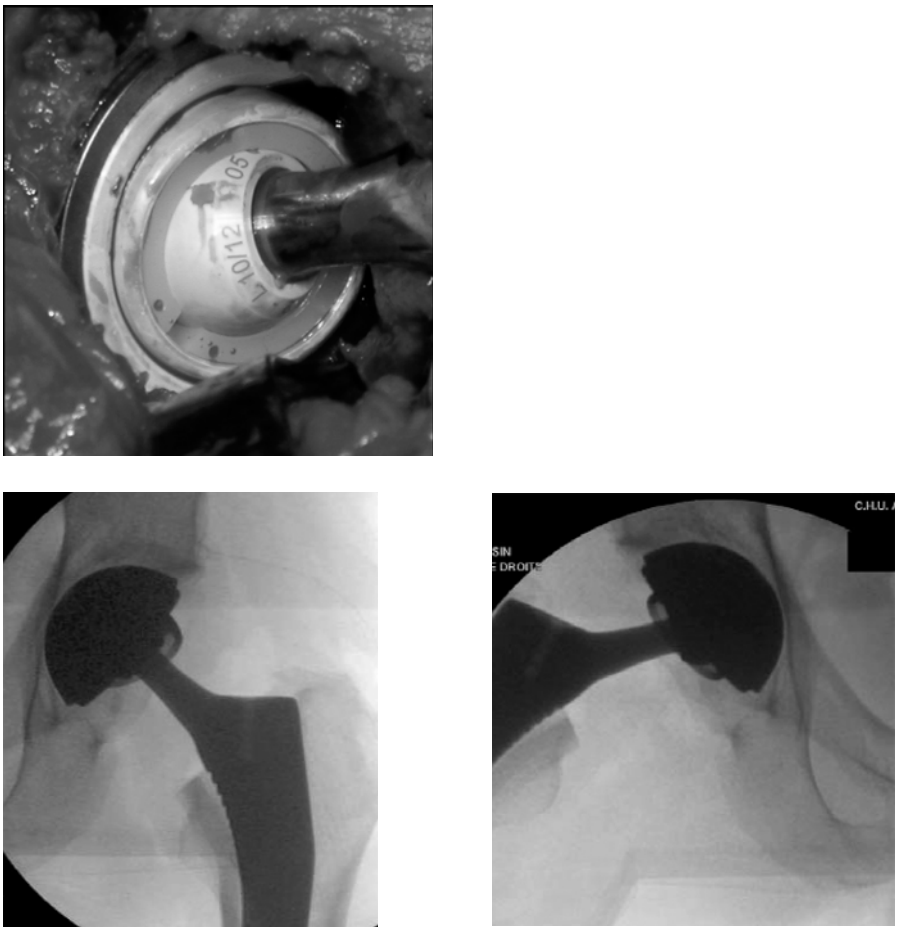

Figure 2:
Implanted 3D system and its adaptation.

Conclusion

The use of the 3D▲ tripolar joint seems an interesting alternative to optimize T.H.A function, as, in some cases, no ideal solution can be found for acetabular implantation. The "self adaptation" of the intermediate cup can be demonstrated: the additional outer-bearing surface motion creates a second "adjustable acetabulum". The efficiency against dislocation and microseparation can be explained geometrically and experimentally.

The tripolar bearing with the mobile ceramic head show very high resistance to wear and stripe wear.

To date, functionnal and radiological results confirm the preclinical studies.

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1.3 Clinical advantages with large diameter heads

N. Santori, R. Giacomi, D. Potestio and F. Chilelli

Introduction

Hip replacement surgery is an elective procedure that is nearly always successful in improving the strength and decreasing pain in a disabled hip. Recently, much interest is focused on the use of large diameters couplings to improve the quality of the results of this operation. In our experience we recognized three major clinical purposes to utilize large heads: decrease dislocation rate, improve feeling of hip stability in young patients and begin accelerated rehabilitation protocol.

Decrease Dislocation Rate

The most common complication the orthopaedic surgeon encounter after total hip replacement is dislocation [1]. This event can be the consequence of a number of factors including previous femoral neck fracture, obesity, osteonecrosis, incorrect "head-to-neck ratio", surgical approach, neuromuscular disorders, cognitive impairment [2,5]. The orientation of the prosthetic components in terms of acetabular abduction and anteversion and femoral anteversion, it is one of the major implant-related factors limiting the range of motion after total hip arthroplasty. Poor positioning of the prosthetic components can determine impingement between the neck and the margins of the acetabular cup, thus facilitating dislocation.

For these reasons, at the very beginning of the hip replacement era, the implants were applied with large diameters balls. These devices were soon abandoned because of the poor quality of the materials available at that time [6]. The improved tribology of modern couplings, with much lower wear, have brought back the large diameters. The advantages of large diameters implants have been specially advocated by those surgeons supporting hip resurfacing. Large diameters enhance stability increase range of motion ROM [7] and reduce the risk of impingement between neck and border of the cup. Other surgeons, not persuaded from hip resurfacing, are now implanting large diameters in conventional total hip replacement. They claim that the advantages of the big heads are the same whether these are applied in surface replacement or on a conventional stem. Obviously this type of coupling can't be used for all patients because of the high costs. However they are gaining more and more popularity for specific groups of patients with high requirements such as young active patients or old patients with neurological diseases [8]. A larger femoral head must travel a greater distance before subluxating or dislocating. This enables a greater range of hip motion before the femoral neck impinges on the acetabular component and levers the head from the shell [9]. All this explains the proportional decrease of dislocation with the increase of femoral head diameter [9,10].

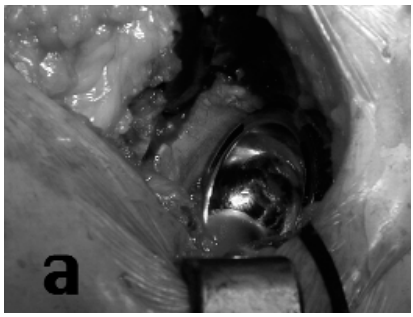
Our current trend for the use of large diameters, either ceramic on ceramic or metal on metal, is largely influenced buy the limited number of implant of this type that the we can perform because of the high costs. The first and main indication is for young and active patients that are likely to be willing to continue an active sportive life. These are the same kind of patients which have recently been considered elective candidates for hip resurfacing. It is our opinion that the same results in terms of hip stability and range of motion, and thus ability to perform sports, can be achieved also with a large diameters head implanted on a conventional, or better, bone preserving uncemented implant. A number of early complications have been described after hip resurfacing [11,12]. We have personally had 2 femoral neck fractures after 4 and 7 weeks respectively, in a limited series of 15 patients. Both fractures occurred raising from a chair without any significant trauma. Other surgeons reported similar high incidence of this serious complication [13]. It is quite difficult, at least in our country, to have our patient accepting these kind of totally new complications, peculiar of the hip resurfacing technique. For this reason, while waiting for more extensive investigations on hip resurfacing, we presently prefer to apply, in young and active patients, an ultra-short bone preserving stem with a large diameter coupling. (Fig. 1a, b).

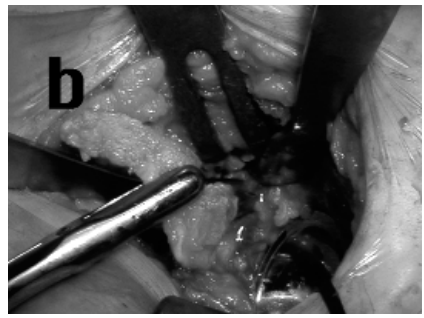
Figure 1a, b:
Ultra short bone preserving femoral implant with large ceramic on ceramic coupling (a) and large metal on metal coupling (b).

Other indication for primary large diameter THR is for us the treatment of a displaced femoral neck patient in a relatively young and active patient. In these patients there is a reported much higher risk of early and late dislocation [14] and, furthermore, there is a high risk of leg lengthening to obtain proper joint tension. In our experience, the use of large diameters significantly lower such complications.

Last, we suggest the use of large diameters in neurological and multiple revision patients. In such cases, the choice of high cost ceramic on ceramic or metal on metal joints or rather a conventional coupling is decided according to life expectancy and level of activity.

Event thought large diameter joints are quite forgetful, this does not mean that the surgeon is allowed to pose less attention during the operation. Maximum care is required in checking the orientation or the components and the absence of impingement with osteophytes (Fig. 2a, b, c).





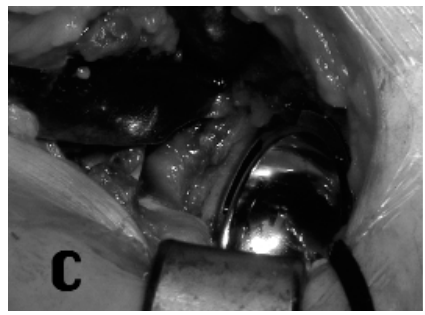


Figure 2a, b, c:
a) A large osteophyte is present on the anterior border of the acetabulum after cup implantation.
b) The exceeding bome is removed with an osteotome.
c) After removal. Impingement of the neck during flexion and internal rotation is no longer possible.

Improve Feeling of Hip Stability

In the healthy hip joint, the femoral head is continually in close and stabile contact with the socket during all movements. The stability of the healthy hip joint is provided by numerous supporting structures around the hip joint, including a thick joint capsule, a system of joint ligaments built in the joint capsule, and a ligament inside the hip joint itself. These joint structures create a passive resistant force on the hip joint that keeps the femoral head in close contact with the hip joint socket during all movements.

Moreover, the 19 muscles surrounding the hip joint provide further dynamic stability. Every surgeon who tried to extract the femoral head from the hip joint in a patient with a broken femoral neck knows how difficult task it is.

On the other hand, during total hip replacement a portion of these supporting structures muscles, ligaments, capsule are divided. Even if the surgeon tries to restore muscle and soft tissue balance by suturing together, there is usually some imbalance of soft tissues left. As a consequence, the artificial head separate transiently from the center of the cup component during gait. This evidence has been demonstrated by X-ray studies of patients with total hip joints. When the operated on leg swings and the hip is not loaded, the femoral ball moves to the upper outer side of the cup component. When the patient's leg comes in contact with the floor and the leg takes the body's weight, the ball returns to the close contact with the whole cup. Thus, the ball moves from the center of the cup to the outside of the cup and then backs like a piston. The "pistoning" movements are small, between 2 to 5 millimeters. Studies showed that these "pistoning" movements occur in all conventional total hips. It is then possible, almost certain, that more movements occur also during other activities without any acknowledgements by the patient.

It is common experience of all those surgeons who have used hip resurfacing, that patients report an increased feeling of having a "normal" hip. It is obviously very difficult to provide a scientific explanation for this finding. Some may believe the better result due to an increased respect of hip proprioception. This is evidently not true. Any operation of hip replacement produces an extensive damage to the peri articular soft tissues and this it is only more true for hip resurfacing were the soft tissue stripping it even more extensive to achieve good exposure of the acetabulum. In that case, the nerve endings around the hip are extensively removed and cannot explain the better feeling of hip stability reported by the patients. What it is more likely, it is that the improved results are due to two other factors. First, in surface replacement, there is, at least in rather normal hips, a better respect of femoral head offset. Second, the large diameter provide less micromovements and a better range of motion. It possible, thought it has not been investigated yet, that the "natural" pistoning, previously described, that occurs in all conventional THR during gait, does not occur here. In our experience, with large diameters metal or ceramic heads applied on conventional femoral implants, we have had exactly the same feed back by our patients. Patients describe their hip as being more "normal" with large diameters coupling, and this is in particular appreciated by those who want to maintain a very active lifestyle.

There is not much science in these assertions because it is not clear why this happen and it is quite impossible to draw a direct relationship between improved results and large diameters. To our knowledge, there is no clear explanations of this clinical findings and we could not find any convincing report explaining the exact mechanism by which large diameters improve the feeling that the patient has of his own hip.

Accelerated Rehabilitation Protocol

One of the request that we have from our patients it is a normal or almost normal range of motion of the artificial joint. Young patients willing to participate in sporting activities require a good range of motion of the hip especially if they are involved in activities like yoga and martial arts. Furthermore, in Asia and the Middle East, many activities are performed while squatting, kneeling, or sitting cross-legged. These positions demand a greater range of motion than that typically required in Western populations. For example, authors report that to squat one requires 130° full hip flexion and 111°-165° (or full) knee flexion. To sit cross-legged one requires 90°-100° hip flexion and 111°-165° (or full) knee flexion [15].

Conventional total hip implants are constructed so that they will allow the patient to flex the thigh from 0 to 90 degrees against the trunk. Flexing the thigh beyond 90 degrees bring the neck of the femoral prosthesis against the rim of the cup. There is no strong joint capsule to keep the ball in place if impingement occur. This is why the patients, in the first weeks after THR, are urged not to bend the thigh beyond 90 degrees against the trunk.

However these restrictions, at least in theory, should not been imposed on those patients receiving THR with large diameters. As previously mentioned, such devices do allow an increased range of motion and thus patients receiving such implants should undergo different postoperative rehabilitation protocols.

In fact, if we want to keep all the benefits of the improved range of motion, we have to allow an early mobilization of the artificial joint. As we know the capsule around the hip is naturally quite thick and also the scar tissue which replaces the capsule after the operation it is very often strong. The result is that, once the soft tissues are healed, not always it is easy to be able to stretch them back. Conventional rehabilitation protocols require no flexion of the hip past 90° for the first 6 weeks and similarly no adduction of the leg past the midline of the body, no combined extension of the hip joint with external rotation and no flexion with internal rotation. These protocols were designed to avoid even the slightest risk of impingement and thus of dislocation. Indeed, such protocols, in most cases do not provide a very good range of motion. By the time the soft tissues are healed, approximately 6 weeks, most of the patients with total hip replacement have acquired only a partial range of motion which is, regrettably, likely to remain all of what they will, get by their new joint. It is obvious that, if the surgeon want to maintain the increased expectations of large diameter THR, should significantly modify his postoperative protocols.

In our practise we have instructed our physiotherapists to have a different approach when they treat a large diameter THR. In particular early flexion above 90° is started from the 2nd week and continued for the first 6 weeks always with the operated leg in external rotation and minimum 10° of abduction. Complete abduction, adduction and internal rotation it is similarly allowed from the 2nd week, but only with the leg in full extension. Internal rotation associated with hip flexion it is never forced at more than 70° of flexion and, anyway, never before the 6th week.

This "aggressive" course of physiotherapy have resulted in a significantly better range of motion for our patients with large diameter THR. Obviously, we would never trust the application of such early mobilization protocol after hip resurfacing where there is already an increased risk of femoral neck fracture [13].

Conclusion

A larger femoral head with a last generation ceramic on ceramic or metal on metal coupling is an useful recent introduction in THR. Most of the clinical advantages reported with the use of hip resurfacing (increased stability, improved ROM and lower dislocation rate) can be reproduced with large diameter joints and a conventional femoral implant. Some concerns still remains on the potential ions release by metal on metal in the long term.

At the present time, not all patients in our practise receive large diameter THR. Restriction of the use of these devices is mostly influenced by the high cost of these components. It is possible that, in the future, large diameter, either metal on metal or ceramic on ceramic, will completely replace the conventional 28mm THR.

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1.4 36mm Ceramic head for "difficult" cases

G. P. Rinaldi, M. Bonalumi, D. Gaietta und D. Capitani

Summary

The heads of big diameter, like Mc Farrar, Ring and Muller, already appeared during the 60's. At that time characterized by a metal - metal coupling, whose sizing generally spared heads from 32mm to 41mm, all the correlated hip joint reconstructions reported quite variable clinical outcomes.

At the end of the 80's new advanced tribological featuring allowed their re-birthing.

The advantages of a 36mm coupling are well known because of a low risk ratio of dislocation, of an high articular range of motion, of it proprioceptiveness and stability.

In our division we are using ceramic heads of 36mm for THA since three years reporting more than 200 cases.

At the beginning of our experience the use of this coupling diameter was elected in according to patient age, because we had availability only of the ceramic-ceramic joint replacement.

Since we have also had the availability of the cross-linked polyethylene for 36 mm coupling, we could extend the indication to almost the totality of the cases. For our THA we use the Delta Acetabular Cup system by Lima Lto company, which allows such a coupling diameter starting from 50mm acetabular size.

We think that the use of this coupling diameter is particularly indicated in so-called "difficult" cases such as:

A. **Acetabular fracture outcomes**, surgically and minimally-invasive treated (Fig. 1, Fig. 2, Fig. 3);

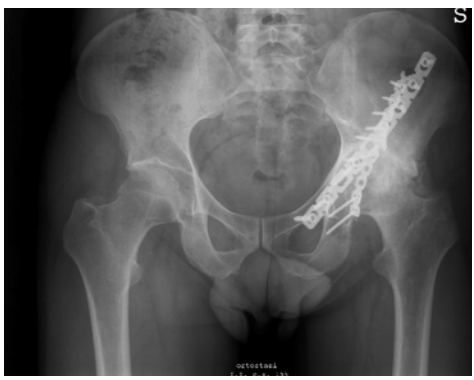

Figure 1:
Preoperative frontal view of acetabular fracture outcome.

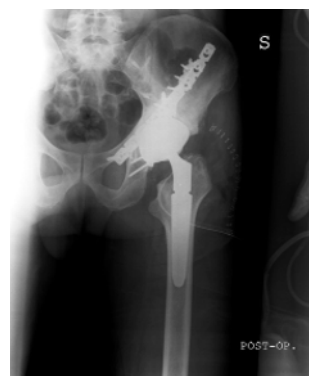

Figure 2:
Same case; postoperative frontal view.

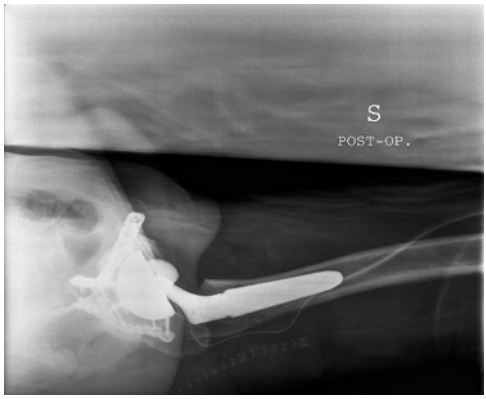

Figure 3:
Same case; postoperative axial view.

B. **Dysplastic Coxarthrosis** as per Crowe grade I° or IV° of severity (Fig. 4, Fig. 5);

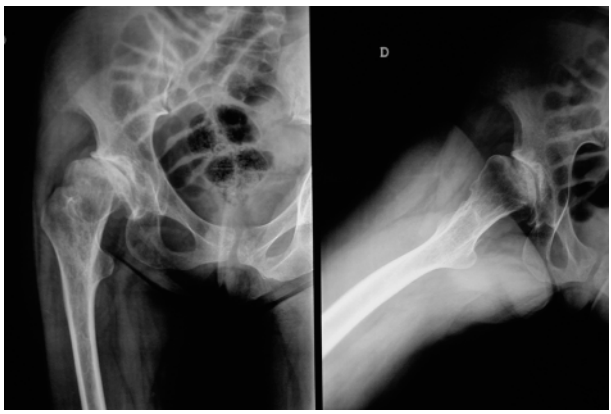

Figure 4:
Preoperative views of dysplasic coxarthrosis.

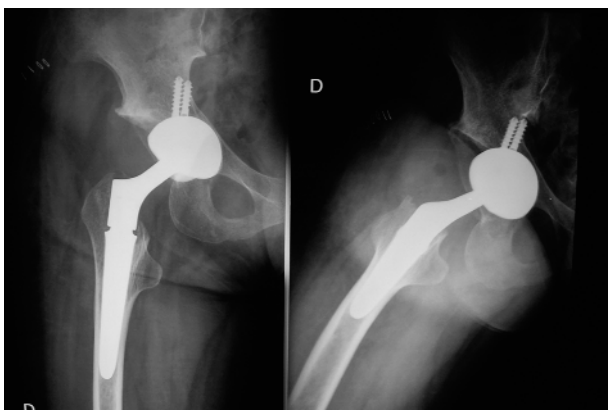

Figure 5:
Same case; postoperative views.

C. **Coxarthrosis in malformed morphologies like** coxa vara, coxa valga, etc, eventually already surgically treated;
D. **Acetabular Revisions**, in elder patients whereas we use 36mm cemented liners supported by Burch-Schneider acetabular reinforcing rings (Fig. 6, Fig. 7, Fig. 8).

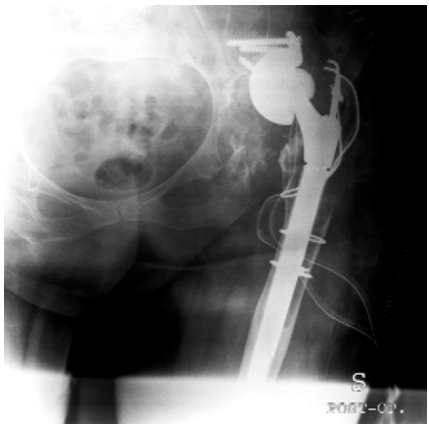

Figure 6:
Acetabular revision; preoperative frontal view.

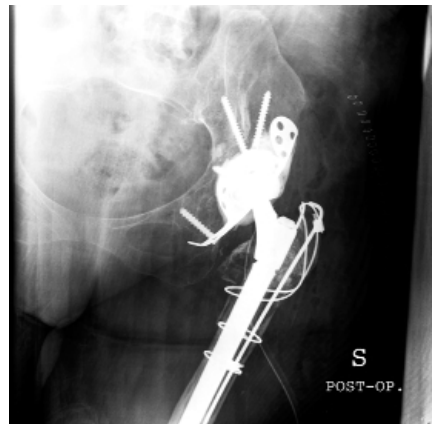

Figure 7:
Same case; postoperative frontal view after implantation of Burch-Schneider acetabular reinforcing ring.

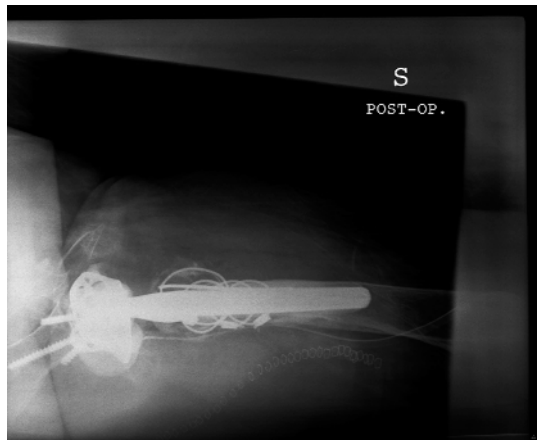

Figure 8:
Same case; postoperative axial view.

For all these cases, the suggested indication to use a 36mm coupling, with eventual ceramic-ceramic joint replacement would take in account of:

- Age: in case of acetabular fracture outcomes, dysplastic coxarthrosis and malformed morphologies, the age of the patients is often inferior to the 50 years and justifies the uses of a ceramic-ceramic joint reconstruction for the neglectable wear (2mm per year).
  In these young patients the demand of functional performance is great, either per use meaning or as per amplitude of articular excursion: the wide range of motion of a 36mm coupling well answers to their requirements.

- Acetabular defects: in case of fracture outcomes and acetabular revisions, the positioning of the cup can not allow a correct anteversion due to a

correlate bone stock loss of the posterior wall, moreover the gluteus muscles is often potentially inefficient, therefore a less risk of dislocation for the 36mm head mm turns out useful.

- In these pathologies the anatomy is often changed profoundly. Osteophytes and ossifications are often present, therefore a big head reduces the risk ratio of a bone to bone or a bone to neck impingement.

- The neglectable wear debris of a ceramic-ceramic coupling does not moreover affect the osteintegration of a morcellized bone-graf, which is often used during the treatment of the aforementioned cases.

Our short Follow-Up of 3 years of experience with the diameter of 36mm, specifically used to treat so-called "difficult" pathologies, considers 30 cases of dysplasia, 8 cases of outcomes of acetabular fractures, 5 cases of dysplasias, 10 cases of acetabular revisions with Burch-Schneider acetabular reinforcing rings.

We have only had an episode of hip dislocation after a complex revision with ring of Burch-Schneider.

The range of motion has been generally evaluated to be 0°-70°, +/- 10° after already 7 days and for all treated cases.

We have not had any loosening of the prosthetic components either in press-fit cups or reinforcing rings combined with cemented polyethylene cup.

We have not had any ceramic incident or breakage.
No signs of radiolucency for each case in correlation with the use of UHMWPE.

At the light of our experience and of the result we have been observing till today, we pursue continually the use of the 36mm joint replacement also for the so-called in the 'difficult' cases.

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SESSION 2

Resurfacing in total hip replacement

2.1 Seven years of experience in MoM resurfacing: Results and open questions

M. Menge

Introduction

Since causal treatment of coxarthrosis as a cartilage disease still is not yet possible, replacing the joint by a total hip replacement constitutes the only solution if conservative therapy fails and affliction is high. While resurfacing has long been practiced in respect of knee joints, early approaches to replace only the diseased or damaged surfaces in the hip joint with artficial surfaces failed mainly for reasons of the materials and fixation techniques used. It was Derek McMinn who in 1991 came up with a metal-on-metal (MoM) hip resurfacing system and later on presented the results obtained from resurfacing [3], which showed that the procedure was useful and safe especially for younger patients. Despite the positive reports that were received from other users [2,11,19] also, there still is a controversial discussion going on after more than 15 years of clinical use. On the occasion of the AAOS in Chicago in March 2006, Lachiewiecz [8] presented the results collected by various authors, and in his conclusion: "Resurfacing Arthroplasty: Time to consider it again?" answered this question by a clear "No". In his opinion, it is especially the rate of early complications, which speak against resurfacing, and he stated that the results obtained from the use of uncemented standard THRs were good enough and would not justify the use of high-risk resurfacing procedures. He stated in particular, that only a "limited number of experienced surgeons" should use resurfacing whereas the majority should wait until the results of 10 years of clinical use were available "before taking on the learning curve". Howie evaluated the results reported by the Australian Orthopaedic Association National Joint Replacement Registry [5] and came to the conclusion that there is a number of well-tried and highly safe procedures available to patients under the age of 65 also. "In younger patients, the theoretical advantages of resurfacing hip arthroplasty are more important, but these need to be balanced against the problem of a young patient unnecessarily entering the downward spiral of multiple revision surgery because of early resurfacing failure" [7].

Failure of resurfacing arthroplasty in the past, as well as the non-approval of implants by authorities in some countries, and the relatively high implant cost or the technical difficulties involved in the surgical procedure, and the possibility of supplementary complications definitely constitute an obstacle to the clinical use of resurfacing hip arthroplasty. Apart from that, good long-term results are reported for some conventional procedures [6]. One thing that seems to be sure is that hip resurfacing is not suited for patients who due to their life expectancy are not likely to have to undergo revision surgery, or for patients whose bone structures are damaged to an extent that will not allow resurfacing for anatomic reasons. On the other hand, there have been complications reported for hip resurfacing, which in the eyes of many surgeons make this procedure inappropriate for younger patients also.

Material and method

We have reported about our own experience several times before [10,11], and came to the conclusion that hip resurfacing should be used in young patients. In this paper, the medium-term experience gained for a number of 1,200 cases over a period of seven years shall be presented, and any unsettled questions are discussed. In the period from 1999 until the end of 2004, we performed a number of 1,201 primary hip resurfacings. The share of female patients was 56.8%, and of male patients was 43.2%. The median age of the male patients was 54.4 [16-73], and of the female patients was 53.6 [21-69] years. The cases treated were either primary or secondary coxarthrosis, and in individual cases was necrosis of the femoral head with the bone structure of the femoral head preserved to a sufficient extent; we excluded cases with extensive bone defects located in load-carrying areas of the femoral head. We did not perform presurgical bone density tests since there was no reason to assume that involution atrophy of the femur would result in an increased fracture rate of the femoral neck in any of our patients.

In most of the cases, the hip joint was accessed from dorsal approach since the patients operated on from lateral access had exhibited a tendency towards postsurgical luxation, and since lateral access of the joint caused higher traumatization of the patient. Apart from that, minimized invasive approach for the purpose of inserting the prosthetis is possible from dorsal access only.
In the following, the problems on which the opponents of hip resurfacing put the spotlight shall be discussed.

Problem No. 1: Early fracture of the femoral neck

A distinction has to be made between early fracture of the femoral neck which may occur as the result of an acute incident without any external cause and without any reliable prodromal signs within a period of up to eight weeks after surgery, and late fracture of the femoral neck which may occur in the form of intracapital fracture with the cap tipping into a varus position, and pain which persists some time before within the first three years after the operation. In our patient group, we had a relatively high rate of 2,8% of postsurgical femoral neck fractures during the first two years. In 1999, there had not been any information provided by McMinn relating to the risks of hip resurfacing. In the seventies, during which Wagner or Freeman caps were used as a resurfacing device, the spotlight had been on problems in connection with acetabular cups although femoral neck fractures also had been observed then [13]. The reason for fracture in our opinion lies in predisposing microfractures, which are generated as a result of the mechanical strain caused when preparing the femoral head and when hammering on the cap, and by excessive exposure of post surgical strain to the hip joint. Also, prolongation of the femoral neck without having the milled head segment covered with the cap naturally will cause increased fragility (Fig. 1). Moreover, notching of the lateral cortex of the femoral neck represents a predisposing factor (Fig. 2).

In the meantime, we are trying to keep the surgical trauma as small as possible, and shorten the femoral head to a level which allows for the cap to cover the milled segment completely, and depending on the type of cap use the smallest

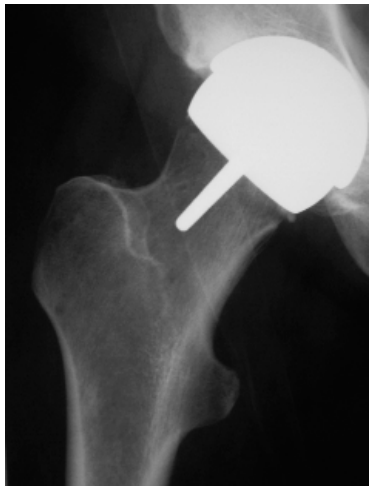


Figure 1a:
50.4 year old female patient with insufficient resection of the femoral head: the milled distal sector is covered by the cap only insufficiently.

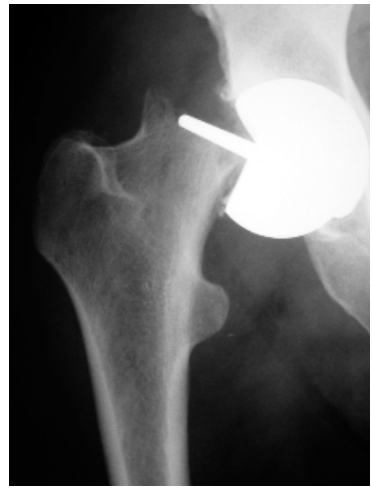


Figure 1b:
The leg was somewhat lengthened. Apart from that, the cap was in a slight varus position. Four weeks later, spontaneous fracture occurred in the spongious area.

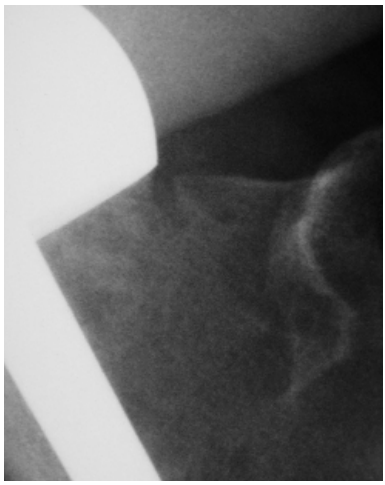


Figure 2a:
In this 55 year old female patient, the lateral corticalis of the femoral neck was affected during milling operations on the femoral head.

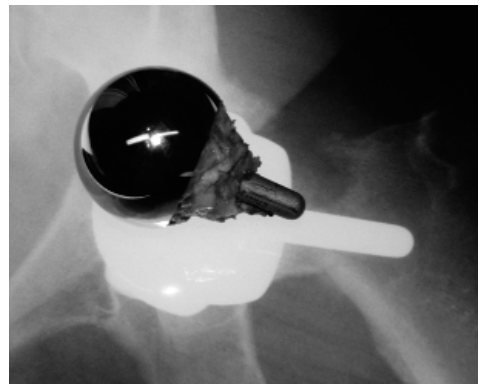


Figure 2b:
Three weeks later, the patient was hospitalized again for reasons of fracture of the femoral neck. Fig. 2b shows a radiograph of the fractured femoral neck with the fracture located in the notch area.

amount possible of low-viscosity cement (Fig. 3). Anchoring holes are reserved for those conditions, where cortical structures cannot be reamed completely. During the first six weeks after the surgical operation, patients are not allowed to do heavy exercise.

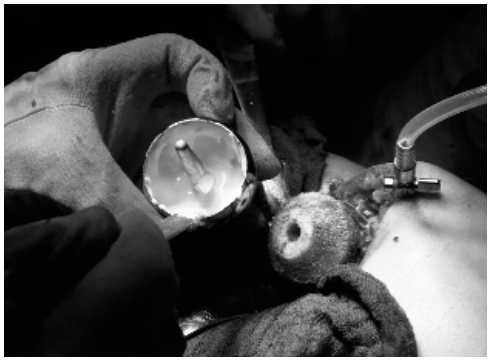
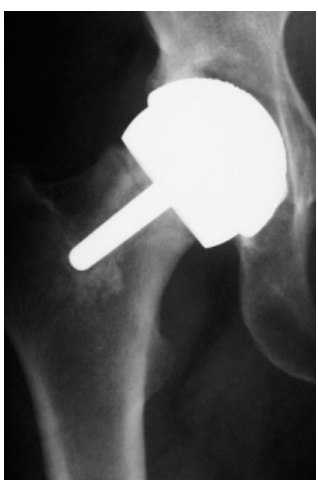


Figure 3:
Cementing was performed using a very thin layer of low-viscosity bone cement on the cap wall. Generally, there aren't any anchorage bores used since leakage of blood to the surface of the femoral head, and increase of intraspongious pressure which may occur when hammering on the cap are eliminated as a result of suction from a cannula located in the greater trochanter.

While in the Australian Orthopaedic Association National Joint Replacement Registry [5] the share of early fractures in the entire number of total revisions is reported to be more than 59%, which corresponds to an approximate rate of 1.3%, the frequency of fractures observed within our study meanwhile is 0.42% in females and 0.5% in males. Hence, we cannot confirm the data indicated by the Australian Registry according to which the risk is twice as high for females. Apart from that, the median age of the patients of our patient group, who experienced fracture of the femoral neck is 53 years, and hence is more or less the same as the one of the entire patient group. For this reason, we cannot confirm that older patients will face a higher risk. As a consequence, we have no longer performed any bone density tests for years but exclusively rely on the radiological presentation of the structure of the femoral head.

Problem No. 2: Avascular necrosis of the femoral head

In our patient group, we revised a number of 12 late fractures of the femoral neck, which occurred after a median period of 19 months (Fig. 4). As causes of such fractures underperfusion of the femoral head accompanied by unphysiological factors including minor circulation are discussed [14]. Since in the case of



a)

b)

Figure 4a, b:
In the first years of clinical use, adhesion bores were provided on the femoral head to enable the use of larger amounts of cement on both the femoral head and the femoral neck. In the sequel, femoral head necroses with intracapital fractures were observed sporadically. The radiograph shows the tipping cap and a seam around the stem (a),with the explant exhibiting necrotic areas of the femoral head underneath the cap (b).

dorsal access the femoral head has to be put into this position only two times for a few minutes each, we believe that this is not a sufficient explanation. We have, however, modified our cementing technique and use only little cement, and avoid anchorage holes. Since then, there has no longer been avascular necrosis of the femoral neck followed by intracapital fracture.

Problem No. 3: Clicking and squeaking

Just like other hard-on-hard bearings, metal-on-metal joints for reasons of the relatively slow movement of the frictional components and the relatively low lubricating capacity of aqueous body fluids tend to be subject to so-called "boundary lubrication" which means that the articulating components are not completely isolated from each other by the fluid film, and that there is a direct contact between the materials mostly under high strain and in slow movements such as in stair climbing. Some patients who had received a BHR-type artificial joint reported squeaking sounds during the first months after the implantation, which lasted for a while and disappeared again after a few days. The rate of such patients is approx. 4% [1]. We have made it a habit to inform the patients about this possible phenomenon prior to the implantation.

Two patients who had received resurfacing arthroplasty the articular cavity of which was smaller than in BHR-type or comparable "classical" implants had to undergo revision surgery because of persisting sounds of the joint, and hence we now use only hip resurfacing devices which respects the classical clearance of about 250µ.

The "clicking sound" which is occasionally observed seems to be due to micro-separation of the articulating components in special movements. At first sight, the larger head diameter seems to allow for improved movability compared to the conventional femoral head which features a diameter of 28 or 32mm, but the obvious benefit offered by the larger head is thwarted by the preserved natural femoral neck: the range of motion offered by hip resurfacing is slightly more than 90° until contact of the femoral neck and the acetabular rim is established. When using resurfacing arthroplasty, the position of the cup is even more important than in conventional standard prostheses. A steeper cup position and a sufficient degree of anteversion of the cup are required to enable sufficient flexion and the preservation of adduction and internal rotation. Otherwise, subluxation involving the relevant clinical afflictions (pain in the groin) will be caused in flexion as a result of impingement of the femoral neck on the acetabular rim.

We had to do revision surgery in four patients for this reason, and had to reposition the cup accordingly.

Problem No. 4: Metal-on-metal

There still is the question of metal abrasion. The concept of using metal on metal is frequently referred to as a knockout criterion as far as the resurfacing procedure is concerned. In the panel discussion which took place on the occasion of the AAOS 2006 in respect of the selection of head and cup materials for the prosthetic treatment of young patients, seven of the nine prominent panelists voted in favor of metal-on-metal bearings (28mm), while only the

remaining two panelists preferred ceramic-on-ceramic bearings. Since both, the large-head version and the 28mm system cause the cobalt and chromium levels in the blood to increase, it is hardly understandable that the resurfacing prostheses are refused for the sole reason of material problems. There wasn't any carcinogenic effect detected [15,18]. Metal incompatibilities are rare [4]. We had to perform revision surgery in three patients because of persisting afflictions, and found lymphocytic infiltrations in one patient only. Also, allergic reactions do not have to be expected even in the case of established cutaneous allergies [12]. Nevertheless, the release of metal ions to the body remains a problem in females of childbearing age: McMinn detected cobalt and chromium ions in the umbilical cord blood in ten females who had received metal-on-metal bearings. It is still unclear whether and in as much such increased levels have an effect on both, the embryonic and the later development of the child [9]. At any rate, this item should be mentioned when discussing prosthetic treatment with female patients who plan to have children. In view of the long-term results obtained from various studies [15,18], the discussion relating to the promotion of tumors has ceased.

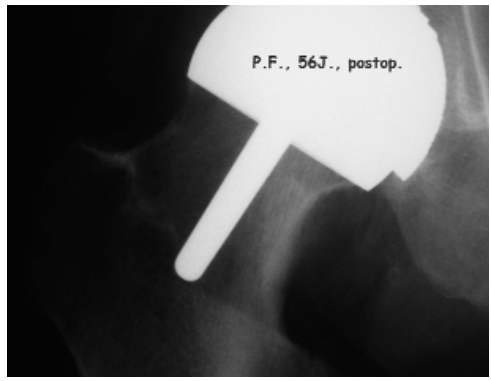
Discussion

It is the low loss of bone substance on the femoral part, and hence the ease of revision, which constitutes the essential benefit, offered by hip resurfacing, and which make this method particularly predestined for patients whose life expectancy is still high. If resurfacing arthroplasty should fail, it will after all be possible to use any other type of prosthesis that will suit the patient. Moreover, the high stability of the joint owing to a larger head diameter, and the preserved proprioception of the proximal femur make resurfacing particularly suited for physically active patients. However, there are special risks connected to hip resurfacing, which seem to be a problem, such as early fracture of the femoral neck that after all causes almost 60% of the revisions reported by the Australian Orthopaedic Association National Joint Replacement Registry. Since resurfacing involves a number of special technical processes, the method should exclusively be used by clinical centers with relatively high operating volumes. The method is not recommended to "low-volume-surgeons" since the learning curve is long.

Conservation of the natural femoral neck prevents the expected benefit of increased range of motion owing to the use of larger heads. The alternative use of a larger head than necessary and hence of a larger cup will be connected to a corresponding loss of bone in the acetabulum and cannot be justified in respect of the general prognosis of an uncemented pressfit cup. Also, the steeper cup position, which is necessary because of possible impingement problems, could harbor the risk of earlier loosening upon exposure of the acetabular implant to eccentric strain. So far, there hasn't been any tendency towards implant loosening been observed.

Release of metal ions to the body owing to abrasion, and the problem of clicking or squeaking joints, as well as rare incompatibilities and possible risks to the unborn child in female patients of childbearing age seem to be further arguments against the use of MoM resurfacing. Apart from that, there have been first signs of possible unfavorable effects of remodeling ("thinning" of the femoral neck, (Fig. 5)), which also could constitute a long-term risk. Finally, it will be the

a)



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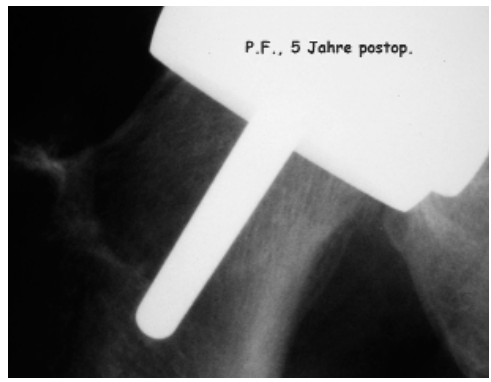

Figure 5a, b:
Remodelling of osseous structures occurs more rarely in resurfacing arthroplasty than in shaft-type THRs. The radiographs show the postsurgical condition (a) of a 56 year old patient, and atrophy of the peripheral structures around the cap opening also referred to as "thinning" after a period of five years (b).

actually measured results that will be decisive. It was shown by the results obtained by us so far, that the supplementary risks of hip resurfacing i.e. early fractures, frictional problems, longer operating times and higher surgical difficulty were compensated by quicker rehabilitation and high satisfaction of the patient [10]. The question "Resurfacing Arthroplasty: Time to consider it again?" asked in the beginning must definitely be answered by "yes". The statement saying that resurfacing will cause "patients unnecessarily enter the downward spiral of multiple revision surgery because of early resurfacing failure" can neither be derived from the data indicated by the Australian National Joint Replacement Registry, nor can it be concluded from the data gathered by us. Selfevidently enough, there still are aspects which should be improved in the further development of hip resurfacing: on the one hand, enlarging the range of motion for instance by providing a notch on the cup rim would be feasible while on the other hand there are first approaches towards the improvement of tribology for instance by using ceramic-on-metal or ceramic-on-ceramic bearings. Until then, the implants according to McMinn, which have been used so far, will provide us with an excellent therapeutical instrument for the treatment of younger patients. However, the use of these devices and the more difficult technique should be restrained to centers with highly trained surgeons where adequate numbers of cases were performed and that are trained to avoid and to deal with the possible complications of hip resurfacing technologies.

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2.2 Surgeon and resurfacing: considerations after a long experience

F. Ravasi and P. Sirtori

Background

Resurfacing prostheses do not represent a novelty in orthopedics. In fact, in the 1950s several resurfacing devices had been already developed by Charnely (1950) and Muller (1968). Although this project was abandoned due to the use of inadequate materials like Teflon and polyethylene, it has been resumed in the last ten years. Since apparently the problems of wear have been resolved, the resurfacing philosophy has spread again following the latest trends in searching bone stock preservation, high implant stability, easer surgical revisions and the possibility of restoring normal hip biomechanics. The cases which have been most accurately studied are those reported by Mc Minn [1] and Amstutz [2] which show interesting data on follow-ups and survival curves.

In the last few years, however, the resurfacing procedure has been largely implemented by surgeons worldwide, even though their experience has not been much consolidated in this field, and their practice has also highlighted resurfacing risks and complications. In particular, some weaknesses have emerged as fractures of the femur neck and avascular necrosis of the femoral head, typical complications due to resurfacing [3,4]. Probably, the surgical technique needed for implanting a resurfacing prosthesis is not so easy, and the required learning curve implies unavoidable failures which are above all due to an incorrect indication for this type of prosthesis, to the vascularization's typology of the femoral head and to an inaccurate implant of prosthetic components.

Our experience, started enthusiastically in 2000, has gone through the stages described below, even though with some standstills and afterthoughts which have allowed us to identify the main causes of our failure and find out how to avoid them.

Methods

From March 2000 to March 2006, 127 resurfacing prostheses were implanted at the Orthopedic and Traumatological Division of St. Raffaele Hospital in Milan. These included 103 BHR and 24 MRS. At present, examinations are performed on the first implants, in particular the first 60 prostheses which had a longer follow-up period. Among the first 60 cases, 33 were male and 27 were female, with an average age of 47.9 years (min.= 25 - max.= 76), and the average follow-up period was 44 months (min.= 27; max.= 72). The candidates for the implant were patients aged less than 60 years with the exception of one case (72 years) who, though being older than the maximum required age, had a good quality of bone. The treatment with resurfacing prostheses was indicated for the cases of coxarthrosis, cephalic necrosis of the femur (Steimberg I-III), congenital hip dysplasia (Crowe I-II), which, however, did not have significant anatomical alterations.

In all the cases included in the follow up had BHR implant (MMT). The acetabular component was cementless, while the femoral one was cemented. Operations were carried out by two surgeons (FR and LT) using a posterolateral approach. A "transosseus" suction system was always used to improve the quality of femoral cementation as much as possible under vacuum conditions.

All patients started walking rehabilitation with the load on the operated limb from the second day after surgical intervention. The use of braces was interrupted within the first 60 days. A clinical evaluation was made according to HHS before the operation and, after discharge, at 5 weeks, 6 months and 1 year from operation. Radiographic examinations were performed immediately after operation at 5 weeks, 6 months, and 1 year. Then, the patients with follow-up were examined clinically and radiographically on a yearly basis.

Results

Clinical checks showed a significant improvement of HHS score at 6 months from the operation (Table 1) in the 57 patients having no complications causing an early failure. Their improvement remained essentially unchanged during the

N° subject				
Follow up	Basal	1 month	6 month	12 month
HHS	51.9	73.6	89.9	90.57
P Value		<0.02	<0.001	<0.001

Table 1:
Mean value of Harris Hip Score (HHS) obtained in subjects undergone to hip resurfacing during follow up; statistical comparisons between HHS obtained preoperatively and those obtained during the clinical evaluations.

subsequent checks (Table 1). Radiographic examinations revealed anomalous positions of the components such as an inadequate insertion, an excessive verticality, and an anomalous antiversion or retroversion of the acetabular component (Fig. 1). At femoral level, an evaluation was made of any anomalous positions in case of excessive varus or valgus deviation, of the exposure of the femoral head spongiosa due to milling, and of the superolateral notching (Fig. 2). Any migration of prosthetic components was also assessed. No migration of prosthetic components was highlighted by the periodical radiographic checks, while a periacetabular lysis occurred three years after implant caused the mobilization of an acetabular component. Five cases showed an inclination of the acetabular component of more than 50°. The anomalies in antiversion and retroversion positions assessed in the axial projection were considered significant if greater than 30° in case of antiversion or equal to neutrality in case of retroversion. Six cases, where an excessive antiversion was observed, did not show any signs of implant instability. In 3 cases we observed a superolateral notching and in 1 case there occurred an excessive circumferential abrasion of the neck of the femur. After 5 years, a periprosthetic thinning of the neck of the femur was noticed in 8 cases. The reported complications included, in particular, those specifically associated with the procedure and those generally caused by hip prosthesis surgery.

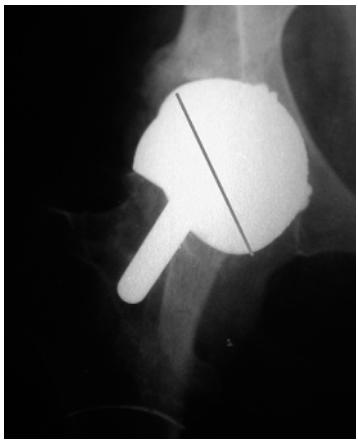

Figure 1:
Anomalous positions of the acetabular components: the AP x-ray reveled excessive verticality of the acetabular component.

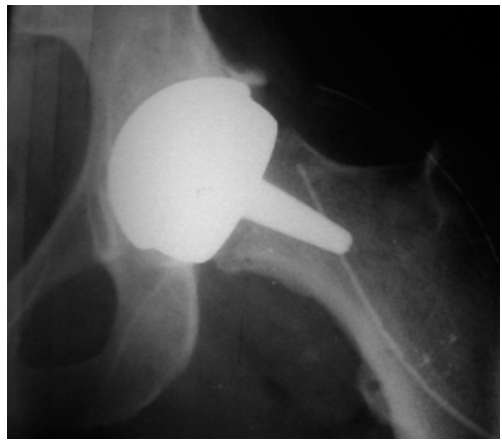

Figure 2:
Anomalous positions of the femoral components: the AP x-ray reveled an excessive varus deviation of the femoral component.

Specific complications comprised two fractures of the neck of the femur at 6 months and 8 months from operation despite the fact that the initial radiographic assessment had confirmed its normal conditions. These 2 cases required an early revision. Both patients were male aged over 50 years.

In 1 patient a revision was performed at 43 months from operation due to a severe metallosis caused by edge wear.

Among common complications associated with traditional prostheses, there occurred a deep infection, two periprosthetic calcifications, and a mobilization of an acetabular component.

The failure rate due to fracture of the neck of the femur was 3.3%, while the revision rate in the cases examined, including the mobilization of the cotyle and the deep infection, was equal to 8.3%.

All the above complications refer to the first 60 implants; in the subsequent 67 cases there were no fractures or revisions of the prostheses, so the percentage of fractures of the neck of the femur fell to 1,6% and the percentage of revisions dropped to 3.1%.

Discussion

Our first experience with resurfacing prostheses persuaded us to analyze the results critically and formulate some reflections.

The clinical results of the 56 resurfacing prostheses which did not cause any complications were definitely favorable for a 5-year follow-up period. The improvement of the HHS score remained constant with time and, in general, patients showed an excellent joint mobility, even if in 2 cases an occasional "squeaking" occurred during movement. Implants proved stable and there were no dislocations. Similarly, our examinations revealed a moderate dysmetria of not more than one centimeter after operation. High satisfaction was reported by the patients who resumed sports activities after operation.

However, when considering failures, we must take note that a percentage of 1.57% of the fractures of the neck of the femur and a percentage of 3.1% of the revisions do not seem acceptable when compared to all cases. Failures apparently occurred during the first phase of our experience and in particular in the first 60 cases. This may be due to the learning curve inherent to the procedure both in terms of technical aspects and indications.

In the 2 cases where the fracture of the neck of the femur occurred, no particular technical problems were found during the implant, and the radiographic check performed after operation did not reveal any misalignment of the implant. The ages of the patients (56 and 59 years) were the highest of the examined cases and one patient weighed 105 kg. The histological examination performed in the patient who had a fracture at 8 months after operation showed signs of cephalic necrosis.

We attributed the two failures to the patient weight and age as well as to technical problems associated with a failure of preservation of the femur neck vascularization.

The international literature reports the same complications we observed in our studies [5]. In particular, the actual risk of this procedure is the fracture of the neck of the femur. Therefore, we have tried to point out the elements of potential failure in an attempt to avoid them.

According to the data reported by literature and in light of our first experience, we can identify some elements which must serve as guidelines for using this type of implant.

Strict observance is required for the indications which must be well defined in terms of age, sex, bone quality, patient weight, and hip morphology [6].
It is common opinion [1-5] that osteoporosis is absolutely contraindicated for this operation and this is related directly to patient sex and age. Poor mineralization of bone, alone or associated with the damages caused by the treatment of the femoral head, produces stress microfractures in the area between the neck of the femur and the implant, which may lead to fracture. The best results are achieved in patients aged less than 50 years, and this is the age range to which we are currently limiting the indication of this implant.

Among the biological and morphological factors predisposing to fractures, it is necessary to consider both the pathology and the morphology of the head and neck of the femur which are connected one to the other [7]. Arthritis is the most suitable pathology for the specific indication even in case of dysplasia, provided that it is low-grade dysplasia. The cephalic necrosis can be treated if it has not damaged more than one third of the head (Steimberg I-III). The varus deviation of the femoral neck predisposes to an increase in bending stress of the prosthesis due to the protuberance of the proximal end of the femur. Moreover, in this case the valgus deviation of the femoral cup often causes the superolateral notching to counterbalance the anatomical shape; the superolateral notching represents another factor predisposing to fracture [8] (Fig. 3).

We believe that the head shape is particularly important: an non spherical head with a relatively large neck will predispose to a higher risk of an excessively milled neck and/or superomedial impingement (Fig. 4).

The aspects most strictly related to the implant technique have made us understand that a treatment with resurfacing prostheses is not easy to perform, if all parameters are to be complied with in order to ensure successful results with time. Our experience and the data reported by literature showed that the main

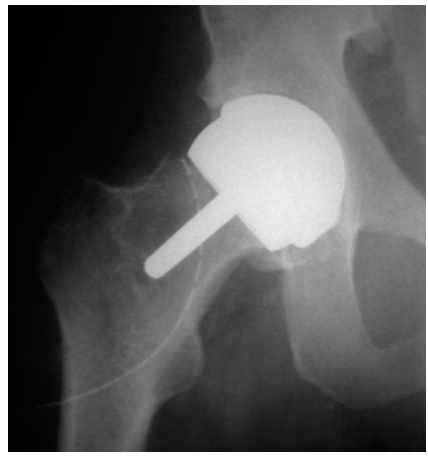

Figure 3:
Anomalous positions of the femoral components: the AP x-ray reveled the supero-lateral notching that represents a factor predisposing to fracture.

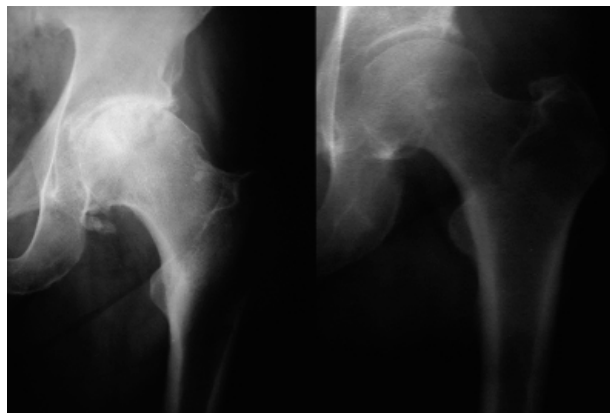

Figure 4:
At the right a normal femoral head, at the left site a "pistol grip" deformity femoral head: a non spherical head with a relatively large neck will predispose to a higher risk of failure because an excessively milled neck.

risk factors of failure due to the implant technique are the varus deviation of the prosthesis, the abrasion of the superolateral portion of the neck, the exposure of the neck spongiosa, the conflict between the prosthesis and the neck due to underdimensioned implants, the excessive verticality of the cotyle and/or implant subdislocations. Finally, we cannot ignore the vascularization of the femoral head during the surgical approach. The main femoral head vascular contribution in adults is given by the femoral medial circumflex artery (FMCA) which from the internal obturator penetrates into the superolateral portion of the femoral neck, at this site it is more likely cause a damaged by the insertion of the prosthetic cup or by the dissection of extra-rotator muscles during surgical approach. Moreover, it is well-known [9,1] that excellent results have been achieved in the treatment with resurfacing prostheses just using a posterolateral approach. The low incidence of cephalic necrosis is explained by the fact that vascularization allows to preserve the pericephalic soft tissues ensuring a correct anastomosis with the FMCA and, as a consequence, with the inferior gluteal artery. Another possibility is that of a prevailing endosseous circle which has become hypertrophic during the development of the atrophic pathology [4]. There exists also a hypothesis based on mechanics according to which, since in most of the cases, the polar portion of the head is removed, a large area likely to be subject to necrosis would

be eliminated, because the resurfacing involves the neck and not the head [4]. However, it is important to revalue the points of access to hip which do not cause any iatrogenic lesion to the FMCA [10]. An evidence of this is given by Wagner's prostheses, which, though being unsuccessful due to tribological problems, did not fail as a consequence of cephalic necrosis, since the author used an anterolateral approach.

Before choosing these prostheses, it must be taken into consideration that we use a metal-metal coupling, in particular chromium-cobalt. This material may trigger intolerances and allergies which should not be underestimated since, they cause prosthesis failure.

Much has been said on the tribological aspect in relation to a possible metallosis caused by the use of metal-metal prostheses [11], but, since the metallurgic element of modern prostheses is considered safe, there remains the personal experience of cases of very severe metallosis due to edge wear. This is the consequence of an incorrect compliance between the surfaces in contact or a misalignment of the acetabular cup which, in case its verticality or antiversion is excessive, puts the femoral cup in contact with its own edge, thus producing a consequent rapid wear of the surfaces and causing metallosis. Attention should then be paid in order not to underestimate the misalignment of the components, since a large diameter head, more stable than a small head, compensates any implant defects in terms of stability.

The thinning of the neck of the femur, which sometimes is revealed by radiographic examinations after some years from operation, is an observational datum which requires further studies for a correct interpretation.

Conclusions

Last generation resurfacing systems represent the best solution between the highest preservation of the femoral bone and the reliability with time in young patients, on condition that indications and exclusion criteria are observed and a high precision technique is used for performing the implant. The main problem is still the fracture of the neck of the femur which must be described in detail to the patient on which this procedure will be carried out. According to the data reported by literature, the incidence of the fracture of the neck of the femur ranges between 0.2% and 2%. When comparing these data with the incidence ranging between 0.33 and 4.51% of the dislocations caused by traditional prostheses, the obvious question is whether this complication, in case of well osteointegrated prostheses, is a problem less difficult to handle than the fracture of the neck of the femur.

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2.3 Hip Resurfacing – a superior articulation concept?

R. M. Streicher

Introduction

Hip Resurfacing is an idea and concept dating back to the end of 1800's and restarted with metal components by Wiley around 1938. The concept of using a thin bearing only covering the affected surface of the hip instead of a total hip arthroplasty (THA) is intriguing. The big diameter implant restores the normal anatomy. Compared to a THA it increases the range of motion and reduces the risk for impingement. The overall stability of the hip joint is improved and the stemless femoral component of the arthroplasty saves bone stock for a later revision. Several attempts with Surface Replacement (SR) arthroplasty have been made historically with various designs and materials, an example shown in Figure 1. First metal-on-metal (MoM) was used, then plastic- or ceramic-on-metal and even ceramic-on-ceramic. All these historic couples failed already in the short-term, either due to surgical issues, lack of permanent fixation, necrosis, deformation with high friction and reaction to wear particles.

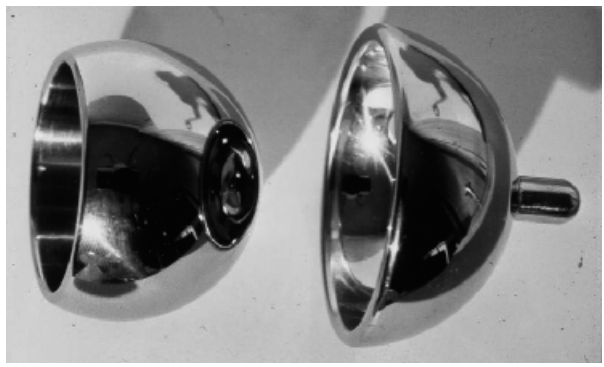

Figure 1:
Historic metal-on-metal Resurfacing (Müller) from 1967.

The renaissance of the resurfacing concept has been started after the re-introduction of the MoM articulation for THA in 1989 [1]. Because the low wear and the high strength and stiffness of the CoCr alloy allowed for thin components the concept of SR was re-evaluated. Apart from improved joint stability it was thought that tribological a large diameter bearing would allow developing a permanent lubrication film to separate the articulation metallic surfaces during the patient's activity from each other and, thereby reducing the friction and also the wear.

Permanent and continuous lubrication in a human joint is difficult to achieve with its varying force and velocity, a turning point at zero velocity and the individual lubrication regime during a walking cycle and tiny wear particles are released into the local tissue. If a MoM concept is used metal wear products can be detected not only in the peri-prosthetic tissue but also in distant organs like liver, spleen and lymph glands [2,3]. Due to the dissolution of the metal in the body environment ions are released, distributed throughout the body creating

potential biological issues. A reduction in the wear rate, especially the high running in wear in the early phase of the ambulation is, therefore important for the long-term success of THA and SR.

Material and Methods

A series of hip joint simulator studies with various MoM couples was conducted. The specimens were manufactured from Co-28Cr-6Mo-0.2C alloy. A total of 27 MoM combinations were fabricated and investigated using two different hip joint simulators and test protocols.

The first set of experiments was conducted using a MTS 8 station hip joint simulator in 50% diluted bovine serum. First, two conditions (cast and cast/solution annealed) of the CoCr-alloy with 40 mm diameter articulation were compared and a second generation MoM THA with 28 mm diameter used as control in a short 1 million cycle test. The as-cast components had an average grain size of 1-2 mm with hard $M_{23}C_6$ and M_7C_3 (M = Co+Cr+Mo) carbides of approximately 20 µm diameter embedded in the matrix. The 28mm articulations were manufactured from hot worked (WF) CoCr-alloy with an average grain size of 20 µm and carbides of 2-3 µm.

Subsequent experiments tested the consistency of the early results using a set of as-cast 40 mm diameter articulations with a radial clearance of 50-90 µm for 5 million cycles. The test was repeated then with another set of 40 mm diameter articulations with a lower radial clearance of 25-50 µm.

A final experiment was conducted using a commercial SR implant of 50 mm in a physiological anatomical Leeds I PA simulator for 5 million cycles. Comparative wear control data was obtained from a previous test using the same simulator and protocol for a commercial 28 mm THA bearing [4].

Results

The result of the comparison between two different types of cast 40 mm diameter MoM articulations and conventional MoM THA of 28 mm is depicted in Figure 2. The average wear rate at 1 million cycles for the solution treated 40 mm bearings was about four times that of the as-cast bearings, indicating that the presence of carbides plays a significant role in the wear performance of MoM joints. Interestingly, the second generation MoM (28 mm) wore less only a non significantly different rate compared to the first generation as-cast bearings (p = 0.29) despite the difference in the diameter and material.

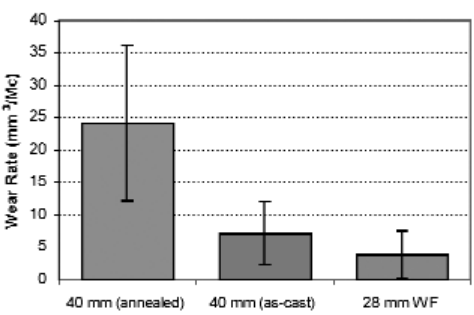

Figure 2:
Hip simulator wear rate of MoM articulations.

The subsequent test for the as-cast 40 mm bearings exhibited inconsistent, erratic wear behaviour, depicted in Figure 3a. While several of the tested bearings showed the well known running in period with a steady-state wear rate later of less than 1 mm³/million cycles, 38% of the bearings showed excessive wear with two bearings exhibiting a run-away wear pattern after 1 and 4 million cycles, respectively.

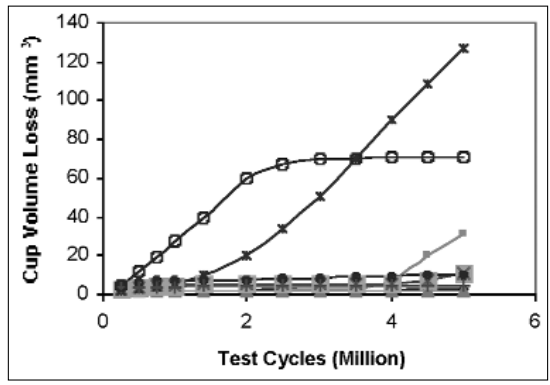

Figure 3a:
Wear rates of 40 mm MoM bearings, showing erratic behaviour.

The run-away wear rates were 30 and 40 mm³/million cycles and the serum of the chamber was discoloured by the high amount of wear particles, shown in Figure 3b.

Figure 3b:
Lubricant during the run-away wear regime.

The subsequent tests with the reduced clearance of the 40 mm bearings yielded similar results with 25% of the bearings exhibiting run-away wear. No reason for this behaviour could be detected.

On the 50 mm SR the wear scars appeared on the head and cup early in the test and were located in the superior quadrant. Figure 4 shows the volumetric wear as a function of the number of cycles for the SR and the comparative data for the 28 mm MoM THA pairings [4]. The running in wear was far higher for the large diameter SR than for the comparative MoM THA. Following the running in period the wear rate of the SR decreased but remained still higher than for the 28 mm THA. At 5 million cycles the total volumetric wear of the SR was 3.27 mm³, and was higher on the cup, making up 62% of the total wear.

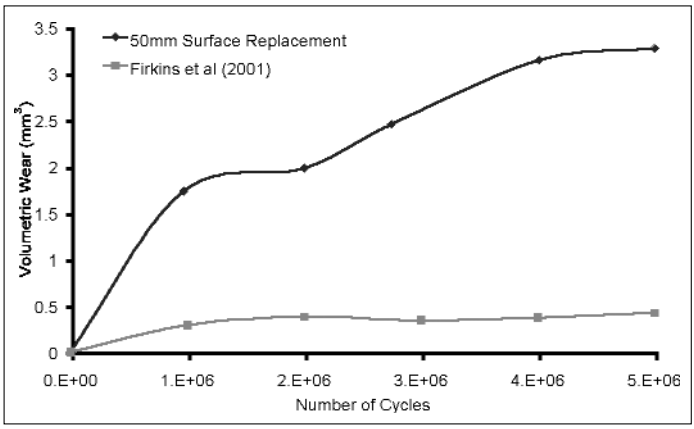

Figure 4: MOM - Surface Replacement versus THA 28 mm.

Discussion

The increase in diameter for MoM Resurfacing changes the tribological system of the hip joint. Assuming a similar clearance for the articulations, a bigger diameter decreases the surface pressure and increases the velocity, both being advantageous for the formation of a fluid film formation resulting in reduced friction and wear. Nevertheless, no favourable tribological results were found in our tribological investigations for the bigger diameter SR bearings. The wear rate under identical conditions in the laboratory was generally higher than for smaller diameter THA bearings but also inconsistent. Given this in vitro evaluation, Surface Replacement does not seem to be a superior tribological concept.

Some comparative in vivo studies have evaluated the metal ion release of a normal 28 mm THA versus a SR. In general it has been observed that Resurfacing articulation releases a higher amount of Co and Cr ions compared to standard THA. The values reported show an increase of 5 to 350% [5,6,7,8]. It has been speculated that these higher levels of metal ions are due to a higher activity of the SR patients but this has not been proven yet. On the contrary, a recent study has shown no relationship between the patient activity and the serum metal ion level [9]. Another possible explanation is the creation of smaller wear particles with bigger diameters, leading to relatively more debris and, therefore a higher ion concentration in blood and urine. On the contrary, at the recent ORS two posters have been presented with comparable clinical wear results between MoM THA and SR [10,11].

Despite the low amount of MoM articulation wear particles in general the amount of Co and Cr ions detected in blood or urine are elevated up to a tenfold over controls [12] and metal sensitivity has been reported as a reason for revisions [13,14,15]. The long-term pathological significance with potential carcinogenicity and metal sensitivity issues are of concern, especially because the main indication for a big diameter or SR MoM bearings is the young and active patient. This has to be weighted against the benefit of these popular bigger diameter bearings with a documented higher joint stability with fewer dislocations [8] and a better range of motion.

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2.4 Consideration on disadvantages and problems of resurfacing

L. Massari, G. Caruso and V. Sollazzo

Abstract

The concept of resurfacing the hip joint is not new, it is a bone conserving alternative to total hip replacement that restores normal joint biomechanics and load transfer and ensures joint stability.

Historically, these appealing characteristics have been recognized by several investigators and various designs and biomaterials have been used. In the early 1950s, Charnley experimented with a cementless all Teflon double cup arthroplasty (Charnley 1961, 1963). Loosening of both components due to rapid wear and an intense tissue reaction resulted in clinical failure and abandonment of the procedure.

In the 1970s and early 1980s a metal-on-polyethylene design was used with results which were poor. Enthusiasm for resurfacing disappeared although it was felt that the root of the problem may have been the materials used rather than the tecnique itself and new materials as shoud be considered.

Over the last decade, the previous problems associated with thin polyethylene acetabular components, reproducible quality of manufacturing of metal-on-metal implants, and component fixation issues appear to have been resolved and a more reliable prosthesis developed.

There are no long-term results available on the new-generation hip resurfacing arthroplasties. Studies of the Conserve Plus (Wright Medical Technology, Arlington, Tennessee), the McMinn and Cormet (Corin Medical, Cirencester, UK), and the Birmingham Hip Resurfacing (Midland Medical Technologies, Birmingham, UK) have a mean of 3 years' follow-up demonstrating survivorship of >97%. These studies demonstrate significantly better survivorship than previous generations of hip resurfacing prostheses (eg, Wagner, Imperial College London Hospital (ICLH), THARIES, Furaya).

Indications and contraindications for a resurfacing procedure are still being defined. The ideal candidate for a hip resurfacing procedure is currently believed to be a young (<60 years) active man with normal proximal femoral bone geometry and bone quality who would be expected to outlive any current conventional prosthesis. Preoperative diagnoses can be varied and include osteoarthritis, osteonecrosis, and degenerative conditions secondary to developmental hip dysplasia, slipped capital femoral epiphysis, and Legg-Calve´-Perthes disease.

Currently, absolute contraindications include elderly people with osteoporotic proximal femoral bone, known metal hypersensitivity, and impaired renal function. Relative contraindications include inflammatory arthropathies, severe acetabular dysplasia, grossly abnormal proximal femoral geometry (as may be encountered with some severe cases of Legg-Calve´-Perthes and slipped capital femoral epiphysis), large areas of avascular necrosis, and large geode formation.

Problems that have been encountered can be divided into two main groups: 1: those associated with any type of hip arthroplasty; for example, dislocation, thromboembolic disease, heterotopic ossification, nerve palsies, and vascular damage; and 2: those that are more specifically related to the hip resurfacing procedure: femoral neck fractures, avascular necrosis, and sound initial and durable longterm fixation of an all-metal monoblock cobalt/ chrome acetabular component. Moreover currently all hip resurfacing implants employ metal-on-metal bearing couples. Metal-on metal bearings produce elevated metal ions with their theoretical concerns related to local and systemic effects. While resurfacing implants with their larger diameter femoral heads should produce lower wear rates, publications to date report equal, if not higher, metal ion levels.

However, despite the attraction of the procedure, unanswered questions still remain.

Does it matter if the serum cobalt and chromium levels rise after surgery? If a resurfacing is eventually converted to a total hip replacement, will the long-term results of that procedure be altered in any way? What is the true incidence of avascular necrosis and fracture of the neck of the femur? Are these technical issues or are they a feature of the prostheses used?

At the present time there are many unanswered questions surrounding the current generation of hip resurfacing implants. It would appear from several sources that early failure rates exceed those of conventional total hip replacements at comparable follow-up intervals.

The current models of hip resurfacing are a considerable improvement on previous versions. Whether they are better in the long term than a well-established total hip replacement remains to be seen.

2.5 In vitro biomechanical properties of a hip resurfacing system

P. F. Indelli, N. Veins, D. Dominguez, K. Kitaoka and T. Parker Vail

Introduction

Articular surface replacement has always made intuitive sense, although the technology has not always favored success. The ultimate goal of any hip resurfacing system is the replacement of the articulating femoral and acetabular surfaces with thin prostheses, leaving intact the healthy host bone.

Historically, in the 1960's and early 1970's, many hip resurfacing systems have been designed and implanted by many excellent surgeons(Sir John Charnley, Dr. Mueller, Dr. Freeman, Dr. Capello and others), achieving promising early results but failure rates up to 35 % at longer follow-up. Those failures were due to acetabular and femoral loosening, avascular necrosis of the femoral head and neck, and non-traumatic femoral neck fractures. Because of those clinical results, many hip resurfacing systems have been abandoned by mid 1980's. In the late 1980's, Mr. Derek McMinn developed the first third generation surface replacement implant, which became a precursor to both the Cormet Resurfacing Hip System (Corin, UK) and the Birmingham Hip Resurfacing (MMT, UK). At the same time, Harlan Amstuz in the United States began a series of developments which culminated in the Conserve Plus Hip System (Wright Medical Technologies, US). Those modern differ from the predecessors in terms of sphericity, clearance, materials, component thickness, size options and instruments. The suggested advantages of those implants are stronger fixation, lower wear bearing, better bone conservation, and lower risk of complication, especially fracture and dislocation.

The objective of this study was to evaluate the biomechanical properties of the Conserve Plus Hip System: the authors investigated the effects of varus alignment, notching of the neck, anteversion and retroversion of the component on the failure properties of the femoral neck in the cadaveric model.

Material and Method

This on-bench study has been designed using the following criteria. Each femur had a photoelastic coating applied for use on cadaveric femora. A specialized apparatus was used to recreate the one-legged stance model established by McLiesh with the shaft 12° from vertical and an upward abductor force applied at 15° from vertical (Fig. 1 and 2). Each femur was loaded to 3 times body weight (210 kg) using a standard MTS device. Strain measurements were take using the Polariscope Model 040 in fringe orders and converted to microstrain using the following equation: $\sum max - \sum min = N\lambda/2tK$, where N is magnitude in fringe orders, t is the thickness of the coating, K is the strain optic coefficient, and λ is the tint of passage in white light (22.7 x 10-6 inch).

The study has been divided in 3 phases.

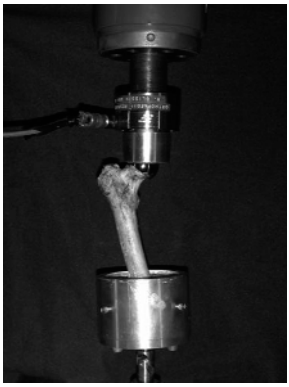

Figure 1: The testing apparatus.

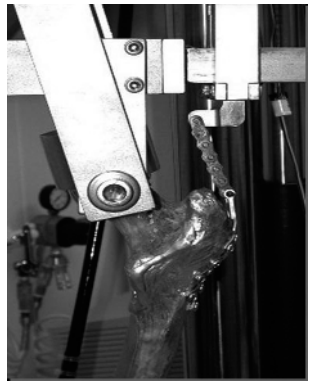

Figure 2: Particular of the one-legged stance model.

First phase (Notching Test): Sixteen cadaveric femurs were tested to failure once the Conserve Plus Hip System was implanted: 8 femurs after a 4mm notching of the neck and 8 contralateral without notching (Fig. 3). The outcome was measured as peak load (N) before failure.

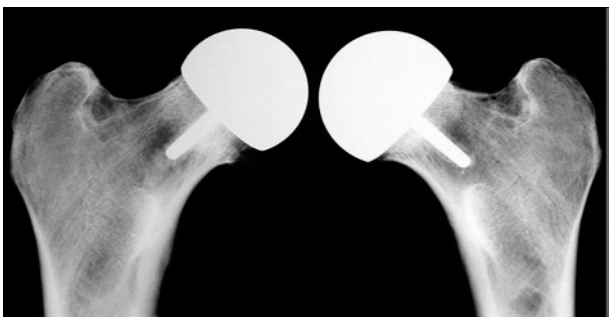

Figure 3: Radiographic evaluation of bilateral femurs: a 4 mm notching was created on the right femur.

Second phase (Varus test): Sixteen cadaveric femurs were tested using a 210 Kg axial load: 8 femurs were tested first intact and then with the Conserve Plus system implanted at 140° and 8 contralateral femurs were tested first intact and then implanted at 10° of varus (Fig. 4). The outcome was measured as average shear strain in μ-strain units.

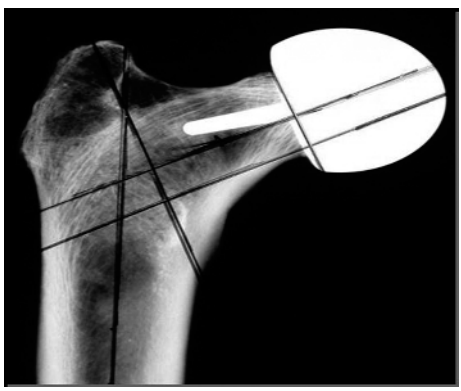

Figure 4: An implant positioned in varus alignment.

Third phase: Eight femurs were tested with the Conserve Plus implant having 10 ° of antiversion of the component and 8 with the implant having 10° of retroversion. The control group was represented by 16 femurs having the system implanted following the natural version of the femoral neck. All femurs were loaded to failure. The outcome was measured as peak load (N) before failure.

Results

First phase (Notching test). Fifteen transcervical fractures and one inter-throcanteric fracture were registered. The normally implanted femurs required on average 25.3% more force to reach failure with a range of 5.4% -53.9% than their contralateral notched pair. The median peak force (N) before failure was 7043 N and 4865 N for the normal and notched femurs, respectively ($p<0.003$).

Second phase (Varus Test). The varus alignment of the implant showed a significant increase in strain in the posterosuperior cortex (15%; $p< .005$) and the anterosuperior cortex (21%; $p< .0005$) respectively. The neutral alignment of the implants at 140° showed an overall decrease in shear strain in all regions of the femoral neck with the posterosuperior having the greatest decrease (21%; $p< 0.015$), both the anterosuperior and posteroinferior having a 17% decrease ($p< 0.033$ and $p< 0.004$ respectively) and the anteroinferior having a 12% ($p< 0.017$) (Table 1).

		Avg. Strain (microstrain units)			
		Anterior Inferior	**Anterior Superior**	**Posterior Inferior**	**Posterior Superior**
10 Degrees Varus	**mean**	1658.62	1027.12	1844.75	1174.12
Intact	**mean**	1644.12	811.37	1745.25	993.5
Diff > 0	**mean**	14.5	215.75	99.5	180.62
P. Value		0.44	0.0005	0.155	0.005

		Avg. Strain (microstrain units)			
		Anterior Inferior	**Anterior Superior**	**Posterior Inferior**	**Posterior Superior**
Natural Angle (implanted normally)	**mean**	1250.25	752.37	1456.25	694.5
Intact	**mean**	1403.87	883	1702	845
Diff > 0	**mean**	- 153.62	- 130.62	- 245.75	- 150.5
P. Value		0.017	0.033	0.004	0.015

Table 1:
Results and comparison in the Varus Test group.

Third phase.
Normal version vs anteversion.
In the normal version group (n=8) the average shear strain in the femoral neck was 600 μS on the anterosuperior cortex, 800 μS on the posterosuperior cortex, 1400 μS on the anteroinferior cortex, and 1600 μS on the posteroinferior cortex. In

the anteversion group (n=8) the average shear strain was 600 μS on the anterosuperior cortex, 650 μS on the posterosuperior cortex, 1650 μS on the anteroinferior cortex, and 1250 μS on the posteroinferior cortex ($p<0.05$).

Normal version vs. retroversion.

In the normal version group (n=8) the average shear strain in the femoral neck was 380 μS on the anterosuperior cortex, 400 μS on the posterosuperior cortex, 1100 μS on the anteroinferior cortex, and 980 μS on the posteroinferior cortex. In the retroversion group (n=8) the average shear strain was 390 μS on the anterosuperior cortex, 450 μS on the posterosuperior cortex, 900 μS on the anteroinferior cortex, and 1150 μS on the posteroinferior cortex ($p<0.05$).

Discussion and Conclusions

This biomechanical study showed that the correct positioning of the implant represents a fundamental requirement for the success of any hip resurfacing procedure. The varus positioning of the femoral component increases stress in the superior cortex, while anatomic placement decreases stress across the femoral neck. Notching of the femoral neck during initial cylindrical reaming significantly decreases maximum loading properties of the femoral neck. The femurs with 10° anteversion or retroversion respect to the normal anteversion of the femur did not show a significant decrease of the maximum loading properties on the femoral neck when compared to femurs with anatomically implanted systems.

2.6 Comparison of functional activity of hip resurfacing with total hip arthroplasty

J. D. Witt, V. Kannan and T. White

Introduction

During the past decade there has been a resurgence of interest in hip resurfacing as a mode of treatment for younger, more active patient with hip disease. Excellent short term results has been reported in a majority of patients with Birmingham Hip resurfacing. Similarly excellent long term results have been reported in literature with uncemented total hip replacement particularly Furlong HAC stem in younger patients but the focus has been on survivorship rather than on functional outcomes.

Very few data are at present available comparing the functional outcome of hip resurfacing with total hip replacement. We report the results of a matched pair analysis comparing the functional activity of Birmingham Hip resurfacing with Furlong total hip replacement.

Materials & Methods

Matched pair of patients were selected from a database of patients who had either undergone total hip replacement (n=242) or hip resurfacing (n=90). It was possible to match sixteen pairs of patients in terms of age (within 4 years), sex and diagnosis with a minimum follow up of 22 months. The mean follow up in the BHR group and Furlong group were 2.4 yrs and 5.2 yrs respectively. Two pairs were excluded because of their co-morbidities. The mean age was 49.7 (range = 19- 64).

Male: Female ratio was 1: 2.5. Of the fourteen pairs, twelve were diagnosed as having osteoarthritis either primary or secondary. Two pairs had juvenile arthritis (Table 1). The etiology of arthritis in both the groups is illustrated in Table 2. All the patients were graded according to Charnley category and there was an almost equal distribution in both the groups (Table 3). A Power calculation showed that to detect a difference of 1.2 on the UCLA score using the unpaired T test, 16 pairs of patients would be needed assuming a SD of 1.5. Fourteen pairs of patients would detect a difference of 1.5.

All the patients were assessed post operatively using the Harris Hip score, WOMAC (Pain, function and mobility), SF36 (Physical, Mental), UCLA and Tegner activity scores.

Diagnosis

Diagnosis	Furlong	BHR
Osteoarthritis	12	12
Juvenile arthritis	2	2

Side	Furlong	BHR
Left	7	7
Right	5	5
Bilateral	2	2

Table 1

Aetiology - Arthritis

Diagnosis	BHR	Furlong
Primary OA	4	6
DDH	6	3
Perthes	2	2
JIA	2	2
AVN	-	1

Table 2

Results

The mean post op Harris Hip score in the BHR and Furlong group were 82.9 and 86.8 (p= 0.38) respectively. There was no significant difference The mean post operative pain, stiffness and function WOMAC scores and SF 36 (Physical, Mental) with p values for the BHR and Furlong group are illustrated in Table 4.

The mean post operative functional activity and p value measured using UCLA functional activity and Tegner activity score is given in Table 4. There was no statistical difference between the two groups

Charnley Category

Category	Furlong	BHR
A	8 (57.1%)	7 (50%)
B	4 (28.5%)	4 (28.5%)
C	2 (14.3%)	3 (21.4%)

Table 3

Post op Mean (SD) scores

	Furlong	BHR	P value
Harris	82.9 (12.4)	86.8 (11.0)	0.38
SF36	79.0 (20.0)	77.3 (15.2)	0.80
UCLA	5.6 (2.3)	6.1 (1.8)	0.52
Tegner	3.2 (1.9)	3.6 (1.8)	0.62

Table 4

Discussion

Daniel et al (2004) reported on 446 hip resurfacings, in patients under 55. In this study 81% of patients had 8 or more on the UCLA activity scale. 79% of the patients were male. Amstutz et al (2004) reported on 400 resurfacings in patients with a mean age of 48. 54% scored 8 or more on the UCLA activity scale and in this study 73% were males. Treacy et al (2005) reported on 144 hip resurfacings in patients with a mean age of 52.1 with 74.3% males. In this study 117 patients were playing sport, but no activity score was recorded. Back et al (2004) in 230 hip resurfacings with a mean age of 52.1 and 65.2% males, did not specifically record an activity score. There are fewer reports of activity scores in young patients with THR's. Singh et al reported on 38 Furlong THR's with a mean age of 42 and with 66.5 males. 39% returned to sport and 48% to outdoor activity. Our study differs from the other resurfacing studies in that we had a higher female to male ratio and it could be argued that this would influence results looking at sporting activities. Be that as it may, we were unable to demonstrate any functional or quality of life difference between the two groups of patients, and therefore we conclude that resurfacing does not confer any specific advantage in this regard as has sometimes been claimed.

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SESSION 3

Hard-hard bearing systems

3.1 Radiological development of an alumina metal back cup during 5 years

J. Bejui-Hugues, H. Chavane, V. Pibarot, J. M. Durand, G. Vaz, O. Guyen, A. Richard and J. P. Carret

Introduction

Periprosthetic osteolysis is the most important element observed during revision surgery of total hip replacements [1, 2, 3]. It is a sign of osseous resorption and of the loss of trabecular bone in the area of the implant bed [1]. This loss of bone substance may be accompanied by periprosthetic fracture and implant loosening, which requires complex surgical revision.

Frequently, this process will not create any symptoms, and leads to major bone destruction. Symptoms will appear as late as during implant loosening [3].
At the same time, osteolytic defects will develop slowly and cannot always be detected on the radiograph during the initial postsurgical period.

Also participating in the modification of the interface between the acetabulum and the prosthetic cup is the dynamics of intraarticular fluids linked to microseparation which promotes wear as a result of the impact of foreign bodies. Microseparation in the range of a few microns may have a considerable effect on the wear and the biomecanics of the implant in the areas of contact. It was shown by studies conducted for THRs with cemented metal-on-metal bearings on polyethylene that acetabular rims were generated over the short term as a result of increased exposure of the cement/bone interface [4].

We have examined the development of bone radiologically in patients who had received metal back implants with alumina-on-alumina bearings, with regard to the aforementioned elements.

Material and method

We have investigated a consecutive series of 5O THRs which were inserted in the period between 1999 and 2000, and which used a metal back cup with alumina insert, and featured a diameter of 28 in 46 patients.
28 of the patients were male, and 22 were female patients.
The patients' median age was 44.2 with the age of the patients ranging between 22 and 62 years.

26 of the patients had primary or secondary coxarthrosis, 19 had aseptic osteonecrosis, and 5 had rheumatic diseases.

The acetabular cups used were coated with hydroxyapatite, and the alumina insert featured an inside diameter of 28 as well as a chamfer and a non-projecting flat flange. The femoral neck used was a modular uncemented stem which was competely coated with hydroxyapatite.

The cup used was a press-fit cup. 32 of the THRs used screws, while the remaining 18 did not use any screws.

3 of the patients could not be contacted. There weren't any septic complications observed. There wasn't any fracture of the insert or of the femoral

head. Examinations started at least 6O months after surgery.
Reexamination was performed after 3 months and after 6 months to 1 year, and then were performed anually.

In 47 THRs, the cup was found to have centered immediately after surgery, and to rest on the dense edge. One of the THRs was subject to protrusion, and 2 were found to have shifted laterally. The results obtained were normal in 37 THRs, while lateral shifting was observed for 7 and medial shifting for 6 THRs. Fracture of the calcar occurred in 2 THRs and was remedied by way of cerclage.

Results

The functional results (HARRIS score) obtained in relation to femoral pain have been excellent or very good in all cases. The presurgical score was 41 and the postsurgical was 96 for the longest postsurgical interval. The survival rate in respect of prosthetic revision was 1OO % (acetabular cup and femoral neck).
The radiological analysis of the front pelvis and of the Arcelin profile did not exhibit any migration of the acetabulum. There weren't any rims or osteolysis observed in the contact area of the cup, of the roof or of the screws. There weren't any signs of densification observed in the contact area of the implant. In 8 patients, subchondral densification rims disappeared (coxarthrosis).

Discussion

The use of hard bearings will provide for longer life of the total hip replacements in active patients as a result of reduced wear which usually is at the basis of osteolysis.

It can be seen from the observation of a number of 5O consecutively inserted THRs in patients the age of whom ranged below 62 over a period of 5 years that there wasn`t any periprosthetic osteolysis or densification involved. The distribution of strain provided for by the metal back and the rigidity of the hard alumina-on-alumina bearings will result in osseous remodelling without any signs of osteolysis. The reduction of subchondral densification should be investigated within the framework of a quantitative study.

On the other hand, the use of metal back cups together with hard alumina-on-alumina bearings will not result in periprosthetic rims over a period of 5 years and will not cause osteolysis which is observed regularly for bearings with polyethylene components.

This difference should be investigated within the framework of complementary study. Nevertheless, the results obtained were as good as the ones obtained from the use of conventional alumina-on-polyethylene or metal-on-polyethylene bearings.

References

References at the author.

3.2 Metal Ion Hypersensitivity in Metal-on-Metal Hip Arthroplasty

Y.-S. Park, Y.-W. Moon and S.-J. Lim

Abstract

Total hip arthroplasty with use of metal-on-metal bearings has been reintroduced as an alternative to metal-on-polyethylene bearings because of theoretical advantages such as reduced wear and a lower prevalence of osteolysis. However, we have observed early osteolysis in nine patients (ten hips) out of 165 patients (169 hips) who had been managed with total hip replacements using a contemporary metal-on-metal hip design and investigated the possible etiologic role of metal hypersensitivity. The nine patients who had an osteolytic lesion had a significantly higher prevalence of hypersensitivity to cobalt, as determined by patch testing, when compared to nine controls ($p = 0.031$). The retrieved periprosthetic tissues from the two revised hips showed no evidence of metallic staining, but microscopic analysis revealed a perivascular accumulation of CD3-positive T-cells and CD68-positive macrophages, and an absence of both particle-laden macrophages and polymorphonuclear cells. Immunohistochemical analysis demonstrated that potent bone-resorbing cytokines such as IL-1β and TNF-α were produced mainly by infiltrated lymphocytes and activated macrophages. These findings raise the possibility that early osteolysis in this second-generation metal-on-metal hip replacement is associated with abnormalities consistent with delayed-type hypersensitivity to metal.

Introduction

Contemporary metal-on-metal hip prostheses have the theoretical advantage of producing less abrasive wear than metal-on-polyethylene prostheses do [15,17]. In addition, the metal particles produced are smaller than polyethylene particles, and hence, they may induce less tissue reaction [5,6]. Recent clinical studies on the outcomes associated with second-generation metal-on-metal hip prostheses have shown mostly good results without osteolysis [7,13,18], and total hip replacements involving these alternative bearings are being performed more frequently, particularly in young, active patients.

However, several studies on patients with metal-on-metal bearings have shown that the serum levels of cobalt and chromium ions were significantly higher than those in normal individuals without implants [3,4,12]. All metals that are in contact with biological systems corrode, and the released ions can activate the immune system by forming metal-protein complexes that are considered to be candidate antigens for eliciting hypersensitivity responses [11,14]. Although some studies have demonstrated the loosening of first-generation metal-on-metal hip prostheses in association with hypersensitivities to cobalt, nickel, and chromium, it has not been determined whether the device failed because the patients had a preexisting metal hypersensitivity of the patient or whether the patients became hypersensitive to metal as a result of the failed implants [2,8,9].

In the present study, rapidly progressive osteolysis was observed in a cohort of patients with a second-generation metal-on-metal total hip design. We investigated the possible role of metal hypersensitivity with skin-patch tests, histopathologic examinations, and immunohistochemical analysis of the samples of periprosthetic tissue retrieved at the time of revision operations.

Materials and Methods

Patients

We retrospectively analyzed 165 patients (169 hips) who had undergone primary cementless total hip replacements with a contemporary metal on metal total hip arthropasty design between April 2000 and March 2002. There were 86 men (88 hips) and 79 women (81 hips); the mean age at the time of the operation was 54.8 years (range, 21 to 80 years). The average duration of follow-up was 27.2 months (range, 24 months to 41 months). The diagnosis was osteonecrosis of the femoral head for ninety hips, osteoarthritis secondary to developmental dysplasia of the hip for twenty-one, osteoarthritis secondary to childhood septic arthritis for nineteen, posttraumatic osteoarthritis for twelve, primary osteoarthritis for eight, and miscellaneous diagnoses for nineteen.

All patients underwent metal-on-metal primary total hip arthroplasty with the S-ROM modular hip system (DePuy/Johnson & Johnson, Leeds, UK). This system consists of an Ultima cup made of Ti-6Al-4V alloy, an Ultima insert made of a cast cobalt-based Co-28Cr-6Mo alloy with a carbon content of > 0.2% (high carbon), an S-ROM head made of a wrought cobalt-based Co-28Cr-6Mo alloy with a carbon content of < 0.07% (low carbon), and an S-ROM stem made of Ti-6Al-4V alloy.

Radiographic review

The immediate postoperative anteroposterior pelvic radiograph, the most current anteroposterior pelvic radiograph, and every anteroposterior pelvic radiograph made between these two time-points were assessed for osteolysis. Osteolysis was defined as a focal area of bone resorption, at least 2 mm wide, that was not evident on the immediate postoperative radiograph [21].

Skin tests

Skin-patch tests were performed according to the standard protocol of the International Contact Dermatitis Research Group for the nine patients with early osteolysis together with nine randomly selected patients matched for age and sex from the series who did not have osteolytic lesion (Table 1). Patients were tested for allergic reactions to nickel sulfate, cobalt chloride and potassium dichromate (Chemotechnique Diagnostics, Tygelsjö, Sweden) using Finn Chambers on Scanpor Tape (Norgeplaster Aksjeselskap, Vennesia, Norway).

Tissue specimens

Two of nine patients who had osteolysis underwent a revision operation. One underwent revision surgery eighteen months postoperatively because of recurrent dislocation, and the other patient, who had well-fixed implants, required curettage and bone-grafting because of a large osteolytic lesion that was at risk to imminent fracture through the greater trochanter. Periprosthetic

tissues were processed for formalin-fixed paraffin-embedded section analysis as well as for multiple microbiological cultures. Histopathological analysis was carried out with hematoxylin and eosin stained tissue samples for general cellular features. The tissue sections were also viewed with polarized light, and the presence of metallic particles was determined using the criteria of Willert et al. [20].

	Study Group	Control Group
Number of patients	9	9
Number of hips with osteolysis	10*	0
Male: female ratio	2:7	2:7
Mean (range) age at index operation (yr)	56.7 (41-68)	54.6 (44-65)
Diagnosis leading to hip arthroplasty		
Avascular necrosis	6	6
Secondary osteoarthritis	2	2
Primary osteoarthritis	1	0
Femoral neck fracture	0	1

* One patient who had undergone bilateral total hip arthropasty had symmetrical features of osteolysis in both hips.

Table 1:
Demographic Characteristics of Skin-Patch Tested Patients.

Immunohistochemical Analysis

Four-micrometer-thick sections were placed onto coated slides, deparaffinized, subjected to a microwave oven treatment (10 mmol/L sodium citrate buffer [pH 6.5] for twenty minutes at 700 W), and immersed in Tris-buffered saline solution with 0.3% (volume per volume) hydrogen peroxide. After blocking with 1% (weight per volume) bovine serum albumin in Tris-buffered saline solution containing 0.05% (volume per volume) twenty for thirty minutes, the slides were incubated for one hour at room temperature with monoclonal antibodies to B lymphocytes (CD20), T lymphocytes (CD3, CD4, CD8), and macrophages (CD68) for characterization of the cellular components. For detection of bone-resorbing cytokines, the slides were incubated overnight at 4°C with a mouse anti-human interleukin-1ß (IL-1ß) polyclonal antibody (Santa Cruz Biotechnology, Santa Cruz, California) at a dilution of 1:20 or a mouse anti-human tumor necrosis factor-alpha (TNF-α) monoclonal antibody (HyCult Biotechnology, Uden, The Netherlands) at a dilution of 1:10. The immunoperoxidase staining was performed with use of the streptavidin-biotin peroxidase complex method (LSAB universal kit; Dako, Carpinteria, California). Equivalent amounts of the subtype-matched normal mouse IgG were used as negative controls, and tissue sections of tonsils were used as positive controls. The final reaction product was visualized with a liquid DAB substrate kit (Zymed Laboratories, San Francisco, California).

Statistical Analysis

To test for differences in the rate of metal hypersensitivity between patients with early osteolysis and the randomly selected age and gender-matched patients who did not have osteolytic lesions, McNemar tests were performed with use of standard software (SPSS for Windows, Version 11.5). The level of significance was set at $p < 0.05$.

Results

Periprosthetic osteolytic lesions were detected in nine patients (ten hips; 5.9%) with at least twenty-four months of follow-up. In nine of the ten hips with osteolysis, the osteolytic lesions were localized within the greater trochanter superior to the proximal-lateral aspect of the S-ROM sleeve (zone 1 according to the system of Gruen et al. [10]). The remaining hip had a large lesion that extended from the bone-prosthesis interface in zone 1 into the proximal aspect of the greater trochanter (Figs. 1a, 1b, and 1c). The average size of the lesions was 132.5 mm^2 (range, 54.0 to 299.5 mm^2). No osteolytic lesions were evident around the acetabular component. In all ten hips with periprosthetic osteolysis, the acetabular and femoral components were stable and well-fixed at the time of the latest follow-up evaluation. As no clear distinction could be made between the edge of the femoral head and the articulation surface of the acetabular component, wear could not be measured on plain radiographs.

A 63-year-old man who had undergone staged bilateral total hip arthroplasty for the treatment of osteonecrosis of the femoral head with a zirconia-on-polyethylene bearing for the left hip and with a metal-on-metal bearing for the right hip with an interval of 4 years and 6 months.

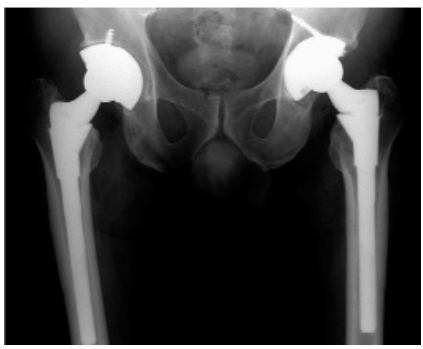

Figure 1a:
Radiograph taken 3 months after index operation on the right hip (4 years and 9 months after the left hip). No osteolytic lesion was seen on the right hip, but polyethylene wear and associated osteolysis were evident in the left hip.

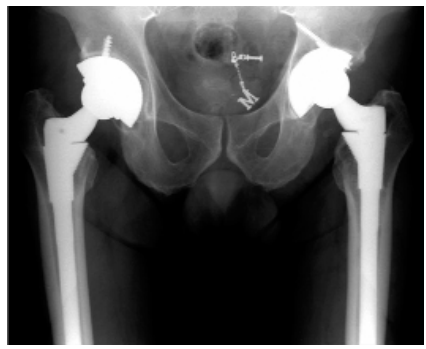

Figure 1b:
Radiograph taken 1 year and 6 months after index operation on the right hip (6 years after the left hip). A femoral osteolytic lesion was present on the right hip, and this had a similar size and location to that on the contralateral hip.

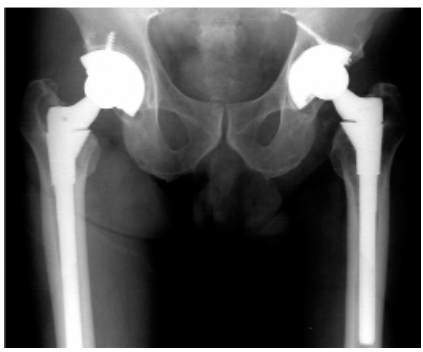

Figure 1c:
Radiograph taken 3 years after index operation on the right hip (7 years and 6 months after the left hip). The size of the femoral osteolytic lesion on the right hip became larger than that on the contralateral hip.

There was no clinical sign of infection in any of the ten hips. The complete blood-cell count, erythrocyte sedimentation rate, and C-reactive protein values were within normal limits in all nine patients.

Eight of the nine patients with early osteolysis, including the two patients who underwent revision surgery, had a positive patch test for cobalt chloride. In contrast, only two of the nine control patients had a positive test for cobalt chloride. Two patients in the study group and none of the patients in the control group had a positive test for nickel sulfate. One patient in the study group and two patients in the control group had a positive test for potassium dichromate. The patients with osteolysis had a significantly higher rate of hypersensitivity reaction to cobalt chloride compared with controls ($p = 0.031$), but, with the numbers available, there were no significant differences between the groups with regard to the rate of hypersensitivity reaction to nickel sulfate ($p > 0.05$) or potassium dichromate ($p > 0.05$).

Two patients who had a positive patch test for both cobalt chloride and nickel sulfate had had cutaneous symptoms. These patients had complained of a generalized eczematous or urticarial reaction after the metal-on-metal prosthesis had been implanted.

The two hips that underwent revision surgery had no evidence of metallic staining in the periprosthetic tissue at the time of the revision, and no notch or groove was apparent in the neck of the femoral component that would have been suggestive of impingement between the socket and the femoral neck. The bearing surfaces of the prosthesis that was retrieved because of recurrent dislocation were inspected with a non-contact, optical, three-dimensional scanner (REXCAN 400; Solutionix, Seoul, Korea). Although there were some fine scratches in the femoral head, there were no visible areas of wear when compared with unused prostheses.

Histologic examination of the retrieved periprosthetic tissues from the two revised hips showed perivascular infiltration of lymphocytes and mononuclear phagocytes in both cases. In one case, several lymphoid follicles also were noted. Neither particle-laden macrophages nor polymorphonuclear cells were seen on standard and polarized microscopic examination of the tissue sections. Immunophenotyping analysis revealed that most tissue-infiltrating lymphocytes in the periprosthetic tissue expressed the CD3 marker and therefore could be identified as T-cells. Additional staining showed that mixed CD4 and CD8-positive T-cells were present throughout the periprosthetic tissue. CD68-positive macrophages also were diffusely distributed throughout the periprosthetic tissue, and small numbers of CD20-positive cells were preferentially encountered within the lymphoid follicles. Immunohistochemical localization for the bone-resorbing cytokines revealed that IL-1β and TNF-α were expressed by T-cells and CD68-positive macrophages.

Summary and Conclusion

In the cases of the two revised hips in the present study, no evidence of impingement of the components was seen at the time of revision surgery, no metallic deposits were detected in the periprosthetic tissues, and no metal particle-laden macrophages or foreign-body giant cells were found on standard and polarized microscopic examination of the tissue sections. We did, however,

observe perivascular infiltrations of lymphocytes and macrophages in the tissue sections, which were similar to the histologic findings recently reported by Willert et al. [19]. Although the lack of observable metal debris under the polarized light microscope does not rule out the presence of undetectable metal wear particles in the nanometer size-range, our tissue findings are inconsistent with those typical of particle-induced osteolysis, which is associated with abundant particle-laden macrophages within periprosthetic tissues [1,16]. Our immunohistochemical analysis of the periprosthetic tissue samples revealed that most tissue-infiltrating cells were CD3-positive T-cells and CD68-positive macrophages. It is notable that CD8-positive T-cells were also abundant in the periprosthetic tissue, suggesting that T-cell-mediated cytotoxicity might be associated with the development of osteolysis. We also identified the potent bone-resorbing cytokines such as IL-1β and TNF-α in the periprosthetic tissue in association with T-cells and activated macrophages.

In conclusion, our findings raise the possibility that early osteolysis in patients with this second-generation metal-on-metal hip replacement is associated with a delayed-type hypersensitivity to metal, mainly cobalt. As a result of our findings, we are reluctant to implant modern metal-on-metal bearings in patients who have a history of allergic reaction to a metal implant or metallic wear. A prospective study in which a large group of patients with contemporary metal-on-metal bearings are evaluated with multiple testing methods, including in vitro delayed-type hypersensitivity assays as well as skin-patch testing, is needed to better explain any causal relationship between metal hypersensitivity and osteolysis.

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3.3 28mm Head in Ceramic/Ceramic Total Hip Replacement

M. Marcucci, P. Aglietti, P. Poli and L. Latella

Introduction

Total Hip Replacement is a successful procedure with relative low complications.

With improvements in fixation, implant design and the introduction of minimally invasive techniques, the goal in THR today is to minimize wear and osteolysis avoiding loosening of the components.

Alumina on Alumina and Metal on Metal bearings are the most suitable solutions especially for young patients. The potential trouble using ceramic is the increased risk of fracture and the higher incidence of dislocation when small size heads are used. Furthermore alumina avoids the risk of ions release connected with M/M bearings.

The purpose of our study was to evaluate the clinical and radiographic outcome of the alumina bearing using a 28 mm femoral head in young patients.

Materials and Method

In 2000 we introduced in the First Orthopaedic Clinic of the University of Florence the use of ceramic bearing in THR for patients younger than 65 years.

In our experience CLS, Heritage and Conus stems with Trilogy cups (Zimmer, Inc., Warsaw, IN) showed excellent results thus we used them as our choise of implants.

With Trilogy cup the employment of 32 mm liner is only possible with large cups size (up to 56 mm). In most cases patients required a smaller cup size, for this reason we used a ceramic bearing with a 28mm head.

Between November 2000 and December 2005, 151 patients received 164 ceramic/ceramic THR with a 28 mm head.

The mean age of the patients was 54.8 yrs (range 25 to 74).There were 53 men and 98 women.

The preoperative diagnosis were primary osteoarthritis in 81 (Fig. 1a, b), secondary osteoarthritis to CDH in 40 (Fig. 2a, b), secondary osteoarthritis for other causes in 21, osteonecrosis in 11, femoral neck fractures in 8 and surface hemiarthroplasty failure in 3.

149 procedures were performed without cement (145 hips with CLS and Trilogy, 4 hips with Conus and Trilogy) and 15 were performed with hybrid fixation with cemented stem and a cementless cup (Heritage and Trilogy).

Patients were classified according to Charnley classification: class A (involvement of only the ipsilateral hip), class B (involvement of the contralateral hip), class BB (THR in both hips) and Charnley class C (involvement of other joints or systemic problems limiting activities) [1].

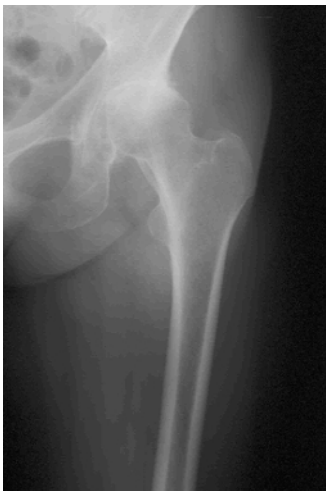

Figure 1a:
Preoperative radiograph of a fifty-eight-year-old woman showing primary osteoarthritis of left hip.

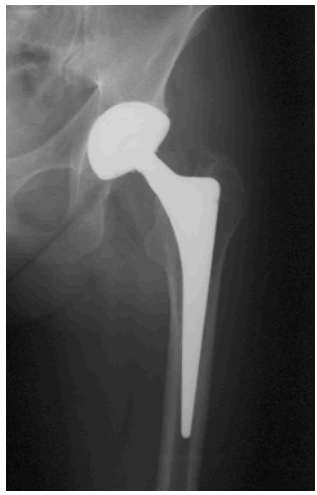

Figure 1b:
Radiograph, made four years postoperatively.

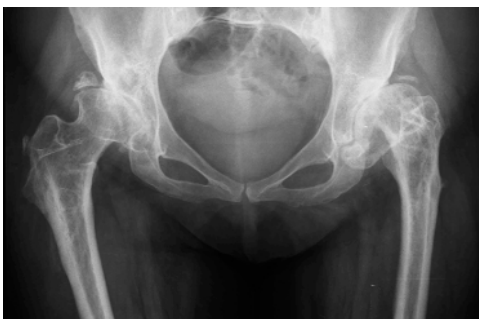

Figure 2a:
Preoperative radiograph of a forty-four-year-old woman showing bilateral CDH (previous bilateral surgery).

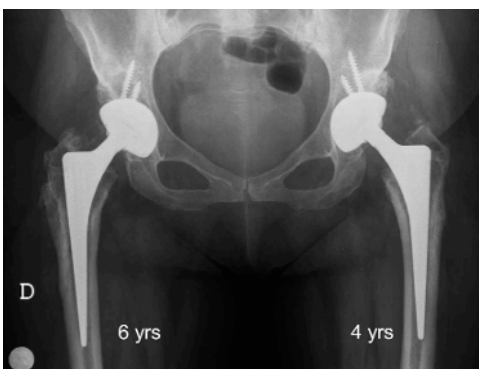

Figure 2b:
Radiograph, made six years (right side) and four years (left side) postoperatively.

The clinical evaluation was performed with use of the Charnley score. Patients were assessed for pain, function and motion. A maximum score of 6 points represented normality (no pain, normal gait, free ROM) while 1 represented a

poor condition (severe pain, bedridden or able to walk for only a few yards, ankylosis). Patients were questioned about the presence of thigh or groin pain.

Anteroposterior radiographs of the pelvis and hip and lateral radiographs of the hip were obtained before surgery. A preoperative planning was performed for all patients to determine the size and orientation of cup and stem with the aim to restore the normal biomechanics of the hip through the femoral offset, the center of the femoral head and the leg length discrepancy.

Surgery was performed through a posterolateral approach with excision of the external rotator muscles and the posterior capsule. This were reconstructed at the end of the operation.

Since 2002 a minimally invasive approach was adopted.

The target cup position were 40° of abduction and 15° of anteversion and, when possible, the stem at 10-15° of anteversion.

Joint stability was evaluated: in extension and in concomitant external rotation, at 90° of hip and knee flexion with concomitant internal rotation and with the shuck, dropkick and resident test. A release was done in presence of improper soft tissue balance.

Clinical and X-Ray evaluations were performed after surgery, at 6 weeks, at 4 months and yearly.

Postoperative radiographs were evaluated for heterotopic bone, according to the classification of Brooker et al [2].

Cup position was measured in reference to the teardrop line. The horizontal reference line was drawn by connecting the inferior apex of the teardrops. The acetabular cup angle was measured from the horizontal reference line.
Radiolucency of >1 mm was assessed in the three zones defined by DeLee and Charnley [3].

If a complete radiolucent line was found, the cup was considered to be probably loose, a change in the position of the cup was considered surely loose.

The position of the femoral component was assessed with use of a fixed point of reference on the prosthesis and the femur (the lesser and the greater trochanter). Component orientation was neutral if the center lines of the component and the femur were within an angle of 5°; otherwise, the component was designated as having varus or valgus alignment. All changes around the femoral component were documented according to the method of Gruen [4]. The stem was considered loose in presence of a complete radiolucency all around and/or in presence of subsidence.

Results

At a mean F.U. of 3.2 yrs (range 4 months to 5 yrs and 3 months) we review 149 patients (162 hips). Two patients were lost at follow up. 78 patients were classified as Charnley class A, 33 as Charnley class B, 30 as Charnley class BB (13 received alumina bearing bilaterally), 8 as Charnley class C.

The mean preoperative Charnley score was 2.8 points for pain, 2.7 points for function, and 3.2 points for motion. At the time of the final follow-up, the mean scores were pain 5.98, function 5.98 (class B and C were not considered because of problems relative to other hip or other disease limiting activities), and motion 5.81.

At the time of the final follow-up 98.65% of our patients were pain free (in 2 cases diagnosis were transient bursitis). None showed thight or groin pain; satisfaction were recorded in 99.38%.

Leg length discrepancy > 5 mm and < 10 mm was recorded only in 5 patients (3.3%): 4 was class B and 1 was class C (in all cases this was secondary to pathology of the contralateral hip). The average cup abduction was 40.9° (range 32° to 51°).

All femoral components alignment was within 5° of the neutral in the coronal plane.

At the latest radiographic follow up 4 hips had radiolucency in zone 1 (2.5%). Periprosthetic osteolysis and loosening were not detected around any component, all the cups and stems were stable.

Etherothopic ossification was detected in 23 hips (14.1%); 12 were at stage one, 9 at stage two and 2 at stage three.

Recurrent joint dislocation occurred in one patient (0.61%) and required revision surgery.

A single episode of dislocation (caused by a fall) occurred in one patient three days after surgery. (0.61%)

Discussion

Ceramics were introduced in THR to address the problems of friction and wear that were reported with metal on polyethylene articulations. Alumina shows excellent tribologic properties, extra low debris generation and low tissue response.

Previous experiences with the first generation alumina bearing have been controversial because of accelerated wear and component fracture [5].

Over the last decade, many improvements have been made in ceramic manufacture and design that lead to increased resistance to mechanical stress and lower wear [6,7].

The outstanding tribologic properties are related to a low surface roughness (Ra=0.02 micron) because of the low grain size; high hardness is responsible for major scratch resistance; high wettability results in low friction, low wear and fluid film lubrification [8].

In vitro wear testing of alumina on alumina showed two phases of wear rates. The first phase or "Run in" Phase concerns the first million cycles during which volumetric wear rate measures 0.1 to 0.2 mm^3. During the second phase, or "Steady State" Phase, volumetric wear rate decreases at less than 0.01 mm^3 per million cycles [8].

Bohler et Al. have shown that the concentration of wear particles in the periprosthetic tissues of loosened implants were 2 to 22 times lower with alumina than with M on PE [9].

Alumina wear debris are well tolerated because they are almost bioinert and after an initial inflammatory phase they induce a low cellular response with minor fibrous scar tissue [10,11].

Alumina particulate wear debris are phagocitosed by macrophages which release the chemical mediators IL-1, IL-6, TNFα and PGE_2. The latter are regarded to be the most active. They are capable of inducing cell proliferation, osteoclast formation and thus resorption of adjacent bone.

The levels of PGE_2 and TNFα in tissues surrounding the implants were higher with PE particles than with alumina particles [12,13].

Also, the induction of macrophage apoptosis was faster and more important with alumina than M/PE [14]. Thus apoptosis may be the major internal mechanism that could explain the differences seen in the osteolysis patterns.

For these reasons alumina bearing is the suitable choise for the young and active patient where high functional demand could induce high wear rates.
For good long term results ceramic require particular care.

Walter et Al. reported with alumina, high wear rates for cup abduction of over 60°, these rates decreased for abduction of less than 45°. He showed that stress contact is related to wear debris amount [15].

Large femoral heads and proper surgical technique are both important for good results.

In our experience the 28mm femoral head was the only choice for cups less than size 56, so we evaluated all risk factors related to joint instability.

Increasing femoral head size results in an increase in the PIF-ROM (prosthetic impingement free ROM) and an increase in the VHD (vertical head displacement) thus reducing the rate of component dislocation [16]. In our experience the 28 mm head showed good results with joint instability rates that were lower than those reported in other clinical studies [21].

Despite ceramic implants' design doesn't allow elevated rim borders and head sizes are available only in limited lengths (-3.5, 0 and +3.5 mm), we think that a preoperative planning and a proper surgical technique are essential to provide joint stability.

As reported by several authors, dislocation after total hip replacement has an overall incidence of 2% to 3% [17]. More than half of all dislocation occurs within the first 3 months after surgery and that more than three fourths occur within one year [18].

Patient risk factors are neuromuscular and cognitive disorders including cerebral palsy, muscular dystrophy, psychosis, dementia and alcoholism. Fackler et Al. has reported high risk of dislocation after primary THR [19].

Surgical risk factors are: surgical approach, soft tissue tension, component positioning, head size and surgeon experience [20].

Masonis et Al. reported a dislocation rate of 0.50% for the lateral approach and a rate of 3.2% for the posterolateral approach [21]. However, meticulous reconstruction of the posterior capsule and short external rotators can reduce the dislocation rate [22].

Lewinnek et Al. recommended acetabular abduction between 30° and 50° and acetabular anteversion between 5° to 20° and described it as "safe zone". Positioning cup within safe zone provides the best ROM associated with low dislocation risk [23].

Biedermann et Al. in a recent study showed a six fold higher relative risk of dislocation for cup anteversion of less than 4° or more than 24°. In a large number of patient, dislocation also occurred within the "safe zone". He stated that there is not an absolute safe cup position that prevents joint dislocation [24].

For this reason we think that soft tissue balancing and offset restoration are the main factors for good long term results. The inability to restore femoral offset adequately has been correlated with increased resultatant forces across the hip joint and their associated deleterious effects on wear rates, compromised abductor function and increased joint dislocation rates [18,25,26,27,28]. For

these reason we recommend the routine use of high offset stems and proper medialized cups.

Conclusion

Our experience with alumina bearing and 28 mm head (at mean F.U. of 3.2 yrs) revealed excellent radiographic and clinical results. Patients were pain free in 98.65% (no cases showed groin or thigh pain), with satisfaction rate of 99.38%. No mechanical failure or alumina fractures were observed in our study.

Joint dislocation occurred in 1.22% of our patients. These results are superimposable to the dislocation rates observed with large heads employment. We are in agreement with the literature and state that adequate preoperative planning, proper surgical technique and restoration of hip biomechanics are the pillars for good long term results.

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3.4 Ceramic Bearings Enlarging the Range of Indications for Bipolar Prostheses

A. Olk, T. Bartscher, J. Gusinde and F. F. Hennig

Abstract

Bipolar hemiprostheses are widely used for the treatment of medial fractures of the femoral neck in old patients with limited life expectancy since they allow for the surgical trauma to be reduced, and involve short rehabilitation times. The typical long-term problems encountered with such type of prostheses consisted in polyethylene wear and destruction of the cartilage in the acetabulum, which as a consequence caused protrusion into the minor pelvis. In conventional dual-head prostheses, the polyethylene used in the internal joint is subject to high mechanical strain which generally exceeds the strain rated for this material. The accelerated wear resulting from this causes loss of the sliding capacity of the internal joint, and hence prepares the way for technical failure of the conventional dual-head prosthesis. For this reason, a ceramic dual-head prosthesis was designed, which allows for the friction inside the technical internal joint to be minimized, and offers maximum biological compatibility of the external ceramic joint.

With this ceramic-on-ceramic dual-head prosthesis, the range of indications can be extended to fitter patients also. So far, the implant has passed the laboratory tests and yielded good initial clinical results, hence its clinical application offers the same safety of use at such early stage as do conventional dual-head implants. Observation of the benefits offered in respect of permanent exposure must be continued.

Introduction

The hemiprosthesis was developed for the treatment of femoral neck fractures in very old patients. The principle of treatment was to provide arthroplastic replacement of only the part of the skeleton which was destroyed by the fracture, if the acetabular cup was in good condition corresponding to the age of the patient. This allowed for the surgical trauma of the patients who frequently enough were very old to be minimized, and for early and rapid rehabilitation to be achieved. This type of surgery was restricted to patients whose life expectancy was below 2 years. However, since the clinical picture at the time of the fracture frequently is misleading, a number of patients survived much longer and the rigid metal head frequently enough caused protrusion which resulted in the necessity of complex revision surgery [8]. The development of bipolar prostheses in the early seventies allowed for the range of motion of the artificial head in the natural cup o be reduced substantially. Depending on the design and the dimensions of the internal head, either a larger or smaller part of the motion was transferred to the socalled internal joint. The increased tendency towards luxation as a result of valgic tipping of the external head was counteracted successfully in the early

teighties when the eccentric bipolar design was introduced [1,5]. One of the first models of this design, i.e. the Hastings II prosthesis [5] was used already in the treatment of patients below the age of 60. The 4 years' results obtained from follow-up examinations exhibited only minor wear of the acetabular joint surface in the radiograph. This type of prosthesis was also used successfully in the treatment of far medial fractures of the femoral head in young patients [19]. This technology allowed for the surgical trauma and hence for the postsurgical morbidity to be reduced in analogy with the known conventional hemiprostheses, and therefore is superior by the short rehabilitation times it enables [12]. Soon, it was possible to transfer the findings gained from the surgery of knee-joint and capsular ligaments to the hip joint. It was shown, that reduction of the trauma in the area of the capsule, of the limbus and of the natural cup enabled the preservation of proprioceptors which clearly alleviate the recovery of a physiological gait especially in the case of old patients. This is the reason why generally there aren't any problems observed during rehabilitation after dual-head implant surgery, which often is astonishing [13]. Owing to these features, the range of indications was enlarged substantially. Resulting from this is that the benefits offered by bipolar prostheses can be enjoyed over a longer implant period only if the bearings are optimized.

Methodology

For this reason, we have conceived a ceramic-on-ceramic dual-head prosthesis. The configuration of ceramic components allows for optimum tribology of the ceramic surfaces in the internal joint. The rate of abrasion is less than 0.005 mm per year. There weren't any cold forming processes observed. Also, there wasn't any elastic deformation reported for the components used, and hence the sliding capacity of the internal joint will not be affected neither by abrasion nor by forming processes. In the external joint, i.e. on the articulation surfaces of the bipolar prosthesis and the natural cup, the high degree of surface lubrication can contribute to improved sliding properties and to the minimization of friction between the ceramic component and the articular cartilage. According to Yunoki [18], the friction coefficient of ceramics/cartilage bearings is 0.2, of cartilage/cartilage bearings is 0.1 and of metal/cartilage bearings ranges at 0.3-0.4. In order to achieve maximum technical precision and functionality, the surfaces of the individual ceramic elements exhibit a high-polish finish and an extremely low roughness [17]. The standard prosthetic head made from this material has been used since many years in various modular prosthetic systems [17]. Safe positioning of the ceramic bipolar system is achieved by offsetting the centers of motion of the external and the internal balls - i.e. by offsetting the external shell and the internal ball – as a result of the auto-centering effect (Fig. 1). Internal luxation – i.e. dislocation of the internal head from the shell – is prevented by a catch ring (Fig. 2). In order to simulate the risk of internal luxation on a testing machine, a dual head was tested using a maximum excursion of 50 degrees in order to understand the theoretical process leading to luxation. In this test configuration, the results obtained from dry testing were lower by approx. 10% than those obtained from direct axial tensile testing. In systems lubricated with water, the results obtained for an excursion of 50 degrees were again lower

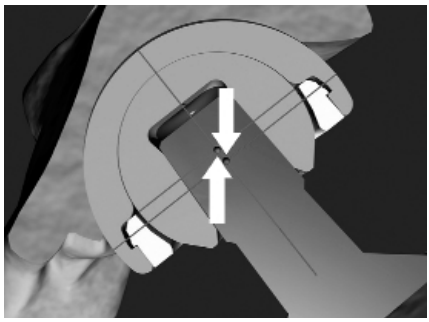


Figure 1:
Process of centering, body load in proportion to the load-carrying axis of the femur.

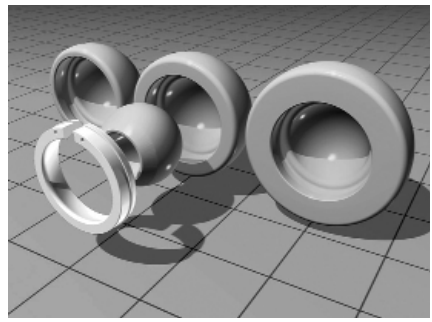


Figure 2:
The three components of the ceramic-on-ceramic dual head (Ceramtech Biolox-System).

by 10 % than the ones obtained from axial testing, and ranged at 800 N. The polyethylene ring will not be subject to any pressure load when exposed to physiological strain, and hence is not subject to abrasion and wear. It will stand unphysiological tensile strain of up to 1000 N without any problems. Moreover, such strain level would cause the internal head to be withdrawn from the external shell. Strain levels of this order will not occur under physiological conditions, since the external shell is held in the natural cup by adhesion forces of more than 1000 N alone (pull-out test of water-lubricated system using 1000 N, of unlubricated system 1100 N). The median breaking load tolerated by the individual components was 110 kN which is more than twice as high as the minimum load of 45 kN stipulated by the FDA. Selfevidently enough, the breaking load was determined for the system's weakest component configuration, and for systems featuring a diameter of 42 mm.

Clinical experience

The newly developed system is the only full ceramic bipolar implant system in the world, in which the ceramic ball is in direct contact with the outer ceramic shell . The outer shell of this implant system, and the ball head moving inside this shell consist of high-purity alumina [6]. The surgical procedure used for ceramic-on-ceramic dual-head systems is the same as for conventional metal/polyethylene systems. There isn't any special surgical technique required. The size of the external head is determined intraoperatively depending on the size of the resected femoral head. The length of the femoral neck of the prosthesis is determined during presurgical planning, and the internal head is selected accordingly. The internal head is inserted into the external head and fixed into place using a catch ring. This assembly will take only a few seconds. Then, either the dual head can be implanted and the stem plugged onto the system located in the acetabulum, or the entire assembly consisting of stem and dual head can be reduced as a whole as usual (Fig. 3). The primary results obtained also are the same as the results reported so far. In this respect, the system at any rate meets the same standards set by well-tried implants. The benefits which can reasonably be expected to show in the long-term results for reasons of the material components used are not available yet.

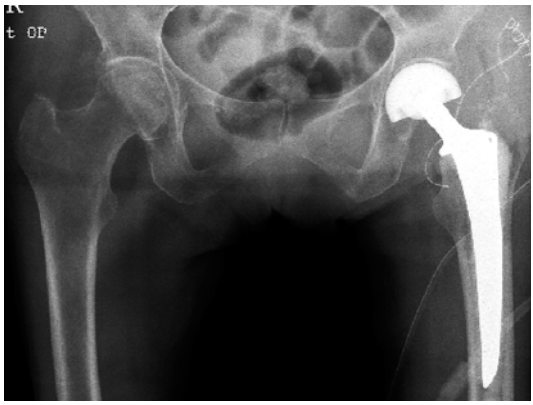


Figure 3:
Radiograph example.

In the period from 02/2001 to 02/2003, a total of 52 systems was implanted. The average age of the patients was 77 years. The youngest patient was 56 and the oldest 91 years old. The 56 year old female patient had an advanced metastatizing mammary carcinoma and hence the patient's life expectancy was relatively short. Of the 42 patients, 41 were reexamined. 8 patients had died in the meantime as a result of diagnoses which were not related to arthroplastic surgery, and 7 patients could not be reached. In both the clinical and radiological examination, the subjective assessment of the patients, the complications incurred and the radiological results were reflected. For subjective assessment of the success of arthroplasty, the patients were asked to evaluate their experience on an analog scale[10] which had 3 categories "very good", "good" and "bad". The circumscription pertaining to the category "very good" was "I am able to live and move just like before the accident, and I don't have any pain", to the category "good" was "I can no longer walk as long as I could before the accident but I am able to manage my household without any help, and occasionally I feel pain", and to the category "bad" was "since the accident, my range of motion has been restricted substantially, and I frequently have pain in my operated hip joint". 18 patients voted for "very good", 19 for "good" and 4 for "bad". With the exception of the 4 patients who had classified their experience as "bad", all of the patients were able to return to a level of activity which enabled them to manage their everyday life without any help. They were able to return to their homes although they were 86 and 85 years old, and did not have any pain but were in need of daily care provided by home nursing services. In one patient, luxation of the external joint occurred after a fall which he suffered 2 years after surgery. In this case, open reposition was required for reasons of interposition of soft parts. In the surgical intervention, the dual head was replaced and examined. There weren't any significant signs of wear found neither on the internal nor on the external joint. The acetabulum was in the same condition as it was at the time of initial implantation, and hence a new dual head was inserted. Biopsy of the acetabular cartilage yielded a normal structure with destructions located on the surface only (Fig. 5). There weren't any complications incurred after surgery. None of the patients exhibited system-related complications, and there wasn't any protrusion or luxation observed, which was not related to any adequate incident. In the radiological examination, there weren't any significant changes of the acetabulum observed compared to the situation prior to surgery.

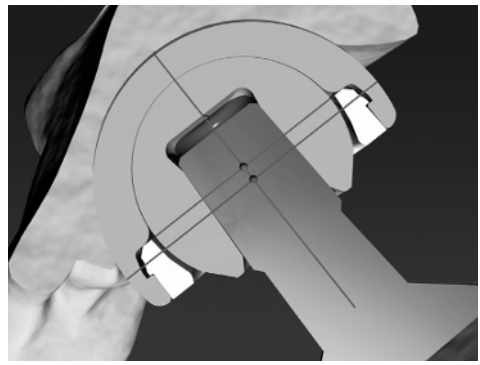


Figure 4:
Sectional drawing.

Also, there weren't any signs of early loosening observed in the area of the stem. When using an image intensifier, it showed that the external joint i.e. the contact area of the acetabulum and the external ceramic ball in abduction participated in the overall motion to approx. 1/3 only, which means that the main motion in the system, takes place in the technical joint as was planned to spare the patient. There will not be any motion taking place in the external joint until the moment when the neck of the prosthesis hits the catch ring, which means that the range of motion available to the old patient by far exceeds the range of motion utilized in the patients' everyday life, and that the external joint hence will not be subject to any significant strain (Fig. 4). This very sparing cooperation between the internal and the external joint is possibly due to an ideal geometry of the dual head and especially to minimized friction in the internal joint. This explains the high satisfaction on the part of the patients since the friction in the acetabulum, which can be very painful is possibly reduced to a minimum.

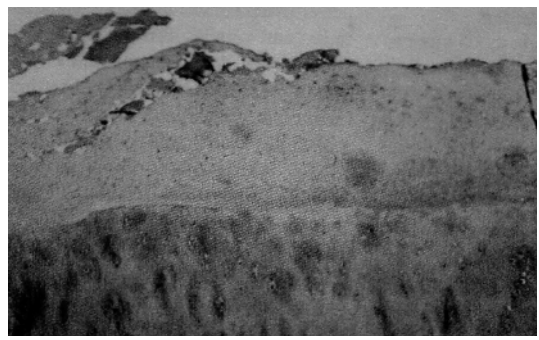


Figure 5:
Sectional view of acetabular biopsy; 2 years after implantation of the dual head.

Discussion

Although the system was originally designed for old patients with limited life expectancy, it was then used in the treatment of ever younger patients [12,17,18] and yielded excellent results. Lately, the modular bicentric dual-head prosthesis has been used successfully in a large number of cases - even in young patients - in which necrosis of the femoral head had incurred subsequent to head-conserving therapies in the treatment of femoral neck fractures, or in young

patients with serious head-destroying Pipkin fractures as an alternative to total hip replacement [13,18,19]. According to this enlarged range of indications, the requirements towards the technical performance of the implant have increased significantly. So far, polyethylene has been used for sliding surfaces in all bipolar prostheses. The wear of the plastic components in metal/polyethylene bearings ranges at 0.2-0.6 mm per year [1,3,4]. Such abrasion will result in increased friction which is caused by deterioration of the congruence of the sliding surfaces. In the case of total hip replacements, this will cause increased mechanical strain especially on the cup component. In the case of bipolar prostheses, this will cause the sliding capacity of the internal joint to decrease. Moreover, the abrasion particles will cause osteolysis of the implant bed, and hence will promote aseptic loosening of the stem [2,3,12,16]. Wear is not only caused by polyethylene ageing but also and mainly by 2 other processes, i.e. by abrasion and by non-elastic deformation of the relatively soft material. The degree of deformation of the polyethylene bed depends on different factors. Increased deformation must reasonably be expected especially in the case of thin polyethylene walls the thickness of which ranges below 6 mm [7,19]. Apart from that, the degree of deformation also depends on the design of the polyethylene implant. The wear processes incurred by polyethylene/metal bearings in total hip replacements have been analyzed to a large extent [2,4,10]. We have measured the non-elastic deformation of the polyethylene in bipolar prostheses in respect of the dual-head implants for which there hasn't been any alternative to the use of polyethylene inlays in the internal joint so far in Europe. Despite the precision of manufacture which generally was high for all of the implants examined (deviation from the ideal circle was less than 0.01 %), the cold flow exhibited by the pertaining polyethylene inlays corresponded to deformation in the range of 20 - 60 µm. This corresponds to a total deformation of 0.2 – 0.6 mm per year, and to a cup wear of approx 10 – 30 % [9]. The non-elastic deformation caused by cold flow constitutes the main reason for incongruence of the bearing surfaces, and hence for the substantial increase of friction. As the friction increases, however, the bipolar joint looses its function and turns into a protrusion-promoting rigid hemiprosthesis [14]. Izumi [11] reported on a study conducted for a number of 117 dual-head prostheses. Thereof, 3 implants had ceramic-on-ceramic bearings (Kyocera). In cases in which acetabular roof reconstruction was performed - e.g. in cases of dysplasia - the share of motion taking place in the technical joint was 81.2 %. The range of divergence was 1 % - 38 %. The ceramic-on-ceramic prostheses were not evaluated separately as far as their distribution in respect of the individual diagnoses was concerned. The patients who did not have to undergo revision of the acetabulum recovered a movability of 50 % of the internal joint and of 50 % of the external joint. All of the data were determined with the implant exposed to body weight. When not exposed to body weight, the shares of motion of the two joint elements shifted more to the external joint [15]. In contrast to the prosthesis presented in this paper, the dual-head prosthesis introduced by Yunoki [18] as early as in 1987 and featuring a ceramic head and a ceramic external joint (manufactured by Kyocera) provided for the motion to take place between a polyethylene inlay and the ceramics as the two ceramic components were separated by a socalled "bearing insert". This principle can reasonably be expected to reduce the rate of wear compared to metal/polyethylene systems. In the newly developed implant presented in this paper, the polyethylene is exclusively used to eliminate internal luxation (cf. Fig. 2).

For this reason, the polyethylene will not be subject to any wear since it will not participate in the motion and will not be exposed to load. The motion will exclusively take place on the ceramic-on-ceramic bearings. In the clinical follow-up examinations, a score of simple answers was used in order to comply with the patients who partly were of a very high age. The objective of the score was to obtain an assessment of the patients' activity level in their everyday life, and to obtain information about the loss of independence incurred by the patients as a result of surgery.

Although it is true that the follow-up examinations will provide preliminary results only for reasons of the number of patients and the relatively short follow-up examination period, it can be seen from the tendency observed that we managed to develop a low-wear and hence long-life implant. This is also confirmed by the findings of the histological examination of tissue specimen from the acetabular area which is exposed to load, which after a dwelling time of 2 years exhibited only minor superficial erosions together with a thin fibrous membrane, which are generally observed in older patients (Fig. 5). This confirms that the main share of motion takes place in the technical joint.

Conclusions

Bipolar hemiarthroplasty of the hip joint is used for the treatment of femoral neck fractures in cases in which the physiological acetabulum is largely intact and deep enough. Thanks to technical refinement and good clinical results, the range of indications which in the beginning was restricted to very old patients has shifted towards younger patients. However, in conventional dual-head prostheses, the polyethylene used in the internal joint is subject to high mechanical strain which exceeds the material's load rating. Accelerated abrasion and the known consequences of the loss of the internal joint's sliding capacity caused technical failure of the conventional dual-head prostheses. The newly developed ceramic-on-ceramic dual head which incorporates the total of positive properties offered by conventional dual heads constitutes a good solution. The implant has passed the laboratory tests and yielded good initial clinical results, and hence its clinical application offers the same safety of use at an early stage as do conventional dual-head implants. Observation of the benefits offered in respect of permanent exposure must be continued.

References

References at the author.

3.5 Kinematic evaluation of total hip arthroplasty with various bearing materials

D. A. Dennis, R. D. Komistek and M. R. Mahfouz

Introduction

Early failure mechanisms in total hip arthroplasty (THA) have included component loosening [16,20,32,42], material failure [3,17], infection [15], dislocation [7], osseous fracture [21,22], and neurovascular injury [41]. More recently, failure secondary to premature polyethylene wear, particularly associated with modular acetabular components, has become prevalent [3,17]. Only limited research has been conducted relating wear with the in vivo motions and forces occurring at the hip joint. Researchers have utilized both telemetry [1,2,9,14,42] and mathematical modeling [4,8,24,25,33,35,39,40] to predict in vivo forces across the hip joint. Data collected from these studies has been utilized in hip joint simulation devices to predict polyethylene wear patterns of acetabular components in THA [5,36,37,43] Unfortunately, polyethylene wear seen with simulated THA has not always produced wear patterns seen with retrieval analyses [5,12,30] Since discrepancies exist between wear patterns of simulated versus actual retrieval specimens, it can be assumed that variations exist between simulated and actual in vivo hip joint kinematics. These variations may be related, at least in part, to surgical alterations in the supporting soft tissue structures of the hip or to biomechanical alterations related to prosthetic geometry.

More recently, video fluoroscopy has been used to determine the in vivo kinematics of the hip joint [11,23,26]. Initially, these studies assumed the motions of the normal and implanted hip joints would differ since many of the soft-tissue supporting structures of the hip joint are altered during THA. These previous fluoroscopic studies confirmed that the femoral head may separate from the medial aspect of the acetabular component during both gait and when performing an active hip abduction-adduction activity [11,23,26]. It has also been reported that subjects having a metal-on-metal (MOM) THA experience less femoral head separation than subjects having a metal-on-polyethylene (MOP) THA [23]. The objective of this report is to perform a comparative analysis of hip kinematics in a large number of THA subjects implanted with differing femoral head and acetabular liner bearing materials to determine if the incidence and magnitude of hip separation in THA subjects is affected by the type of bearing material utilized.

Methods

The present report consists of a summation analysis of eight individual studies performed in our research laboratory over the last five years. Overall, 195 subjects implanted THA were analyzed under fluoroscopic surveillance while performing either gait on a level treadmill or an abduction-adduction maneuver. Institutional Review Board approval was obtained before commencement of each individual

study. Inclusion criteria included only those subjects with hip arthroplasties considered highly clinical successful (Harris Hip Scores[18] > 90 points) without pain or functional deficits. None of the subjects reported any signs of hip instability and none had suffered a dislocation postoperatively. No patient walked with a detectable limp and all could actively abduct their operated hips against gravity without difficulty. Average follow-up periods for the eight individual studies ranged from three to 26 months.

All THA subjects were implanted with one of four articular bearing surface combinations. These articular bearing surface combinations included metal-on polyethylene (MOP), metal-on-metal (MOM), alumina ceramic-on-polyethylene (AOP), or alumina ceramic-on-alumina ceramic (AOA) THA designs. The number of subjects tested during each of the three activities tested (swing phase of gait; stance phase of gait; abduction-adduction maneuver) is listed in Table 1. Due to the multi-center nature of this summation analysis, the arthroplasty procedures were performed by multiple surgeons.

Abduction / Adduction Maneuver
• 25 MOP / 10 AOP / 10 AOA
Gait: Stance Phase
• 10 MOP / 40 MOM / 10 AOP / 10 AOA
Gait: Swing Phase
• 10 MOP / 50 MOM / 10 AOP / 10 AOA

Table 1:
Number of subjects analyzed during each activity tested.

Those subjects tested during and abduction- adduction maneuver were analyzed in a stationary position with fluoroscopic visualization in the frontal plane. Those analyzed during gait performed normal walking while on a level treadmill. During the swing-phase of gait, the initial position analyzed occurred just after toe-off. Then throughout the swing-phase of gait, every third fluoroscopic video image was analyzed, including the image just before heel-strike. The number of images analyzed for each patient depended upon their stance phase of gait (average = 8 frames/subject). All subjects were analyzed using a computer automated three-dimensional (3D) model fitting process [10,27,38] to determine the distance between the femoral head and the medial aspect of the acetabular component (Fig. 1). Initially, 3D computer assisted

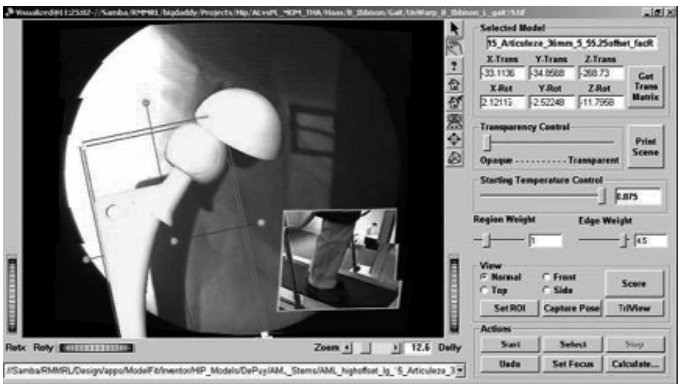


Figure 1:
Example of the 3D automated model-fitting process in which the computer assisted design (CAD) models of the femoral head, stem and the acetabular component are overlaid onto the 2D fluoroscopic image to determine three-dimensional position of the prosthetic components.

design (CAD) models of the acetabular component and proximal portion of the femoral component are entered into the two-dimensional (2D) fluoroscopic scene. Using an interactive approach, the operator, assisted by the computer algorithm, fits the 3D CAD model of the acetabular component onto the 2D fluoroscopic image of the acetabular component. Thereafter, the 3D CAD model of the proximal femoral component is precisely overlayed onto the 2D fluoroscopic image of the femoral component. The acetabular and femoral head components are then grouped together and rotated to a pure frontal view. The distance from the medial most aspect of the acetabular component and the medial aspect of the femoral head was then measured to determine if separation of the femoral head from the acetabular component had occurred (Fig. 2).

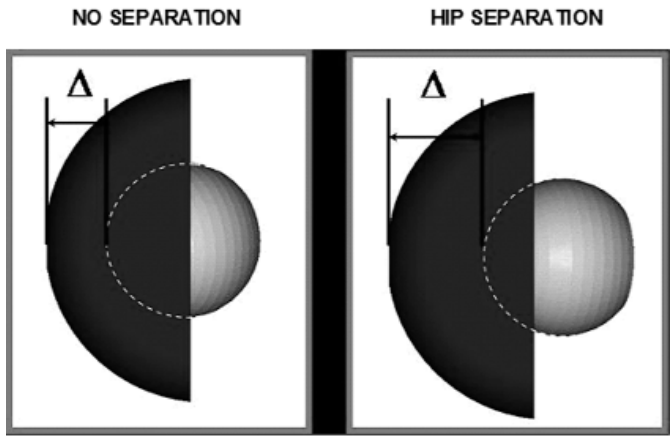


Figure 2:
Upon completion of the three-dimensional overlay process, the acetabular and femoral head components are grouped together and rotated to a pure frontal view. The distance ( ) from the medial most aspects of the acetabular component and femoral head is then measured to determine for the presence of hip separation.

An extensive error analysis was conducted using three different methods to verify the accuracy of the 3D model-fitting process. Initially, a mechanical apparatus that allows for two prosthetic components to be translated and rotated relative to each other was used. The known versus predicted implant positions were then compared [10]. Using this process, the relative rotational error was < 0.75 degrees and translational error < 0.5 mm. Next, the two components were similarly placed at known positions in space relative to each other. The fixated components were then rotated and translated while under dynamic fluoroscopic surveillance. The average error for this dynamic analysis was < 0.5 mm in translation and < 0.5 degrees in rotation [38]. Finally, the two components were surgically implanted into a fresh cadaver. Ninety relative orientations (translations and rotations) were captured using video fluoroscopy. An Opto-Track system (Northern Digital, Inc., Waterloo, Ontario, Canada), was used to determine the ground-truth (known position of each component relative to a fixed reference frame). Then the model fitting process was used to predict relative orientation of the implanted components. The error of all 90 trials was

< 0.5 mm in translation and < 0.5 degrees in rotation. Therefore, femoral head separation was predicted to occur if the femoral head-acetabular component distance was greater than our error threshold of 0.5 mm [27].

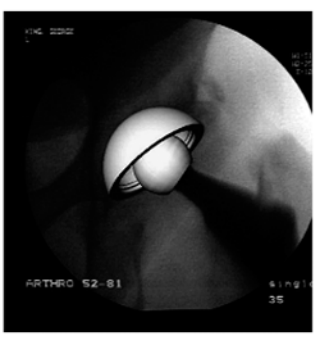
Results

The magnitudes of hip separation during an abduction-adduction maneuver are demonstrated in (Table 2). The greatest amount of hip separation was observed in those with a MOP THA (average 2.3mm; maximum 6.4mm; Fig. 3) and the least occurred in subjects implanted with an AOA THA (average 0.6mm; maximum 0.7mm). The incidence of hip separation greater than 0.5mm during an abduction-adduction activity was high in all implant designs ranging from 80-100% (Table 3a). This high incidence of hip separation persisted in MOP THA subjects when assessing the incidence of hip separation greater than 1.0mm (92%), but was much less in AOP THA patients (30%) and totally absent in those implanted with an AOA THA (Table 3b).

The magnitudes of hip separation during the stance phase of gait are shown in Table 4. Similar average magnitudes of hip separation were observed in MOP, MOM, and AOP THA subjects (1.1 - 1.3mm). The average hip separation was the least in subjects implanted with an AOA THA who exhibited an average hip separation value of 0.3mm which is less than the 0.5mm error value of the analytical process utilized. The incidence of hip separation greater than both 0.5mm and 1.0mm during the stance phase of gait varied substantially among the different THA designs tested but was greatest in MOP THA subjects and least in those with an AOA THA (Table 5a, 5b).

	AVERAGE (mm)	MAXIMUM (mm)
MOP THA	**2.3**	**6.4**
AOP THA	**1.1**	**3.2**
AOA THA	**0.6**	**0.7**

Table 2:
Magnitudes of hip separation occuring during an abduction-adduction maneuver.



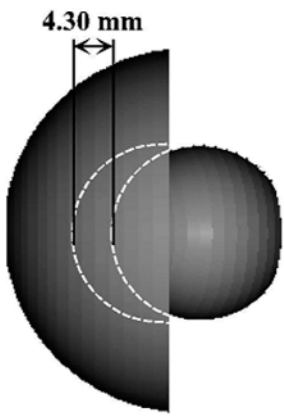


Figure 3:
Overlaid fluoroscopic image (left) and computer analysis of a subject implanted with a MOP THA demonstrating 4.30 mm of hip separation during an abduction-adduction maneuver.

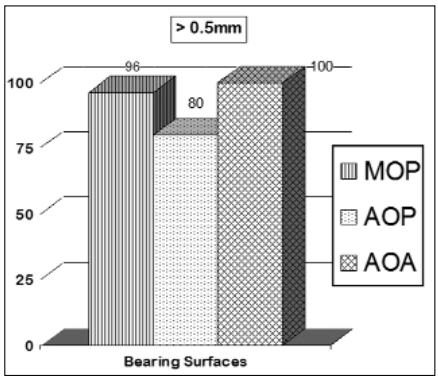


Table 3a:
Incidence of hip separation >0.5mm occurring during an abduction-adduction maneuver.

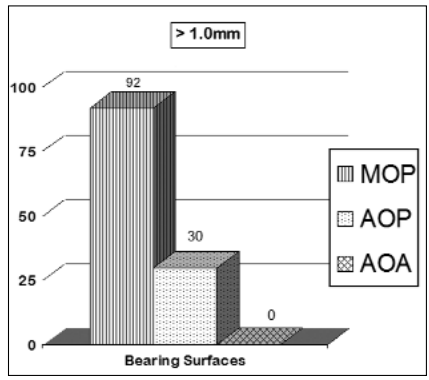


Table 3b:
Incidence of hip separation >1.0mm occurring during an abduction-adduction maneuver.

	AVERAGE (mm)	MAXIMUM (mm)
MOP THA	**1.2**	**2.8**
MOM THA	**1.1**	**3.1**
AOP THA	**1.3**	**7.4**
AOA THA	**0.3***	**0.6**

Table 4:
Magnitudes of hip separation occuring during the stance phase of gait.

***< Error Value of 0.5 mm**

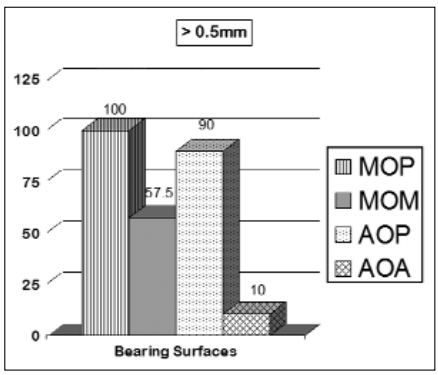


Table 5a:
Incidence of hip separation <0.5mm occurring during the stance phase of gait.

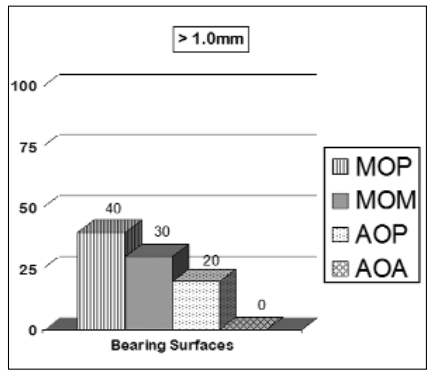


Table 5b:
Incidence of hip separation >1.0mm occurring during the stance phase of gait.

The magnitudes of hip separation during the swing phase of gait are demonstrated in (Table 6). Again, the greatest average values of hip separation were observed in those with a MOP THA (average 2.1mm; maximum 3.1mm) and the least occurred in subjects implanted with either a MOM or AOA THA (average separation 0.9mm and 1.0mm respectively). The incidence of hip separation greater than 0.5mm during the swing phase of gait was greater than 50% in all implant designs ranging from 50-100% (Table 7a, 7b). This incidence of hip separation greater than 1.0mm varied from 10-80%, being greatest in those implanted with a MOP THA (80%) and least in those with an AOP THA (10%).

	AVERAGE (mm)	MAXIMUM (mm)
MOP THA	**2.1**	**3.1**
MOM THA	**0.9**	**2.9**
AOP THA	**1.2**	**7.0**
AOA THA	**1.0**	**2.2**

Table 6:
Magnitudes of hip separation occuring during the swing phase of gait.

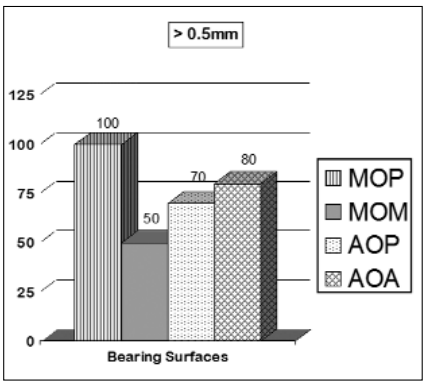


Table 7a:
Incidence of hip separation >0.5mm occurring during the swing phase of gait.

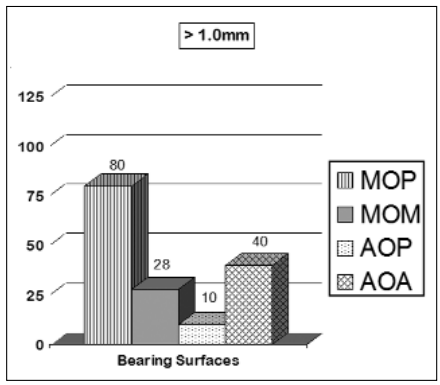


Table 7b:
Incidence of hip separation >1.0mm occurring during the swing phase of gait.

One cohort of patients in this multi-center analysis implanted with MOM THA was tested twice at two different time intervals. When tested early postoperatively (3-6 months postoperatively), no hip separation greater than the error value of 0.5mm was observed. This same group was re-analyzed at a mean follow-up period of two years and demonstrated an average separation value of 1.6mm, suggesting the magnitude and incidence of hip separation may increase over time.

The typical separation pattern observed is separation of the femoral head from the medial aspect of the acetabular component while maintaining contact with the polyethylene superolaterally. In this situation, the femoral head is therefore often pivoting on the peripheral rim of the polyethylene liner in extreme cases of hip separation.

Discussion

In an initial study analyzing subjects while performing a hip abduction-adduction maneuver, femoral head separation from the acetabulum was not observed in subjects with normal hip joints or those implanted with a constrained THA, but occurred in all subjects implanted with an unconstrained MOP THA [11]. Similar findings of a high incidence of hip separation were observed in an initial evaluation subjects having a MOP THA during gait [26]. These findings resulted in the hypothesis that patients implanted with an unconstrained MOP THA are subjected to inertial forces that produced separation of the femoral head from the acetabular component during several different dynamic activities. This evidence necessitated further analyses to determine if the incidence and magnitude of hip separation was affected by the type of bearing surface material utilized in primary THA.

In the normal hip joint, retention of the femoral head within the acetabulum is provided by numerous supporting soft tissue structures, including the fibrous capsule, acetabular labrum, ligament of the head of the femur (LHF), and the iliofemoral, ischiofemoral, pubofemoral, and transverse acetabular ligaments. During a THA, the LHF is surgically removed. Additionally, a portion of the remaining supporting soft tissue structures are transected or resected to facilitate surgical exposure. It is therefore logical to assume that the kinematics of the implanted hip may vary from the normal hip since the stabilizing soft tissues are altered at the time of operation. Hip separation is potentially detrimental and may play a role in complications observed with THA today including hip instability, premature polyethylene wear, and prosthetic loosening.

The role of hip separation in instability following THA is unclear and deserves further evaluation. Coventry [7] reviewed a group of 32 patients who suffered late dislocations following THA. He postulated that stretching of the supporting soft tissue structures (i.e., pseudocapsule) over time and extremes of range of motion may lessen soft tissue constraints and allow for late dislocation. Continued study of our present patient group is indicated to see if the amount of hip separation increases over time, suggesting a role in late hip instability.

The presence of hip separation may contribute to premature polyethylene wear due to increased shear forces placed on the polyethylene material during impulse loading cycles. The impulse generated by the collision of two objects has been shown to potentially compromise the structural integrity of mechanical components [40]. A simplified kinetic analysis indicated a predicted average increase in hip forces of 289.5 Newtons due to hip separation and the subsequent reduction of the femoral head back into the acetabulum resulting in the development of impulse loading conditions [11]. This increased load may potentially compromise implant fixation, resulting in premature component loosening. Additionally, during separation, the femoral head typically remains in contact and pivots on the polyethylene liner superolaterally, creating higher eccentric loads which increase the potential of premature polyethylene wear in this region.

Yamaguchi et al. [44] performed a three-dimensional evaluation of wear vectors in 104 retrieved acetabular components and found that 31 (30%) demonstrated multidirectional wear vectors which were highly variable among differing specimens. The maximum linear wear in retrieved liners with multi-directional wear vectors was greater than in those with unidirectional wear

patterns. They hypothesized that the multidirectional wear pathways observed may result in accelerated polyethylene wear due to increased shear forces. Pooley and Tabor [34] reported that when high density polyethylene is subjected to unidirectional sliding, the molecules tend to align along the direction of sliding, resulting in lowering of the coefficient of friction, potentially reducing wear of the material. With multi-directional wear patterns, they observed the shear stresses are increased and wear rates accelerate. Further study is required to define what role hip separation may play in creation of multidirectional wear vectors and accelerated polyethylene wear.

While hip simulator experimentation has been valuable in providing information on polyethylene wear, in vivo wear has proven to be a complex and multi-factorial process [6,12,13,29,30,37]. Data from hip simulators has not always equated well with retrieval studies with variations seen in wear rates and patterns as well as debris particulate size. These inconsistencies are likely related to multiple factors such as variations in the level of polyethylene oxidation, the rigidity of component fixation, the strength of periacetabular support [28], and hip kinematics of test versus retrieval specimens. Incorporation of hip separation into hip wear simulators may allow more accurate replication of in vivo conditions. The significance of the findings in this study is supported by the recent work of Nevelos et al. [31] who conducted an analysis to assess the significance of hip micro-separation in AOA THA. Using a hip simulator, micro-separation of the femoral head from the acetabular component during gait was incorporated into the simulated hip motion patterns. Their simulated specimens were then compared to in vivo clinical retrievals of the same implant design. They determined that contact between the femoral head and the peripheral rim of the acetabular insert as a result of micro-separation produced damage to the components which was similar to the damage observed in retrieval studies. They also observed similar grain boundary fracture wear mechanisms. Therefore, they concluded that micro-separation during simulator tests reproduced, for the first time, clinically relevant wear rates, patterns, debris and mechanics compared with THA retrievals.

Data collected from telemetric hip studies has demonstrated an increased force magnitude peak typically is present immediately after heel strike compared to the force magnitude at toe-off [1,2,19,42]. It has been hypothesized that this increase in force is due to muscle contraction. Based on the present fluoroscopic evaluations, we theorize that the increased force seen immediately after heel strike results, at least in part, from the femoral head translating back into the acetabular component at heel strike, producing impulse loading conditions. This hypothesis is supported by the work of Taylor et al [42] who conducted a telemetric study in which two proximal femoral replacements were instrumented to determine axial forces at two sites within the prosthesis. When analyzing consecutive steps during normal gait, they observed that the force just after heel strike and immediately before toe-off were often of differing magnitudes. Again it can be hypothesized that the increased force they observed immediately after heel strike could be attributed to hip joint separation resulting in generation of impulse loading conditions between the femoral head and acetabular component. Similar force patterns have been observed in the telemetric hip studies of Bergmann et al [1,2].

The reduced incidence of hip separation in subjects with AOA THA, and to a lesser extent, those implanted with a MOM THA, may be related to the narrow tolerance bands and high surface finishes of AOA and MOM THA components which allow for a thin film of fluid to become entrapped between the femoral head and acetabular liner. Because of the defined finish diametral trial clearances and the rheological properties of synovial fluid under physiological kinetics and kinematics, a thin micro-electric hydro-dynamic lubrication film can be present. The tighter radial tolerances of the AOA and MOM THA designs do not allow for discontinuities or voids between the femoral head and acetabular liner, which in turn, creates a fluid film cohesion with higher radial tension. Due to the increased wetability of ceramic surfaces, this film can effectively connect and constrain the femoral head to the acetabular liner during gait. This cohesive force only needs to sufficiently overcome the inertial forces causing the leg to separate from the body during the swing phase of gait. In MOP and AOP THA, larger diametral clearances between the femoral head and polyethylene liner exist. Additionally, wetability of polyethylene is less. We therefore hypothesize that the cohesiveness of the lubricating film of MOP and AOP THA is reduced, allowing hip separation to occur. The reduced incidence and magnitude of hip separation in subjects having an AOA or MOM THA leads to the hypothesis that patients implanted with these designs are subjected to more favorable mechanical environments and more uniform wear kinematics during gait.

Although hip separation was initially only found (and thought to only occur) during the swing-phase of gait, a high incidence and magnitude of hip separation during the stance-phase of gait was also observed (Fig. 4). It appears that during the stance-phase of gait, the acetabular component slides away from the femoral head from 66% of stance-phase to toe-off. In the normal hip, as the momentum of the pelvis moves forward, the capsular and ligamentous structures of the hip joint help maintain the femoral head within the acetabular component, even while the lagging foot remains planted on the ground through toe-off. We hypothesize that disturbance of capsular and ligamentous structures during THA allows the femoral head to separate from the acetabulum as the pelvis thrusts anteriorly along with the contralateral leg as it moves anteriorly through swing-phase and the lagging foot remains on the ground, completing stance-phase through to toe-off.

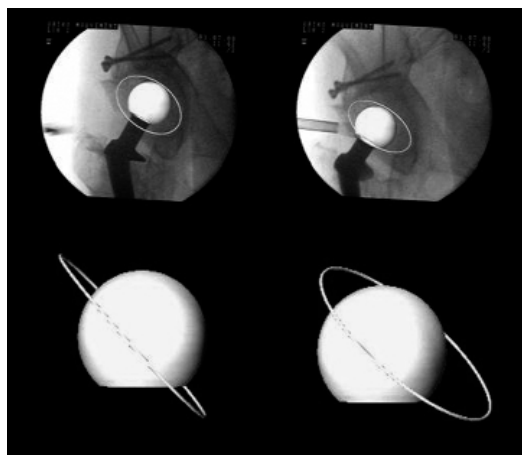


Figure 4:
Fluoroscopic (top) and computer analysis (bottom) images of a subject implanted with an AOP THA who experienced 7.4 mm of femoral head separation (right images), occurring from mid-stance to toe-off of the stance-phase of gait.

Summary

The present study demonstrates that femoral head separation from the acetabular component can occur under weight-bearing conditions during gait and an abduction-adduction activity in subjects implanted with various designs of THA. The incidence and magnitude is greatest in those with MOP THA and least in subjects implanted with an AOA THA. Potential detrimental effects resulting from hip joint separation include premature polyethylene wear, component loosening secondary to impulse loading conditions and late hip instability. The reduced hip separation observed in AOA THA subjects is likely related to the increased wetability of this material as well as reduced diametral clearance typically seen in hard-on hard bearings which results in a cohesive fluid film lubrication regime.

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3.6 Total hip replacement with all alumina bearings in patients under 30 years of age

G. Biette, R. S. Nizard, P. Bizot, F. Lemonne and L. Sedel

Introduction

Young patients with hip pathologies undergo heavy handicaps within their personal and professional lives. Total hip arthroplasty must last as long as possible and take into account the bone structure and the soft tissues.
With wear rates of less than 5 µ/year and almost no osteolysis on the long term, total hip replacement with all alumina bearings is an answer.

Materials and Methods

Between September 1979 and July 2002, 101 consecutives total hip arthroplasties with all alumina bearings (53 rights, 48 lefts) were performed on 75 patients (42 women and 59 men). Their average age was 24.1 years (13 to 30 years old). 24 arthroplasties were bilateral and 16 of them were implanted in one operation. 2 revisions of the same hip on under 30 year olds are included.

The preoperative diagnosis was avascular necrosis in 56 hips (steroid induced for 39 hips), inflammatory diseases in 13 hips, consequences of an acetabulum fracture in 8 hips, infection in the newborn in 7 hips, epiphysiolysis in 6 hips and miscellaneous in 11 hips.

76 of these arthroplasties performed in 56 patients (24 women and 32 men) have had a 2 years follow-up or more. 25 hips had previous surgery and 10 had a previous history of infection. The average preoperative Postel Merle d'Aubigné score was 11.3 ± 2.5 (Pain : 3.0 ± 1.2, range of motion : 4.7 ± 1.3 and walking ability: 3.6 ± 1.3).

As for the femoral stems (Ceraver Osteal company, Roissy, France), 60 were cemented and 16 cementless.

There were 5 different types of sockets (Ceraver Osteal company, Roissy, France) : 31 alumina cups (23 cementless, 8 cemented), 6 threaded titanium shell with an alumina liner, 13 cementless press-fit Ti alloy shell with an alumina liner and 26 Ti alloy rough and hydroxyapatite-coated.

Results

At the latest follow-up, one patient (2 hips) had deceased before 2 years, five patients (5 hips) were lost (foreign countries) and 69 hips (50 patients) were examined. The average follow-up was 7.3 years (2 to 18.6 years).

There were 9 revisions (average follow-up : 8.5 ± 5.2 years). 2 bipolar revisions : 1 infection (patient with rheumatoid arthritis with 10 years follow-up) and 1 aseptic loosening (18.6 years). There was 7 other aseptic loosenings of the

acetabular component (2 after a road accident (Fig. 1, 2) and 1 after pseud-arthrosis of the graft). 5 revisions were due to acetabular failure (1 bipolar) and 3 of them were cementless alumina cups.

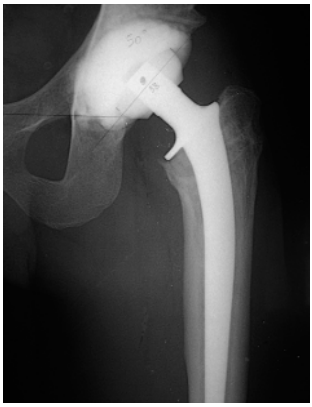

Figure 1:
Post-operative.

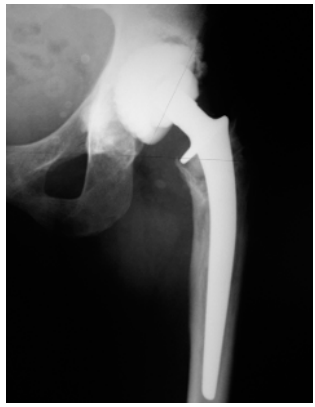

Figure 2:
7 years follow-up, road accident.

55 arthroplasties had a Postel Merle d'Aubigné score that was very good or good (16 to 18), 5 had a fair one (12 to 15) and 1 had a poor one (less than 12). 53 hips were in sports or active categories (36 before surgery). 3 women with unilateral arthroplasty gave birth without any problem.

Radiologic data showed 7 sockets with a radiolucent line. Only one of them was circumferencial without any migration of the cup. There were 10 stems with limited radiolucent lines in zone 7. No osteolysis was observed in either the femur or the acetabulum.

At the latest follow-up, 52 hips were graded A (good and very good clinical results, no radiological problem) (Fig. 3-6), 5 were graded B (good or very good clinical results but evidence of a radiological problem), 2 were graded C (poor clinical results, no radiological problem), and 10 were graded D (poor clinical results, evidence of a radiological problem. 9 revisions were included).

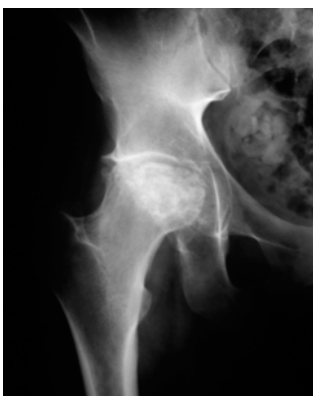

Figure 3:
Preoperative X-ray.

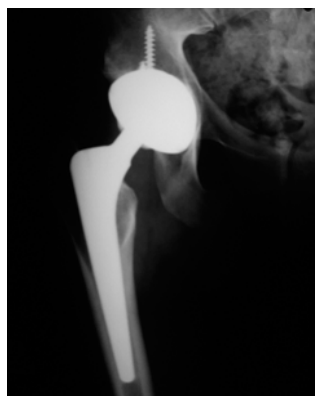

Figure 4:
7.5 years follow-up.

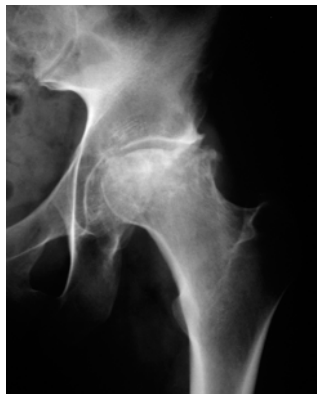

Figure 5:
Preoperative X-ray.

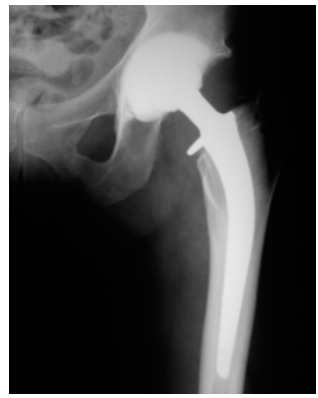

Figure 6:
7.5 years follow-up.

Conclusion

Total hip arthroplasty with all alumina bearings in young patients give acceptable results but it is difficult surgery. The main problem is related to socket fixation. There is an apparent improvement with metal backed alumina that needs to be confirmed with long-term results.

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SESSION 4

Ceramic knee

4.1 PE wear in ceramic/PE bearing surface in total knee arthroplasty: Clinical experiences of more than 24 years

H. Oonishi, S. C. Kim, M. Kyomoto, M. Iwamoto and M. Ueno

Abstract

We started to use a combination of alumina ceramic and ultra-high molecular weight polyethylene (UHMWPE) for total knee prostheses (TKP) in the late 1970s based on our good clinical results in total hip prostheses as well as the results of knee joint simulator tests. From 1982 to 1985, we operated 137 patients with TKP, which were mainly alumina/UHMWPE-typed. Since 1990, cemented alumina or zirconia ceramic/UHMWPE TKP have been used for more than 530 patients. In this study, we report the results of worn surface observation and the clinical wear with respect to the retrieved metallic TKP. The results of metal/UHMWPE bearing surface in TKP were compared with our clinical results of ceramic/UHMWPE one, in order to examine the efficacy of ceramic bearing surface in TKP. In the SEM observations, many scratches due to clinical use were observed on the retrieved metallic femoral component only. The scratching damage on the articulating surface was linear, which was produced by plowing of microscopic asperities on the opposite metallic surface. From clinical results and observations of the retrieved bearing surfaces, ceramic/UHMWPE TKP is superior to metal/UHMWPE TKP.

Introduction

In 1970, Boutin et al. started clinical use of highly pure alumina ceramic for total hip prostheses (THP) [1,2]. Also, our clinical results of THP around 1977 indicated that the wear of ultra-high molecular weight polyethylene (UHMWPE) socket was lower in combination with an alumina ceramic head than in combination with a metallic head. Since then, highly pure alumina ceramic has been widely used because of its good wear properties as well as high chemical durability and biocompatibility. We started to use a combination of alumina ceramic and UHMWPE for total knee prostheses (TKP) in the late 1970s based on our good clinical results in THP as well as the results of knee joint simulator tests [3].

The knee simulator wear tests were performed on TKP consisting of an alumina ceramic femoral component (F-comp) with an UHMWPE insert and a Co-Cr alloy F-comp with an UHMWPE insert (Total condylar knee arthroplasty), and these results were compared [4]. After 1.0×10^6 cycles in the simulator test, the linear wear of UHMWPE insert was 0.3 mm in the case of combination with the metal F-comp, whereas no linear wear was seen in many portions of UHMWPE with the alumina ceramic F-comp. The linear wear rate of the UHMWPE insert in the latter was less than one tenth that in the former (Fig. 1).

Some refinements of the ceramic TKP designs have been carried out to improve the kinematical properties and the fixation of TKP with living bone up to now (Fig. 2).

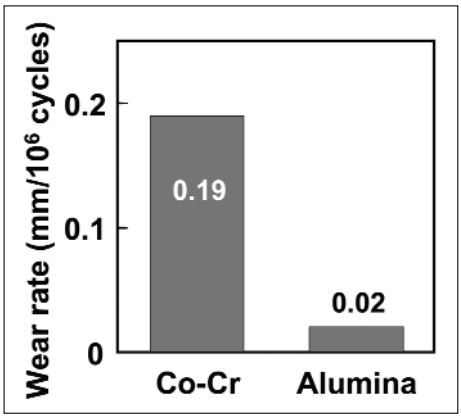
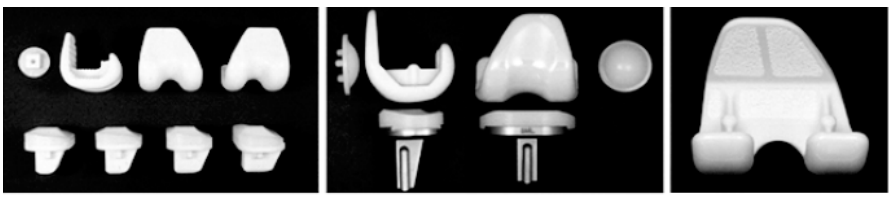


Figure 1:
Wear rate of UHMWPE insert with Co-Cr and alumina femoral component from knee simulator test.



a) The 1st generation (1981-1985).

b) The 2nd generation (1990-1996).

c) The 3rd generation (1993-1998).

Figure 2:
Development of ceramic total knee prosthesis.

The first generation TKP used from 1981 to 1985 consisted of an alumina ceramic F-comp, an alumina ceramic tibial-component (T-comp), and an UHMWPE insert. As an alumina ceramic raw material, a polycrystalline alumina with 99.5% or higher purity was used. The stem of an alumina ceramic was positioned at the center of the T-comp so that load was transmitted from the stem to the cortical bone in the posterior portion of the tibia. On the portion of the bone contacting F- and T-components, small and shallow grooves were observed. Both F- and T-components can be used as both cementless and cement fixation. In the first generation TKP, 137 joints have been followed-up for 20 to 23 years after implantation (Fig. 3). The rates of loosening, sinking and revision were higher in cementless fixation than in cemented fixation [5,6].

The second generation TKP used from 1990 to 1996 consisted of an alumina ceramic F-comp, a titanium alloy T-comp and an UHMWPE insert. The alumina ceramic T-comp in the first generation TKP was changed to the titanium alloy T-comp to be fixed with bone cement, because an alumina ceramic T-comp was thick and brittle, and the relatively high incidence of sinking and occurrence of radiolucent lines were observed on the components in the case of cementless fixation. In the third generation TKP used from 1993 to 1998, the porous coating of ceramic beads was made on the surface of F-comp in order to improve the fixation between the bone cement and the ceramic F-comp.

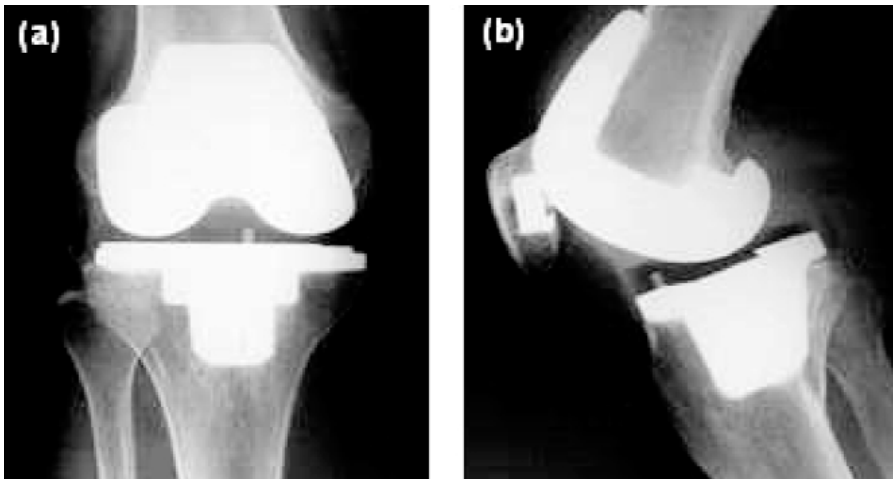


Figure 3a, b:
The 21 years-postoperative radiographs of the patient implanted with the first generation TKP. (a) anteroposterior and (b) lateral.

In Japan, Zirconia ceramic has been used for TKP (KU type, Kyocera Corp. Kyoto, Japan) since 2001 due largely to its higher strength than that of alumina ceramic (Fig. 4). We reported the clinical results of the second and third generation ceramic TKP (total 534 joints, 1990-2005). All the components were implanted with bone cement. In total 249 joints after 6-14 years of follow-up, no case of loosening or sinking was observed (Fig. 5). The radiolucent lines were observed at rates of 4.3% and 2.1% at the medial and lateral areas of tibia, respectively. Osteolysis has not occurred in all of the cases observed.

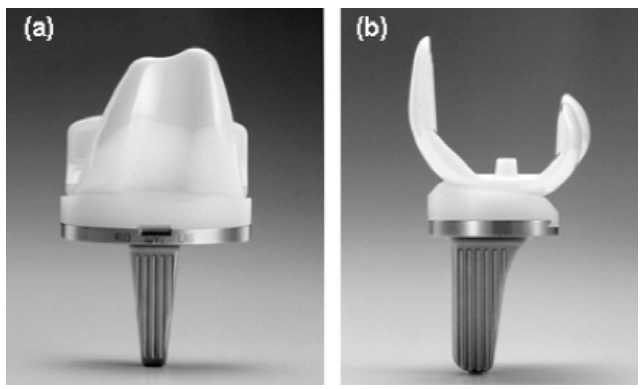


Figure 4a, b:
Zirconia ceramic TKP (KU type).

In the previous studies, we compared the surfaces of retrieved UHMWPE inserts against a ceramic (alumina) F-comp with those against metallic (Co-Cr alloy) F-comp, which were used for short term [5]. The former was the first generation TKP (KOM type, Kyocera Corp. Kyoto, Japan). No loosening and postmortem were observed after 6 years-implantation. The latter TKP (PCA type, Howmedica Corp., Rutherford, NJ), which was retrieved by late infection after 3 years-implantation, also showed no loosening.

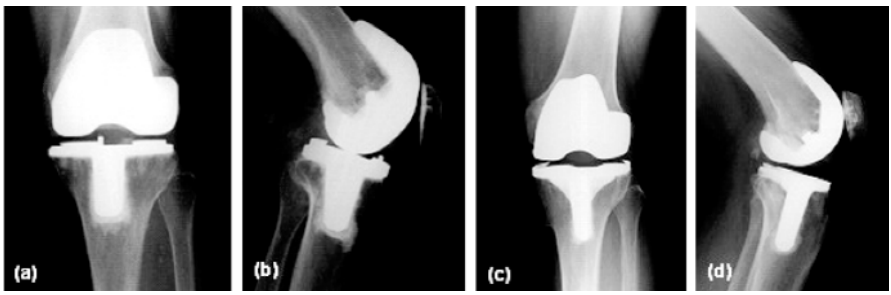


Figure 5a-d:
The 14 years-postoperative radiographs of the patient implanted with the second generation TKP. (a) anteroposterior and (b) lateral. The 6 years-postoperative radiographs of the patient implanted with the third generation TKP. (c) anteroposterior and (d) lateral.

The UHMWPE insert surfaces in the KOM were found to have gently sloping machine marks on non load-bearing areas, while machine marks on load-bearing i.e. worn areas completely disappeared after 6 years-operation (Fig. 6a). Overall observation revealed that almost all the surfaces were smooth and burnished without scratches or pits. The polyethylene folding phenomenon, which is thought to be caused by third-body wear occurring as a result of interposition of polyethylene wear particles between components, was also seen in places, though to a small extent. It was suspected that a part of the tip of this folded polyethylene was torn into debris when a force was transmitted onto the tip from the femoral component. In the case of a PCA with a combination of Co-Cr alloy and UHMWPE, burnishing was seen where machine marks disappeared, and small scratches were observed at these sites after 3 years operation (Fig. 6b). The folding phenomenon was observed frequently, and the folding area mingled with scratches in many parts.

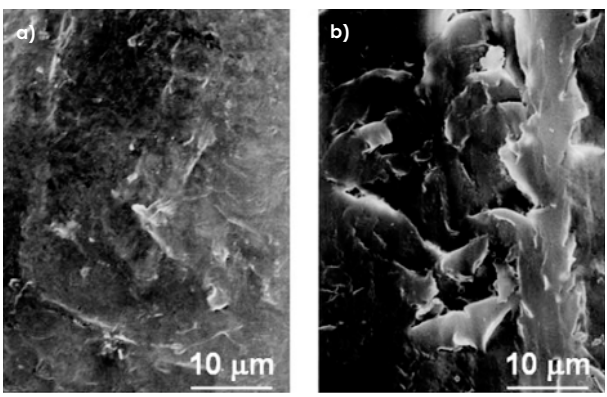


Figure 6a, b:
SEM images of worn areas of retrieved UHMWPE insert surfaces. (a) KOM type (with alumina), (b) PCA type (with Co-Cr).

We reported the detailed wear pattern and wear volume for the retrieved ceramic TKP which was used for long term (23 years) [7]. The KOM type TKP implanted in 1979 and retrieved in 2002 was examined. This KOM type was the clinical trial of the first generation TKP. The patient was a 60 years woman at the time of the first surgery and the original diagnosis was osteoarthritis of the knee. The reason for the revision surgery was subsidence of the T-comp due to

osteoporosis yet without pain. The osteolysis was not observed on the X-ray image in the course of the follow-up before occurrence of the sinking of the T-comp (Fig. 7). This case was a cruciate ligament sacrificing cementless TKP. The UHMWPE insert was machined from a GUR412 sheet (Hoechst AG), and then sterilized with ethylene oxide gas.

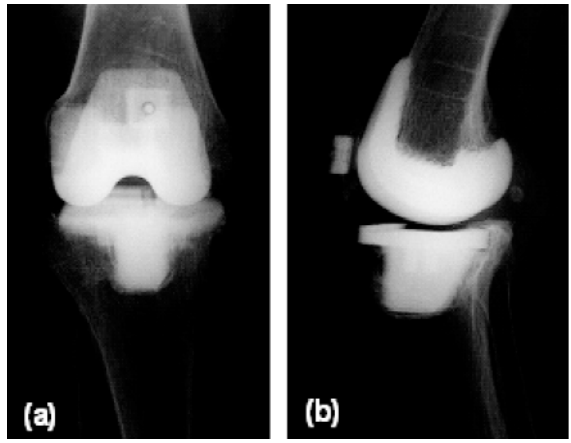


Figure 7a, b:
The 23 years-postoperative radiographs of the patient implanted with the first generation TKP.
(a) anteroposterior and
(b) lateral. radiographs of.

The worn area of the alumina F-comp and the UHMWPE insert surfaces were observed by scanning electron microscopy (SEM). Lots of small pits of several micrometers were observed on the F-comp (Fig. 8a, b). The pits observed in areas without contact with the UHMWPE insert were ascribed to be formed in the manufacturing process. Even higher-magnification observations demonstrated no scratches or pits caused by wear. In contrast, a lot of wear scratches were clearly observed even in lower-magnification (x35) observation of the UHMWPE insert (Fig. 8c and d). However, higher magnification (x1000) observations did not show severe wear as a wear analysis with metallic F-comp as shown in Figure 6b.

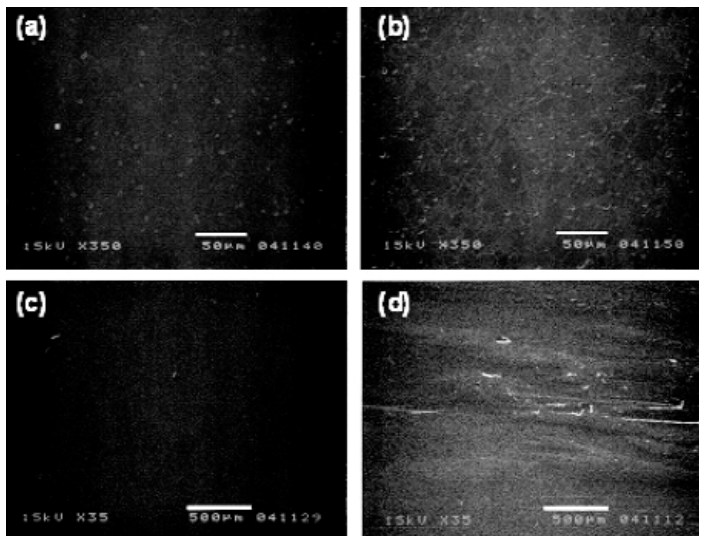


Figure 8 a-d:
SEM images of bearing surface;
(a) unworn area of alumina F-comp (bar: 50 µm),
(b) worn area of the alumina F-comp (bar: 50 µm),
(c) unworn area of the UHMWPE insert (bar: 500 µm) and
(d) worn area of the UHMWPE insert (bar: 500 µm).

The maximum deformation distance of UHMWPE insert from the original shape was 0.851 mm. The linear and volumetric wear rates were estimated at 37 μm/year and 18.8 mm^3/year, respectively.

In this study, we observed the worn surface of the retrieved TKP, which were implanted for long term, and evaluated their clinical wear. The results of metal/UHMWPE bearing surface in TKP were compared with our clinical results of ceramic/UHMWPE one, in order to examine the efficacy of ceramic bearing surface in TKP.

Materials and Methods
Retrieved metallic TKP

The retrieved TKP (case 1) was implanted on April in 1983, and retrieved on June 22, 2004 because of painless sinking of the T-comp. The original disease of the patient (female) was osteoarthritis of the knee. This TKP (made by Zimmer, Inc., Warsaw, IN) consisted of a Co-Cr alloy F-comp and an UHMWPE insert (Fig. 9a, b). The components were designed for cement fixation.

In the other case (case 2), the retrieved TKP was implanted in October 1987, and retrieved in July 2004. The patient was female. This TKP (PCA type, made by Howmedica Corp., Rutherford, NJ) consisted of a Co-Cr alloy F-comp, a Co-Cr alloy T-comp, and an UHMWPE insert (Fig. 9c,d).

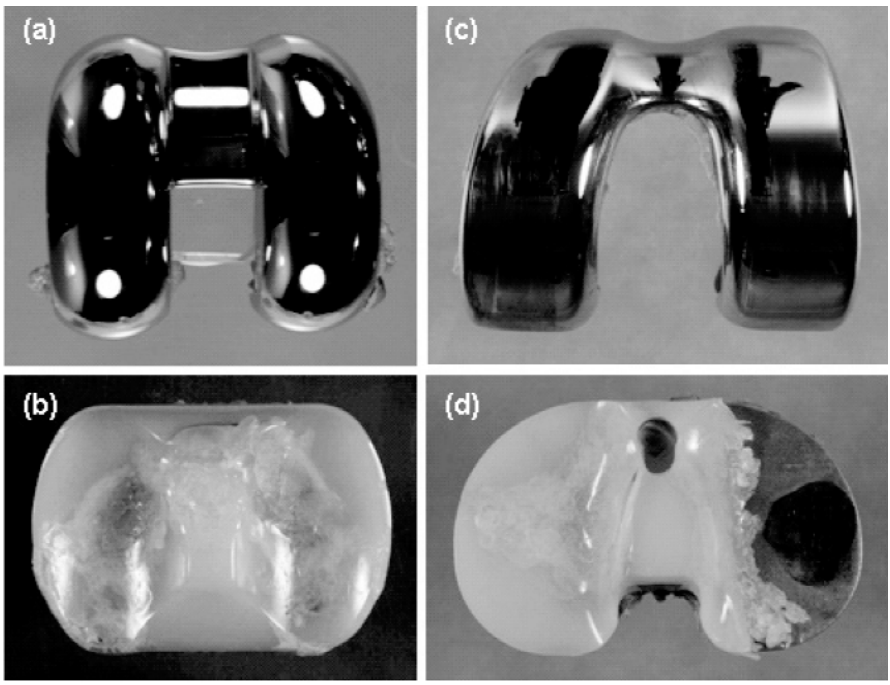


Figure 9a-d:
Pictures of retrieved TKP after 21 years operation (Case1); (a) Co-Cr alloy F-comp, (b) UHMWPE insert and 16 years operation (Case2); (c) Co-Cr alloy F-comp, (d) UHMWPE insert.

Methods

The wear pattern and linear wear of metallic TKP were investigated. The worn surface of the Co-Cr F-comp and the UHMWPE insert were observed by an optical microscope and a SEM. A model VHX-200 optical microscope (Keyence Corp., Osaka, Japan) was used for the optical microscope observation. A model S-3400N scanning electron microscope (Hitachi Ltd., Tokyo, Japan) was used for SEM observation at an acceleration voltage of 15 kV.

The surface roughness was measured by a model S-405 surface roughness analyzer (Kosaka Laboratory Ltd., Tokyo, Japan). Each measurement consisted of 3 parallel traces 0.8 mm in length in unworn surface and worn surface of the Co-Cr F-comp.

The shapes of the medial and lateral areas of the UHMWPE insert were determined by a shape tracer (CONTOURECORD 1600, Tokyo Seimitsu Corp., Tokyo, Japan). Comparing the shape of the retrieved components with the original one, which was estimated from marginal (i.e. unworn) shape of insert, linear wear was calculated.

Results and Discussions

In the optical microscope observations, the frosting (dim) part was observed at worn area for both condyles of F-comp (Fig. 10a, b).

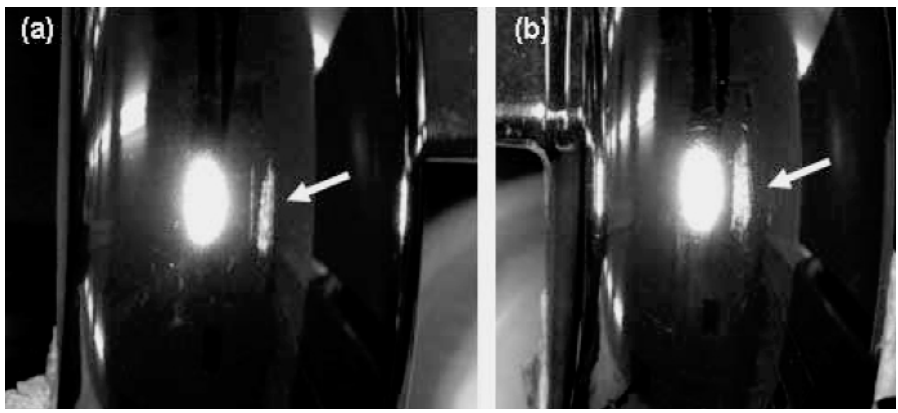


Figure 10a, b:
Optical microscope images of surface of Co-Cr alloy F-Comp after 21 years operation. (a) medial, (b) lateral. Arrows indicate frosting of surface.

In the SEM observations with high magnification (x350), a lot of scratches parallel to a direction of anterior-posterior were clearly observed on those areas (Fig. 11). The scratches were also observed on the surface of the UHMWPE insert.

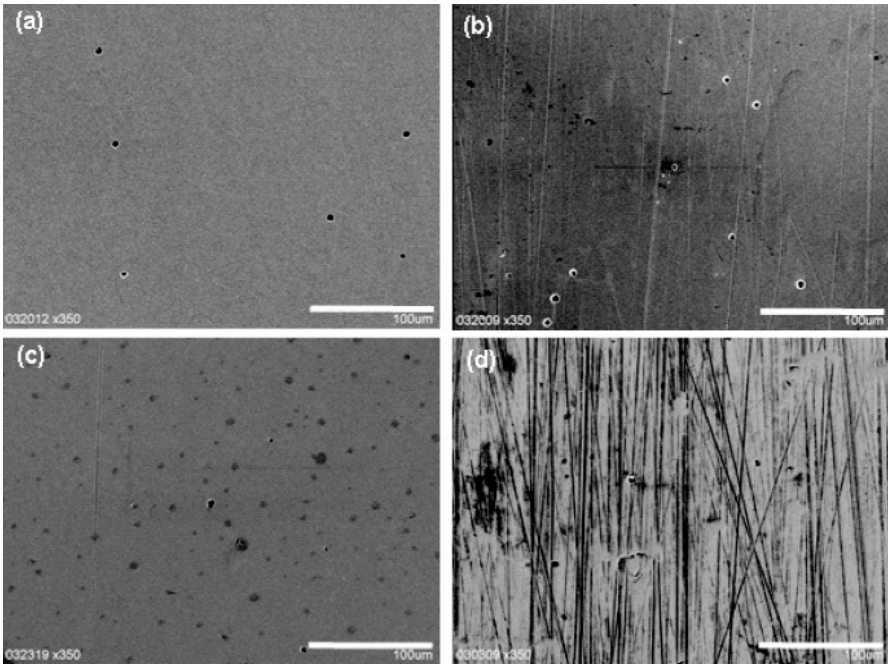


Figure 11a-d:
SEM images of surface in unworn and worn area of Co-Cr alloy F-Comp. (a) unworn area, (b) worn area: Case 1; (c) unworn area, (d) worn area: Case 2. Bar indicates 100 µm.

The average surface roughness, Ra, and the maximum surface roughness, Rmax, of the unworn and worn surface of the Co-Cr F-comp are shown in Table 1. In the case 1, the surface roughness (Ra, Rmax) of the worn surface was significantly higher compared with that of the unworn surface. In the case 2, the surface roughness (Rmax) of the worn surface was higher compared with that of the unworn surface.

	Case 1				**Case 2**			
	unworn	surface	worn	surface	unworn	surface	worn	surface
Measuring direction	A-P	M-L	A-P	M-L	A-P	M-l	A-P	M-P
Ra (µm)	0.02	0.03	0.07	0.07	0.05	0.05	0.06	0.07
Rmax (µm)	0.18	0.22	0.26	0.37	0.18	0.15	0.24	0.38

Table 1:
Surface roughness in unworn and worn surface of Co-Cr F-comp.

Based on these results, linear wear was calculated. The surface profiles of the UHMWPE insert (case 1) are shown in Figure 12.
The maximum linear wear was observed at the medial-central position.
The maximum deformation distance from the fit shape was 1.680 mm (Table 2).

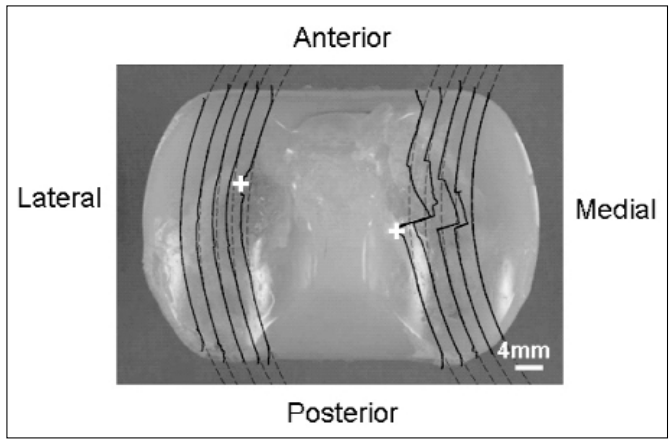


Figure 12:
Optical image of UHMWPE insert (case 1) estimated by using a shape tracer. Lines indicate surface profiles. "+" marks indicate the maximum deformation point at each area.

	Medial	Lateral	Total
Maximum deformation distance (mm)	1.680	1.460	–
Linear wear rate (mm/year)	–	–	0.08

Table 2:
Maximum deformation distance and linear wear rate in the case1.

The linear wear rate was calculated as 0.08 mm/year. In the case 2, extreme damage at medial area of the insert was through the UHMWPE insert to metallic T-comp. The linear wear was over 6 mm in this case.

The orthopedic literatures contain thousands of articles describing the clinical performance of knee replacement with various designs and materials. As in the hip replacement, the clinical performance of knee replacement can be unambiguously defined in terms of survivorship. Surgeons may disagree as to the precise etiology of a TKP failure, but the date of a revision surgery is a precise endpoint for the procedure.

On the other hand, survivorship alone does not fully capture the clinical performance of UHMWPE in the knee. The surface damage and wear of the UHMWPE insert are also important measures of clinical performance of TKP. When the surface damage (e.g. Abrasion, delamination) in UHMWPE insert for TKP is discussed, the resin grade and sterilization method have to be considered. Also, the design of bearing surface is an important factor. However, the scratching damage on the UHMWPE insert surface, produced by plowing of microscopic asperities on the opposite metallic surface. Lots of scratches during clinical use were observed on the retrieved metallic F-comp only. In contrast, ceramic F-comp substantially maintained virginal surface quality as reported in the previous study [7]. Therefore, ceramic F-comp has a large advantage on the wear of UHMWPE insert.

Conclusion

Detailed observations of wear for retrieved implants are important to examine actual clinical performance of artificial joints. In this study, we investigated the wear of retrieved metallic TKP which were implanted for long term. The results of metal/UHMWPE bearing surface in TKP were compared with our previous clinical results of ceramic/UHMWPE one. The metallic TKP showed higher wear rate with scratching surface damage compared with ceramic TKP. The lower wear rate and the milder wear nature observed in the latter suggest the possible reduced wear of the UHMWPE against the alumina ceramic F-comp. Thus, the alumina ceramic TKP is expected to retain high performance even for long clinical use.

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4.2 Hypersensitivity reactions in association to arthroplasty

M. Thomsen and P. Thomas

Some patients undergoing arthroplasty may develop clinical complications that are not explained by common causes like infection or mechanical problems. Reactions as local or generalized eczema, urticaria, impaired wound or osseous healing, seroma formation and implant loosening are seen in some cases [4,5,6, 10].

In such patients hypersensitivity reactions may be the underlying cause. Typical elicitors are metals like Ni, Cr or Co which are known to induce contact sensitivity. According to a recent german study cutaneous metal sensitisation rates in the general population are: to Ni 13.1% (females 20.4%, males 5.8%), to Co 2.4% (females 3.4%, males 1.4%) and to Cr 1.1 % (females 1.5%, males 0.7%) [8]. Occasionally hypersensitivity reactions have been seen to Tantalum and Vanadium [1,10], as well as rarely to Titanium [7,11]. But also bone cement components (acrylates, additives like benzoyl peroxide, p-toluidine, antibiotics) may provoke hypersensitivity reactions [3,12]. However, in patients with endoprosthesis related complications not only allergological work-up is rarely performed but in the case of allergological testing, bone cement components are often neglected.

But apart from allergological diagnostics by patch test , which may not always detect hypersensitivity [2,9] and assessment of lymphocyte reactivity, also analysis of periimplantar tissue may indicate T-cellular hyperresponsiveness [9,13]. Based on a series of patients, characteristic clinical and in vitro findings will be presented.

Case 1

A 73-year-old female patient had developed eczema at the left knee two months after implantation of a cemented Co-Cr-based knee arthroplasty. With the exception of a diabetes mellitus and an arterial hypertension the patient was at good health. There was no history of preceding allergy. At examination, the left knee was swollen, warm and showed local eczema. Patch testing to standard series, additional implant metals and bone cement components gave a + reaction (D3) to benzoyl peroxide and to molybdenum chloride. Since eczema disseminated and the left knee was increasingly painful, a revision surgery was performed. Upon introduction of a titanium based, cement free endoprosthesis eczema still continued over the next weeks and then gradually resolved.

Case 2

At the age of 66 a female patient received an uncemented CoCrMo-based right knee arthroplasty. Within few weeks she developed pain, recurrent swelling and erythema/eczema at the knee and proximal part of the lower leg (Fig. 1a).

There was no history of pre-existing allergic disease nore of cutaneous intolerance of metallic daily use articles. Upon patch testing an isolated Co-allergy was shown (Fig. 1b) and in vitro lymphocyte hyperreactivity to Co was found. Since symptoms persisted and initial loosening was suspected, revision surgery was done.

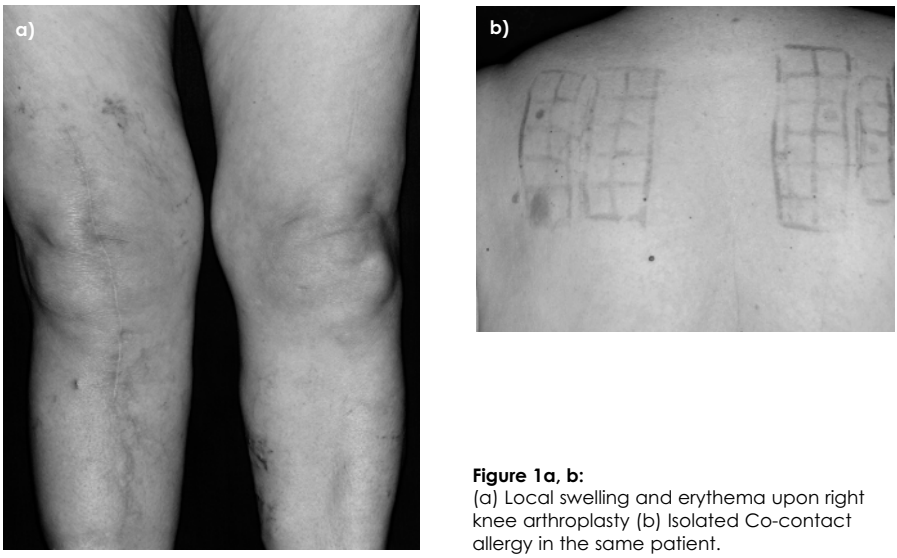

Figure 1a, b:
(a) Local swelling and erythema upon right knee arthroplasty (b) Isolated Co-contact allergy in the same patient.

Case 3

A 55-years-old male had developed increasing pain, local seroma formation and implant loosening following a metal-to-metal arthroplasty of the right hip. Patch testing showed no metal allergy. Upon revision surgery periimplantar tissue was obtained and gave no signs of infection, but showed dense lymphocytic infiltrate (Fig. 2). In addition prevalence of memory-type T-cells was found. Furthermore, out of periprosthetic tissue, Co-reactive T-cells could be expanded. Thus, a periimplantar metal- (Co-) hypersensitivity was concluded [9].

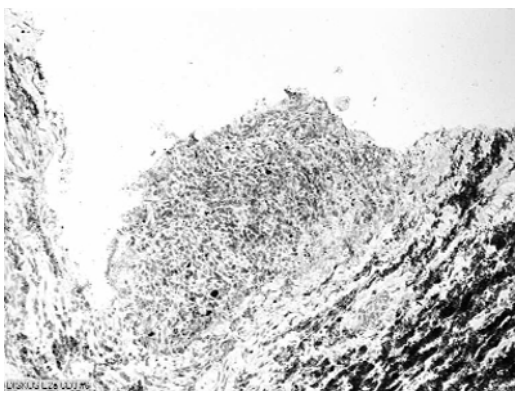

Figure 2:
Periimplantar tissue showing metallic debris and dense T-cellular infiltrate (anti-CD3-stain), [from 9].

Although case reports as our here described patients demonstrate the existence of allergic reactions to implant materials, their incidence seems to be rather low. In the case of suspected allergy, patch testing to a standard series, especially extended metal series and selected bone cement components are recommended. The role of lymphocyte transformation test still needs to be evaluated. Histological analysis of periimplantar tissue would be a further step, which however yet cannot be done routinely.

Most important is the preoperative awareness of allergic sensitisation as well as the individual information of the patient about potential risks and optional treatments.

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4.3 Ceramic Knee Design

P. Dalla Pria, L. Giorgini, M. Kuntz and T. Pandorf

Introduction

The first ceramic knee prosthesis was implanted in 1972 by G. Langer at the Orthopedic Clinic at the University of Jena [1]. It was an alumina partial prosthesis where only the unicondylar tibial surface was replaced. This prosthesis was used in 73 cases from 1972 and 1980. Since the direct contact between ceramic and cartilage produces a limited wear, such solution is studied still today for special cases [2].

The first alumina total knee prostheses were produced in the early 80s by Kyocera Corp. in Japan (Kyoto) and were implanted by Oonishi. Throughout the years, the interest of Japanese orthopedists for ceramic prostheses has increased and today several different models are being produced (all by Kyocera Corp.).

For ceramic total knee prostheses, polyethylene has been always used as the articular liner. Even though the most critical element with respect to polyethylene, in tribological terms, is the femoral component, alumina was used also for tibial plates in the first Japanese ceramic prostheses. The primary fixation of the first ceramic knee implants was predominantly attempted without using bone cement.

Remarks on the Ceramic Knee Prostheses

It is questioned in the orthopedic community whether the use of ceramics for knee prostheses can offer real advantages with respect to traditional metal. For hip prostheses, alumina provides considerably better mechanical properties than any other material. In case of ceramic-ceramic couplings, implants can be considered everlasting from the tribological point of view, apart from the exceptionally rare fracture problem. Even if alumina is used only for the femoral head, when coupled with polyethylene, its advantageous wear behavior in comparison to metal femoral heads is statistically acknowledged. However, the articulation of hip and knee joint is very different. In case of hip prostheses, the clearance between the diameters of the ball head and the acetabular liner is in the range of 100 µm, and lubrication may be a critical issue. In particular, there is an adverse influence of gravity to the formation of the fluid film between the head and the liner. Thus, the use of ceramics is recommended because of its superior wettability with water based fluids like synovia. On the other hand, in knee prostheses the difference of curvature between the femoral component and the tibia liner is very high (especially in flexion) and the gravitational effect is such that the synovia liquid is preferably directed to the articulating interface, thus improving lubrication.

Due to the improved wettability of the ceramic, we expect lower friction in the articulating interface and consequently a lower wear rate. Furthermore, as the lubrication also decreases the shear forces in the polyethylene liner, pitting may be suppressed.

In vitro tests on ceramic prostheses

From the tribological point of view, laboratory analyses have shown that ceramic femoral components have somehow higher quality properties than CoCrMo alloy models. When comparing alumina and CoCrMo femoral components, Yasuda [3] reports a polyethylene wear rate 5 times lower when it is coupled with alumina as well as the absence of scratches due to abrasion on the ceramic surface, unlike the case of metal surface. The latter observation was also reported by Davidson [4]. However, a very important factor when evaluating polyethylene wear in vitro is the surface roughness of the femoral component. According to the tests carried out by Lancaster [5], when comparing femoral components with the same roughness, there seem to be no significant differences between ceramic and metal models. In practice, however, it is well-known that the ceramic surface finishing is usually better than the one which can be obtained on metal surfaces.

Clinical experience with ceramic prostheses

Oonishi et al. [6] reported the results of 108 patients treated surgically with alumina prostheses (both femoral and tibial) for rheumatoid arthritis and gonarthrosis with a follow-up ranging approximately from 5 to 8 years. Most of these implants were performed without acrylic cement. No pain was reported by 62% of the patients, while 26% felt moderate pain during walking. In 9 cases, for which no cement was used, aseptic mobilization occurred, and in most of cementless cases displacement of components was reported; the authors therefore concluded that fixation without cementation was not recommendable.

The same conclusion was drawn by Tateishi et al. [7]: among their 23 cases of cementless implants of KC-1 prostheses (Kyocera Corp.) for rheumatoid arthritis, 6 cases of mobilization for poor bone trophic characteristics were reported.

The importance of cementation was underlined by Koshino et al. [8] whose experience with cemented YMCK prostheses (Kyocera Corp.) in 90 cases (follow-up of 56± 20 months), still in patients suffering from rheumatoid arthritis, was considerably better, since they had a survival rate equal to 99.1% at 8 years, without periprosthetic osteolysis.

The work by Yasuda [9] is very interesting: long term results (follow-up ranging from 5 to 10 years) were compared between a ceramic prosthesis (LFA-I, Kyocera Corp.) and a metallic model (Kinemax, Howmedica). Both models were cemented and all patients followed the same post-surgery protocol. Considering 105 ceramic prostheses and 84 metal prostheses, the results are considered comparable (HSS score: 85 e 86, ROM: 112° e 113°, respectively). However, a significant difference refers to radiolucency lines (2.7% in ceramic prostheses and 10.5% in metal models). Yet it must be remembered that the polyethylene wear in prosthetic implants is not exclusively due to friction between materials, either ceramics or metal, but also, and above all, to the sterilization method used for polyethylene. In Yasuda's work no mention is made to the differences, in terms of treatment and sterilization, between the polyethylenes used for the two groups of prostheses.

The LFA-I tibia plate is made of alumina and one case of fracture occurred. It is noteworthy that this case is the only fracture of a ceramic knee component reported in the literature. On the other hand, fractures of metal tibia plates have also been reported [10,11]. According to Akagi [12] one should take into account the significantly lower average body weight of Japanese people in comparison to North American and European.

Ceramic is an important alternative to CoCrMo alloy in all the cases where patients are allergic to metal ions. The incidence of metal allergy is constantly growing and the use of ceramic materials will have to be taken into consideration for knee arthroplasty in the same way as it is acknowledged in hip arthroplasty.

Designing a Ceramic Knee Prosthesis

Alumina is by far the most widely used ceramic material for prosthesis components. For the design of ceramic components it must be considered that the tensile strength is much lower than compressive or shear strength. Consequently, high tensile stresses should be avoided. In total hip arthroplasty relatively simple shaped alumina components are used (axisymmetric ball heads and inserts), with a well developed taper fit fixation to the metal components (femoral stem cone and acetabular shell). These conditions produce low stresses in the ceramics even if joint loads are high.

Total knee prostheses require components (specially the femoral component) with shapes and contact conditions dimensioned adequately in order to avoid high stresses near the corners of femoral resections (tension stresses) and points of contact with the polyethylene. Therefore, a prosthesis of conventional alumina was thicker than the corresponding metal prosthesis, thus requiring a higher bone resection (Fig. 1).

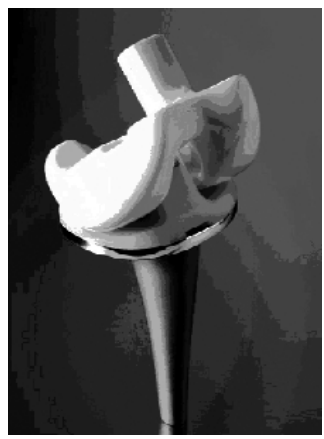

Figure 1:
CeramTec's Prototype of a Biolox® femoral component designed by Dr. Doerre in the 80s.

As time went by alumina was improved significantly, but new ceramic materials with higher mechanical and impact strength were needed in order to reduce thickness and femoral resections accordingly. An optimal material for femoral component manufacture is BIOLOX® delta (CeramTec AG, Plochingen, Germany), an alumina matrix composite featuring extremely high mechanical properties.

CeramTec and Lima-Lto are developing femoral components made of BIOLOX® delta, starting from a well-known prosthetic system (Multigen Plus system, Lima-Lto SpA, San Daniele del Friuli, Italy). The femoral component formerly made of CoCrMo alloy (Fig. 2) is replaced by the ceramic. The initial goal was a ceramic femoral component with shapes and dimensions equal to CoCrMo components, in order to use the same surgical instrument set. This concept offers the surgeon the intraoperative choice of the appropriate material, according to clinical or functional needs.

Figure 2:
Multigen Plus knee prosthesis (Lima-Lto SpA, San Daniele del Friuli, Italy).

The first step for the design of a prosthetic device is the definition of critical cyclic load conditions, i.e. the definition of the maximum dynamic stresses supported by the device during its in vivo performance. Once they are determined, these stresses are compared to the so-called allowed stresses, values known for each material which determine its strength.

Based on Literature [13-20], load and constraint conditions to which a patient is subject during ordinary activities have been determined. Dynamic conditions supported by posterior condyles and patellar component (patient getting up from sitting position or going up the stairs) and dynamic conditions in extension while walking are particularly important.

The following figure summarizes the load conditions and values considered proportionally to the body weight (Fig. 3). The knowledge of in vivo load and constraint conditions gives useful information for the design of BIOLOX®delta femoral components and achievement of mechanical setup for experimental tests.

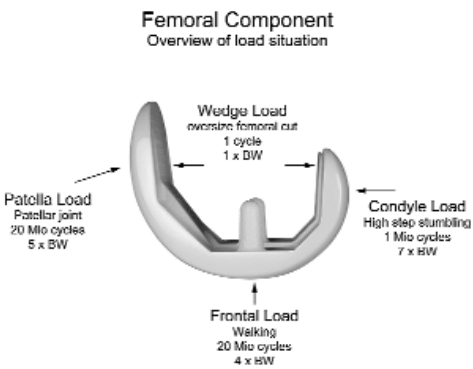

Figure 3:
Overview of loading conditions.

The creation of a FEM (Finite Element Method) model for Multigen Plus femoral components, to which the elastic constants of BIOLOX®delta (Young's modulus, Poisson's ratio) have been assigned, allows the structural simulation and selective design modifications in order to avoid stress concentrations (Fig. 4).

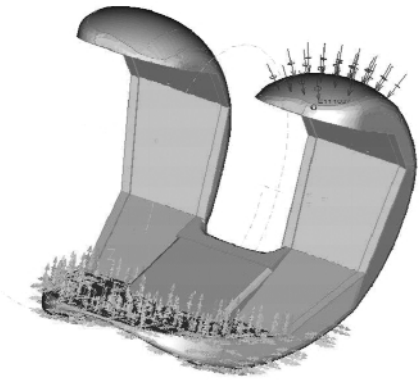

Figure 4:
FEM model.

The stresses occurring in different in vivo load conditions have been calculated with the FEM analysis and the areas of stress concentrations have been detected (Fig. 5, Fig. 6).

A specific algorithm has been developed which provides the conversion of the in vivo load situation into appropriate test conditions. Thus, the reliability of the components can be established by a well suited test procedure.

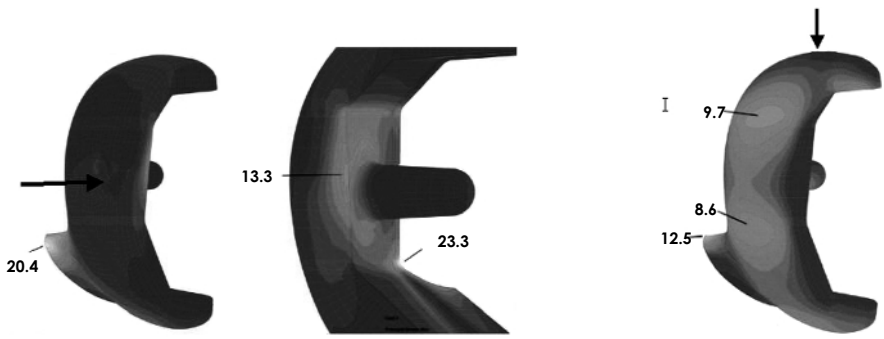

Figure 5 and 6:
Stress results at in vivo loading conditions.

Two opposing loading conditions have been considered: Regular Load and Wedge Load. Leg extension from a flexed position generates a load on the posterior condyles caused by the support over the tibial plate and an anterior load over the patellar component caused by the quadriceps tension. The analogous load situation is a "closure" of the femoral component, i.e. the posterior condyles move closer to the patellar region. This condition has been named "Regular Load".

The insertion of the femoral component onto the resected femur generates the opposite effect: the femoral prosthesis tends to be "opened", i.e. the posterior condyles and the anterior region tend to separate, as if a wedge was inserted. Consequently, this condition is named "Wedge Load". (See Fig. 3)

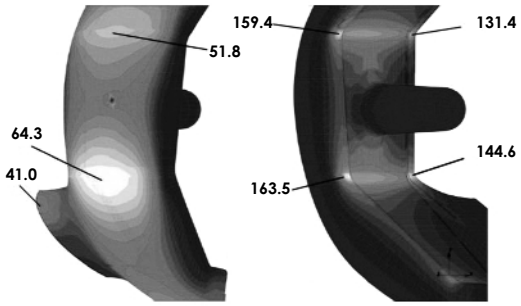

Figure 7:
Stress results at 'Regular Load' (left) and 'Wedge Load' (right).

The mechanical tests correspond to these two opposing load situations. Consequently, two different tests have been established, the regular test and the wedge test. The regular test produces tensile stresses at the outer polished surface, whereas at the wedge test the maximum stresses are concentrated at the back side of the knee prosthesis. Marginal changes in design details on the back side have led to a substantial decrease of stress concentrations. On the contrary, no modifications of the articular surfaces were necessary.

Mechanical tests have been carried out in order to establish:
- static strength;
- fatigue strength;
- post-fatigue static strength. (Fig. 8 and 9)

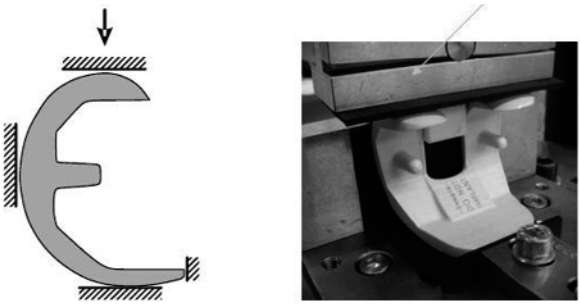

Figure 8:
Static strength test for 'Regular Load'.

Figure 9:
Static strength test for 'Wedge Load'.

The most critical in vivo load scenario in terms of fatigue strength is attributed to standing up from a chair. Therefore, fatigue simulations of this condition have been carried out in the laboratory (Endolab GmbH, Rosenheim, Germany).

With a steadily increasing dynamic load up to the component fracture, a maximum strength of about 14 kN at approximately 20 million load cycles has been reached. Furthermore, alternating load tests have been performed with a dynamic load of 6.675 kN per 5 million cycles with no fractures of the components. Finally, the post-fatigue burst test has been performed on the same components which revealed an average burst load of about 17 kN. Analysis of these results show that this strength by far exceeds the maximum load which is expected under worst case in-vivo conditions.

Prosthesis-cement interface

Experience in early applications of ceramic knee prosthesis as mentioned in the introduction implies the need for using cement to fix ceramic components on bone surfaces.

The clinical experience on alumina and zirconia knee prostheses is encouraging. However, a reliable design for BIOLOX® delta femoral components requires dedicated tests on the function of the ceramic-cement interface. At present, adequate simulator tests are being performed at the Medical Technology Laboratory of Rizzoli Orthopedic Institutes in Bologna. These tests are designed in order to compare the bone cement fixation of Multigen Plus prostheses made of metal (CoCrMo alloy) and BIOLOX® delta. These tests are focused on both the strength of the ceramic-cement interface and the polyethylene in vitro wear rates.

Proof testing

BIOLOX products of CeramTec undergo a 100% mechanical test procedure (proof test). Due to the probabilistic nature of ceramic strength the proof test was established in order to reject weak components and consequently to provide a minimum strength. The proof load is chosen such that a substantial safety margin in comparison to in-vivo loading is provided. This concept is also adapted for the ceramic femoral knee prosthesis. According to the unique load situation, two separate proof tests in regular and wedge configuration are applied to each individual component.

Summary

The joint project of CeramTec and Lima-Lto reveals Biolox® delta ceramic components which are nominally identical to those made of CoCrMo alloy already available on the market. It therefore allows the surgeon to choose the most adequate material according to the patient age and his/her expectations as well as any sensitivity to metal ions. Operation technique and instrument setup remain unchanged.

The use of the high strength BIOLOX® delta ceramic has allowed us to produce structurally reliable femoral components without increasing the thickness of the cross sections and, therefore, the dimensions of bone resections (Fig. 10). The well elaborated test concept provides high reliability of each individual ceramic knee component.

Figure 10:
Multigen Plus ceramic femoral component in BIOLOX® delta.

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4.4 Ceramic knee endoprostheses: reality or future?

W. Mittelmeier, S. Ansorge, D. Klüß, J. Kircher and R. Bader

Introduction

Osteoarthritis of the knee is a common disease in the human population with an increasing incidence due to the rising life expectancy in western civilizations. Usually patients are successfully treated for a long time conservatively with physical therapy and medication. Non-steroidal drugs are used to reduce pain and inhibit inflammation.

The indication for joint replacement surgery is failed conservative treatment. A successful total knee arthroplasty also in younger patients delivers a pain free joint with restored function and additional correction of deformities. This routine procedure is supposed to be one of the most effective and successful operations overall. Total knee arthroplasty (TKA) has reached a high degree of reliability and is a rapidly growing treatment. Approximately 800,000 total knee arthroplasties were performed in 2003 worldwide [Leyen 2002].

Problems in total knee arthroplasty

Despite good long-term results in total knee arthroplasty loosening of components remains the leading cause for revision surgery. Other possible causes of failure are wear, malpositioning, maldimensioning and inadequate design of the used implant components, infection and allergy against implant materials [Bader 2006].

Efforts have been made to improve the results of total knee arthroplasty with the reduction of wear and the improvement of biocompatibility of used materials. Implant design and surgical instruments are continuously developing. Aseptic implant loosening (Fig. 1) due to polyethylene wear induced osteolysis has been discussed for several years. Today it is widely accepted and well documented that even small surface scratches at the functional area of metallic implants will lead to increased polyethylene wear. Improved materials and designs of the articulating surface have achieved reduction of wear.

Modern TKA components are made of titanium or cobalt-chromium alloy. Cobalt-chromium and nickel have the potential to generate allergic reactions [Thomas 2001]. The incidence of allergic reactions to metal or bone cement is up to 20% of the population. Thus a non-allergic implant potentially could improve functional and long-term results.

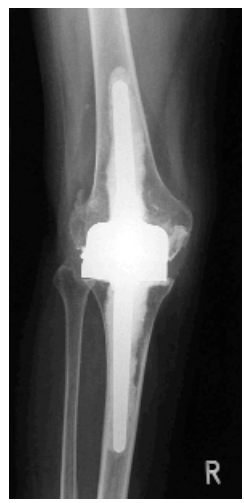

Figure 1:
Osteolysis and aseptic loosening of a cemented total knee endoprosthesis.

Bio inert ceramic implants are an option for metal sensitive patients. It is assumed that the use of ceramic components in total knee arthroplasty can reduce wear and osteolysis in comparison to the metal-on-polyethylene couple. H. Mittelmeier et al. were the first to publish promising long-term results with ceramics in total hip arthroplasty [Mittelmeier 1996]. Modern compound ceramics (BIOLOX® delta®) have been successfully used in total hip arthroplasty for femoral balls since 2005 [Mittelmeier 1974].

History of ceramic knee endoprosthesis

The 1960s were marked by major activities in the development of artificial joints, mainly for the lower extremity. The Ceramic Company Hermsdorf situated in the German Democratic Republic succeeded in developing a bio inert ceramic material, which was highly wear-resistant. The first clinically usable product was an uncemented ceramic ti-bial plateau. It was produced in two sizes each with three heights. In 1972 the first implantation using a ce-ramic implant was performed. From 1972 until 1986 Langer performed 73 of such operations using ceramic tibial plateaus. At the end of the 1980s the positive early results of modern modular total knee endoprostheses using different components available in different sizes became known, and the usage of the ceramic tibial plateau was no lon-ger practiced [Langer 2002].

In 1982 the KOM-1 (Kokuritsu Osaka Minami Hospital) total knee system was implanted. The femoral component, tibial base plate and the patella backing of the KOM-1 knee were made of alumina ceramics, combined with a polyethylene insert attached to the patella and tibia. These components were implanted without bone cement in 137 patients. At 15 to 18 years after the operation a high incidence of implant failure was noted. Most failures occurred due to inadequate ceramic component fixation to bone [Bal 2003].

The second implant generation (KOM-2), developed in 1990, was a cemented metal tibial tray was used. The articulating surfaces consisted of alumina-on-polyethylene. 112 total knee arthroplasties were performed and available for follow-up at 4-10 years. None of these implants had failed [Bal 2003].

The KOM-3 ceramic knee was introduced in 1993. The principles of cement fixation were retained in this design. Beads to enhance cement fixation had improved the alumina femoral component. A number of 111 patients received a KOM-3 total knee replacement and were available for follow-up at 2-7 years following the operation. Occasional apparent radiolucent lines around the implants were the only significant radiological finding and no clinical failures occurred [Bal 2003].

Akagi et al reported of 223 total knee replacements with the Bisurface ceramic femoral component. The survival rate of the implant was 94% after six years of follow-up. No aseptic loosening and no alumina ceramic femoral component breakage occurred [Akagi 2000].

Yasuda et al. reported on 32 total knee arthroplasties with a ceramic femoral component at 2-4 years after implantation. The results were evaluated as being excellent for 59%, good for 28%, fair for 10% and poor for 3%. Radiographic analysis demonstrated neither loosening nor sinking using the alumina ceramic prosthesis. Radiolucent lines were observed in four cases (12%). All were observed around the tibial components, but were less than 1 mm in thickness [Yasuda 1993].

Oonishi et al reported on a long clinical function of a ceramic total knee prosthesis. The alumina ceramic component had been implanted in 1979, and was revised 23 years later [Oonishi 2005]. Until recently there were only few ceramic knee arthroplasty concepts due to the expensive manufacturing process and restraints based on the brittleness of filigree components consisting of alumina.

Delta ceramic knee

Major prerequisites for the development of ceramic knee components is the use of existing designs to ensure the same surgi-cal techniques as well as the same instruments as for the standard metal femoral components. BIOLOX® delta as a novel material has increased density and burst strength and reduced structural flaws. The low friction coefficient of the novel BIOLOX® delta Ceramic causes a change in load. The unique material properties of BIOLOX® delta can reduce polyethylene wear in total knee arthroplasty and the potential detrimental effects of wear particles. Today a CE-Mark has been granted to the CeramTec AG for ceramic femoral components to be used on Polyethylene tibial components.

Experimental testing

Various experimental tests were conducted by the CeramTec AG to guarantee the mechanical safety of the newly developed ceramic femoral component. A schematic overview of the experimental tests is shown in Figure 2. There were four dynamic tests run for different durations with varying loads. The 'Frontal load' test simulates the walking cycle and is run at four times bodyweight for 20 million cycles. The load is introduced at the inferior surface of the femoral component. The 'Patella load' test is conducted to simulate forces being developed by the patella during the walking cycle. A force of five times bodyweight acts at the posterior-caudal surface for a duration of 20 million cycles. The 'Condyle load' simulates stumbling while proceeding a high step. During the test, the posterior part of the femoral component is bended inside with a force of seven times bodyweight for one million cycles. A static execution of the 'Condyle load' showed that the prosthesis could withstand a maximum force of 15-20 kN until breakage. The fourth dynamic test is the 'Edge load' which simulates a deep knee

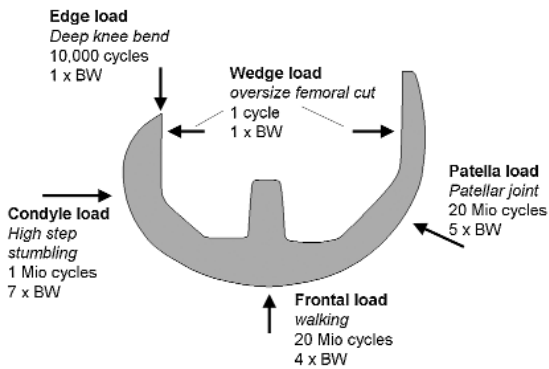

Figure 2:
Schematic illustration of the experimental tests [CeramTec AG].

bend. The force acts at the upper rim of the posterior part of the femoral component. The duration is 10,000 cycles at a force of one times bodyweight. The static test called 'Wedge load' is proceeded to investigate the bending behaviour of the femoral component. The forces act at the inner posterior and anterior surfaces of the implant at opposite directions, causing the implant to bend up. Such a situation might occur if the femur is resected oversize and does not properly match the femoral component. This test is also proceeded with one times bodyweight.

Component fixation

Leyen et al. suggested that ceramic knee endoprosthesis should be fixed with bone cement [Leyen 2004]. The implant-cement interface affects the mechanical situation of the total knee system and can cause loosening of the implant. The bone cement acts as a force transmitter between bone and ceramic with two different Young's modulus.

To determine the adhesive strength of ceramic / cement tensile tests were carried out with a testing on a universal testing machine [Leyen 2004]. Wafers of BIOLOX® delta were bonded to metal stamps by bone cement (Palamed® G). Thinner cement layers lead to an increase of the tensile bond strength.

Finite-Element-Analysis

Facing the brittleness of ceramics, the risk of breakage caused by stress peaks in the implant has to be considered intensely. The Finite-Element-Method (FEM) is a powerful mathematical tool to gain information about the deformation and the stress states a physical body develops under a defined load. Using nonlinear two- and three-dimensional Finite-Element (FE)-models, the force transmission from the distal femur through the bone cement into the endoprosthesis was analysed at different implant positions. To evaluate the influence of the bone cement, different cement layer thicknesses were modelled and analysed under load. Initially, two-dimensional FE-models with different cement layer thicknesses and different implant positions were created by cutting the implanted prosthesis at the median plane. A distributed force of 4000 N was applied at the inferior surface of the femoral component while the proximal part of the femur was fixed. The stress analysis showed that the applied load causes a deformation of the prosthesis being similar to the 'Wedge Load' in the experimental investigations. It was also shown that a higher cement layer thickness reduces the von-Mises-stress in the femur due to a smaller gradient in stiffness between the contacting surfaces.

Successively, three-dimensional analyses including anatomical bone morphology were performed in order to gain knowledge about quantitative stress states in the distal femur, the bone cement and the ceramic femoral component. The design of the FE-model is illustrated in Figure 3.

The finite element mesh consisted of 10-node tetrahedrons. Tied contact was simulated between the femoral component and the cement layer as well as between the femur and the cement layer. Again, the cement layer thickness was varied with 1.0mm, 1.5mm, 2.0mm. Loads from the fast walking cycle were

applied at the inferior face of the femoral component, divided onto the lateral condyle with 664.5 N and the medial condyle with 1362 N [Lenthe 1997]. The proximally located nodes of the femur were fixed. Cortical bone was assigned a constant Young's modulus (17 GPa), while the trabecular bone Young's modulus was derived from CT-data [Zacharias 2001, Rho 1995]. All material data being used in the study are given in Table 1.

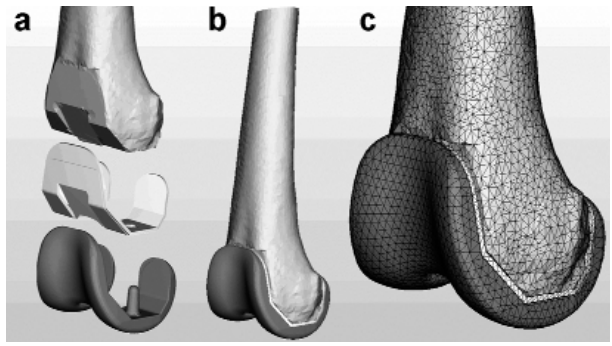

Figure 3:
Design of the finite-element model: **a:** assembly of resected femur, bone cement and ceramic femoral component; **b:** geometry of the whole model; **c:** finite-element mesh consisting of 10-node tetrahedrons.

Material		**Young's modulus (N/mm²)**	**μ**
BIOLOX® delta ceramic		E=350,000	0,21
Bone cement [Lenthe 1997]		E=2,700	0,3
Femur [Zacharias 2001]	trabecular bone	HU interval: 0-600	0,3
		E=6.28*HU+367	
	subchondral bone	HU interval: 601-700	0,3
		E=128.65*HU-73,055	
	cortical bone	HU interval: > 700	0,3
		E=17,000	

Table 1:
Material data that was assigned to the incorporated bodies (HU=Hounsfield Unit).

In all cases, the prosthesis was bent up by the applied load, as simulated in the 'Wedge load'. Accordingly, higher stresses occurred at the inner surface of the femoral component, especially at the vertices between the planar surfaces. While the results from the two-dimensional analysis should be handled comparatively only, the 3-D analyses predicts qualitative strain and stress values in the bone, the cement layer and the endoprosthesis. As shown in Figure 4, the areas where the highest stresses occur match the areas where, in metallic components, stress fractures appeared formerly [Wada et al. 1997, Whiteside et al. 1993]. Such stress peaks result from the implant design. However, at the applied loads taken from the fast walking cycle, the highest von-Mises stresses in the ceramic component were found to be far below critical values. The predicted stresses of the worst case at 30° flexion in combination with 2.0 mm cement layer thickness were below one quarter of the flexural strength of Zirconia Toughened Alumina (ZTA) ceramic (450 MPa).

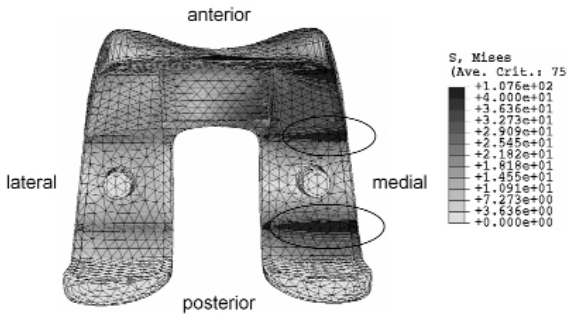

Figure 4:
Von-Mises-stress in the femoral component at 30° flexion in combination with 2.0 mm cement layer thickness. Note areas at the vertices between the planar surfaces. Higher loads at the medial condyle cause higher stresses in the implant.

First clinical application of BIOLOX® delta knee

An international prospective multicenter study starting in June 2006 will be performed at 9 centres in Germany, Italy and Spain to obtain clinical and radiological data. The patients will receive an unconstrained Lima Ceramic Delta Multigen Plus knee (Fig. 5) with a BIOLOX® delta femoral component, polyethylene-inlay and a cobalt-chromium tibial component.

Clinical and functional outcome as well as quality of life is evaluated using standard scoring systems to enable comparison of the results to those with standard total knee replacements. Clinical performance is evaluated using the Ranawat and Shine (HSS) score. Patient satisfaction and quality of life is evaluated using the WOMAC-Score and the Short Form 36-score. The position of the femoral component, the tibial plate and patella are radiologically evaluated. The first follow-up is immediately postoperative, three months, one year, two and five years after the operation.

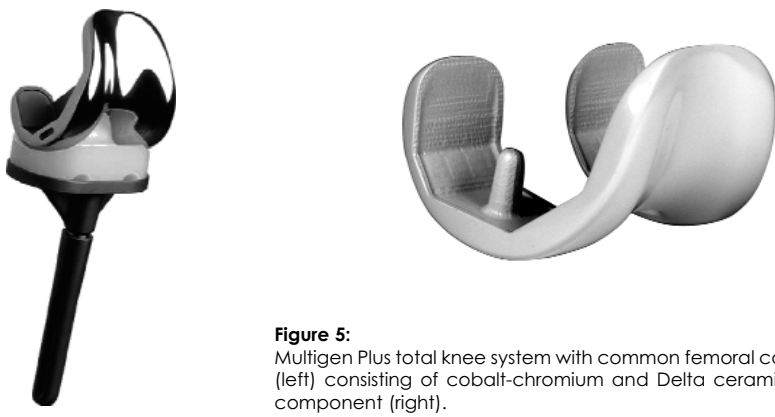

Figure 5:
Multigen Plus total knee system with common femoral component (left) consisting of cobalt-chromium and Delta ceramic femoral component (right).

Conclusion

The use of ceramics in total hip arthroplasty is widely accepted with good long-term results [Mittelmeier 1974, Boutin 1972] and is a standard in modern orthopaedic surgery, but excellent solutions in total knee arthroplasty are still missing.

The investigations by Langer have shown positive results with advanced ceramics in total knee arthroplasty and structural reliability of the components. The improved values of the mechanical strength and reliability of the new BIOLOX® delta ceramic as compared to the successfully used today's alumina ceramic justify the re-evaluation for the application of ceramics in total knee arthroplasty. The objective is a further reduction or complete avoidance of polyethylene particles and their contribution to implant loosening.

Furthermore it has to be proven that the new ceramic components result in a sufficient quality of life for the young and active patient or the metal sensitive patient. The most wear resistant materials currently available for joint replacements are today's alumina ceramics as confirmed in total hip replacement. The substantially improvements of the mechanical properties achieved with BIOLOX® delta allows the production of ceramic components for total knee arthroplasty. Further improved long term success rates based on reduced polyethylene wear particles can be expected in total knee arthroplasty in the future. A prerequisite is an exact and thorough implantation technique.

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SESSION 5

Hip Revision

5.1 Comparison of clinical results between Ceramic-Ceramic Bearings and Metal on Polyethylene in Total Hip Arthroplasty

J. P. Garino and B. Vannozzi

Introduction

Total hip arthroplasty is considered among the most successful and cost-effective surgical innovations of the twentieth century [17]. Beginning with the early work of Charnley and others that demonstrated predictable successful results from prosthetic replacement, metal-on-polyethylene has been the standard bearing surface for total hip arthroplasty in the United States [9]. Given the ability of total hip arthroplasty to restore high levels of comfort and function more dependably than any other procedure for hip arthritis, in recent years its indications have been extended to include both younger and more active patients. This increase in indications and spectrum of younger, healthier patients receiving THAs, coupled with the continued increase in life expectancy, places a premium on implant survival and avoidance of revision at all costs. Since many studies have shown the ability to obtain high rates of durable cementless fixation of both components with many different designs and coatings, it can be argued that the bearing surface is the most vulnerable aspect of the prosthetic replacement. In fact, wear of polyethylene and biologic reactions to wear debris leading to periprosthetic osteolysis are the leading cause of revision of hip implants [14]. This demonstrated need for improved, more durable bearing surfaces has led to the study of alternative bearing materials, including cross-linked polyethylene, metal-on-metal, and ceramic-on-ceramic articulations. Of these options, contemporary alumina ceramic/alumina ceramic articulations are harder, more scratch resistant, and more hydrophilic than other bearing surfaces, which results in reduced wear and particle load to the surrounding tissue, making ceramic/ceramic an attractive option for THA in younger, more active patients.

Background & Basic Science

Alumina ceramic is a monophasic polycrystalline, and belongs to the family of ceramics defined as nonmetallic and inorganic materials [19]. Alumina is extremely hard, very stable, and has an ionic structure that creates a hydrophilic environment and fluid-film lubrication which result in a wettability greater than polyethylene or cobalt chrome. [10]. These material properties have several consequences for an alumina ceramic/alumina ceramic bearing surface. The hardness of alumina allows for construction of a bearing surface composed of very smooth components with a high scratch resistance. Smooth components resistance to scratch result in a reduction of abrasive (mode 1) wear, as well as a resistance to third body (mode 3) wear, because less hard materials surrounding the prosthetic replacement, such as bone and cement, cannot scratch the alumina bearing. The hydrophilic nature of ceramic and the resultant wettability

allows for greater lubrication and a reduction in adhesive (mode 2) wear. Several in vitro studies have clearly shown that alumina-on-alumina is one of the best friction couples available to date [6,7,11]. In vitro wear data from Clark et al [11] showed alumina liners wore of .004mm^3 per million cycles at steady state, which was 2000-5000 less than that of a metal-on-polyethylene friction couple. This result was also confirmed in vivo by retrieval data, where the number of wear particles in periprosthetic tissues were observed to be 2-22 times less than previously seen for metal-on-polyethylene couples [5]. Another in vitro study showed that alumina-on-alumina bearings produce between 0.2 and 2 billion wear particles/year, compared to 0.6-1.2 trillion wear particles/year for metal on polyethylene bearings, and the ceramic particles were smaller [3].

This decreased amount of debris of smaller size also seems to be better tolerated, because after an initial inflammatory response, alumina particles are almost bioinert, inducing a low cellular response with minor fibrous scar tissue [22]. Therefore, in vivo and in vitro data have demonstrated that the improved hardness, scratch resistance and wetability of ceramic-on-ceramic bearings provide greatly superior wear characteristics with decreased inflammatory response compared to metal-on-polyethylene bearings.

Clinical Results

One potential downside to ceramic-ceramic articulation is the possibility of component fracture. A recent review of over 5500 implanted alumina components found 13 fractures, only five of which occurred without obvious explanation (trauma or abnormal component design). Of those five, two came from first generation ceramic manufacturing and likely a weaker ceramic and the final three fractures were related to the design of the implant. The authors concluded that fracture is a rare complication which is infrequent and easy to solve by limited revision, and should be balanced with other complications of THA, including mechanical failure and osteolysis [21]. Another recent review of 118 patients with >20–yr follow-up of ceramic-on-ceramic THA implanted by Pierre Boutin showed no fractures of the alumina head or socket, and wear of the prosthetic components was undetectable on plain radiographs [18]. Table one is a brief review of recent studies published since 2000 on modern ceramic-on-ceramic THA, showing that there have been no reported failures of any ceramic components. Also no components have been revised for wear, although these are early results and wear at this time would not have been anticipated.

Year	Journal	Author	Country	F/u (yrs)	N	# Ceramic failures
2002	CORR	Bierbaum [3]	USA	4	514	0
2002	JBJS	Hamadouche [18]	France	> 18	118	0
2001	CORR	Bizot [4]	France	< 3	96	0
2001	J Arthro	Delauney [13]	France	5-10	133	0
2001	JBJS	Urban [28]	USA	17-21	64	0
2000	CORR	Garino [16]	USA	1-3	333	0

Table 1

Early catastrophic fractures of ceramic heads during the 1970s-1990s were multifactorial, and included causes such as insufficient material quality, femoral head-neck taper mismatch, impingement of the metal neck on the ceramic liner, and technical errors [1]. Most of the material property problems have been addressed by the introduction of a third generation of ceramic manufacturing with significant improvements including increased purity of the ceramic, smaller grain size, laser etching, hot isostatic pressing, and proof testing which have resulted in stronger material with improved reliability [29].

Discussion

A successful predictable outcome from total hip arthroplasy can be expected with current proven implant designs and cementless techniques. The variable that now limits the longevity of total hip arthroplasties is the inflammatory response to wear debris, subsequent osteolysis and implant loosening [23]. Decreasing the wear of the bearing surface, and therefore decreasing osteolysis, should enhance the longevity of total hip arthroplasties, which is of utmost importance given the current widening of indications for prosthetic replacement to include young, healthy, active individuals. In these patients a primary goal beyond stable painless fixation should be avoidance of revision surgery for any reason. Attempted improvements on the standard metal-on-polyethylene bearing include cross-linked polyethylene, which been reported to have improved wear properties and promising early clinical data [27]. However, the long term performance of this material is not yet known, and there is concern about the fracture toughness and ultimate strength [26]. Beyond these concerns, optimistic estimates at the increase in wear properties make cross-linked poly 5-8x better, which may not be good enough to prevent significant osteolysis and possible implant failure in young patients with >40 year life expectancy. Another possible alternative bearing is metal-on-metal, which also has shown improved wear compared to metal-on-PE. However, exposure to metal ion levels remains a concern, particularly in young patients, and there is the possibility of long term consequences including metal allergy/hypersensitivity, autoimmune and dermatologic disease, and even an increased risk of neoplasms [25].

There are many reports of successful metal-polyethylene THR procedures. Most of these studies are design specific and there are many reports of early failures of THR as well. In order to get a general perspective on this situation, it is valuable to review the information published in the Swedish and Norwegian joint replacement registries [30,31]. Keep in mind that these countries are small and that a multiple of 10 to 100 times would closely estimate the world volume of THR and related complications. Basic observations from the Swedish registry in clued the fact that 75% of the revisions performed were done so due to aseptic loosening largely related to wear. Periprostetic fractures represented another 6%, but then again the vast majority of these fractures occurred in the face of wear related osteolysis. The revision rate in younger patients is quite impressive with only a 67% 13 year survival rate in men under the age of 50 at the time of initial surgery. That number drops to 61% in females. From the Norwegian registry we observe that successful femoral fixation, such as the Corail, had a 95% survival at 15 years. However, the acetabular components that it was coupled with did not fair as well. The Atoll had 10-year failure rate of 18% while the Tropic had a 27% 15-year

failure rate. Patients undergoing revisions are older and often have more medical problems. Revision surgery, with the need for extensive reconstruction in a significant portion of the cases is harder and takes more time. For these reasons the complication rate, morbidity and mortality of revision surgery is higher than primary THR. Avoiding revisions, therefore, is a goal that both patients and surgeons are seeking. The most obvious way to easily achieve that goal is by reducing or eliminating wear related complications.

Ceramic-on-ceramic bearing surfaces have far superior wear rates compared to metal-on-polyethylene, and the particles that are produced are biologically inert. These characteristics mean that wear and osteolysis are virtually nonexistent with current third generation ceramic-on-ceramic surfaces. This bearing surface has the potential to eliminate or drastically reduce osteolysis, the current leading cause of implant failure, and therefore may result in significantly fewer revision surgeries and longer implant survival, even in young, healthy, active and high demand patients. With the high expense related to revision surgery, a significant economic burden would also be improved with a reduction in the patients in need of such intervention.

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5.2 Revision strategy after metal on metal THR failure: Conversion to ceramic on ceramic

Y. Catonné, J.-Y. Lazennec, A. Nogier, E. Fourniols and B. Masson

The new technology of ceramic heads with titanium alloy adapter sleeves allows to consider new developments for the use of ceramic – ceramic wear couples in T.H.A. revisions .One of the main topics is now the revision of second generation metal on metal T.H.A. The authors report their early experience and the new perspectives for other revision procedures.

Six patients have been revised using this technique .

Five cemented Weber cups were removed due to dysfunction of the Metasul wear couple; the socket was not loose but worrying osteolysis and local radiolucencies were observed. The serum metal ion levels were significantly increased One of those cases was already a failed revision (a previous Metasul T.H.A. revised using again a Metasul friction couple with the same local problems). In all of those cases, the anodised titanium femoral stem was cemented; no loosening of the implants could be observed .

The last case was a Durom wear couple with a cementless cup and a well fixed titanium

Zweymuller stem. This revision was due to an anterior impingement between the big metallic femoral head and the ilio-psoas muscle. The cup fixation was doubtful.

For all of those stems, the characteristics of the 12/14 Titanium alloy taper trunnions were checked to assess the compatibility with the Ceramtec sleeves.

The procedure was the same in all cases; the revision was performed using the previous approach (anterior approach) in a lateral decubitus for the first five cemented cases and posterior approach for the Durom implant.

The Titanium alloy taper was carefully preserved and inspected to detect delerious lesions excluding the indication for a conservative procedure using delta alumina femoral heads. In no case, we observed corrosion or macroscopic lesions of the titanium alloy taper trunnions.

We encountered 3 severe macroscopic metallosis cases due to the chromium cobalt alloy of the friction surfaces with a good correlation with serum samples tests.

The acetabular cups were removed and cementless Ceramconcept cups were implanted using classical XLW delta alumina inserts. The 32mm delta alumina heads were adjusted on the femoral stems using the precise technique for impaction of the titanium alloy adapter sleeves. We did not face any problem at this stage. We did not notice any parasitic impingement due to the additional sleeve.

To date, we did not observe any complications. The CT scan scout view has been used to check radiographically the sleeve assembly in those first cases. During the follow-up, we observed the progressive normalization of the metal serum levels.

Figure 1:
Ceramic Biolox® Delta revision ball head with 4 different neck lengths (S,M,L and XL).

The innovative technology using femoral heads with sleeves has been made possible by the delta alumina matrix composite. This procedure seems very promising as it allows conservative procedures for metal on metal T.H.A. revisions which is today a topic of concern. In our experience, revision of a failed metal on metal Metasul T.H.A. using metal on polyethylene wear surfaces is not a secure option; the implantation of a new metal–on–metal wear couple is a contraindication.

The implantation of classical Biolox femoral heads on a previously used femoral titanium alloy taper trunnion is not recommended by CeramTec; the only solution was to remove the femoral stem which is somewhat invasive. The conservative procedure using sleeve-heads provide us with new perspectives for other revision procedures, and especially zirconium on poly or ceramic on poly T.H.A. when changing the wear surfaces is the aim.

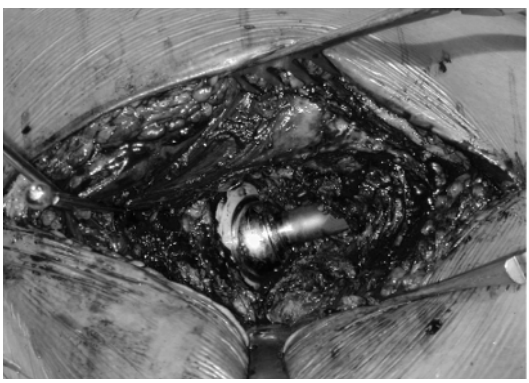


Figure 2:
Revision of cemented Metasul Weber cup with metallosis (iterative anterior approach in a lateral decubitus).

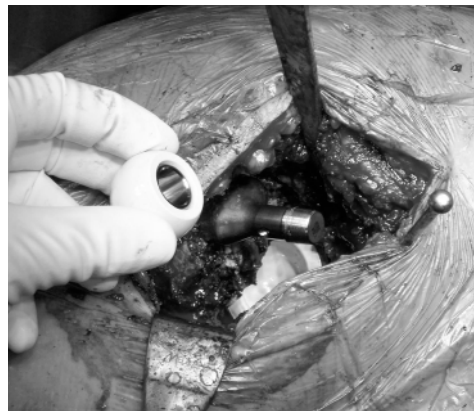


Figure 3a:
Biolox® Delta revision ceramic femoral head with its sleeve before implantation. A cementless cup with standard XLW delta insert was used for the Weber Implant replacement.
Soft tissues with metallosis have been removed.

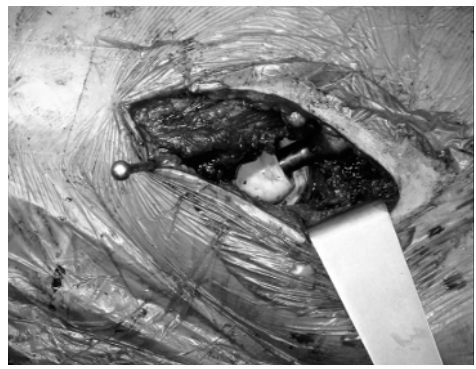
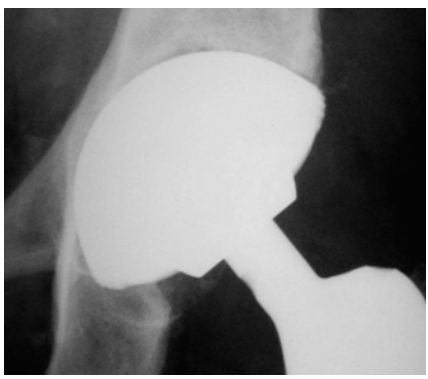


Figure 3b:
Per operative testing of the construct after relocation of the 32 mm head inside the ceramic liner: the sleeve system does not induce parasitic impingement.



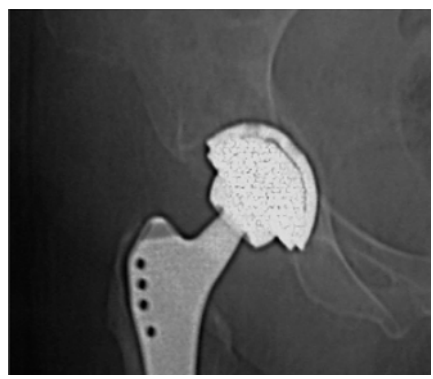


Figure 4a, b:
Two post operative radiological controls one with plane X Rays , one with CT scan scout view: no additional increase of the stem neck dimensions.

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5.3 Modular neck and ceramic on ceramic coupling in revision total hip arthroplasty

G. Pignatti, C. Stagni, D. Dallari, V. Bochicchio, A. Raimondi and A. Giunti

Introduction

Being able to change the geometry of the prosthesis enables the surgeon to choose intraoperatively the best configuration for the articular morphology of the patient: leg length, offset, ante-retroversion. Besides the head and the cup, the prosthetic neck may also be modular, therefore extending the range of choice for different clinical situations, in both primary and revision total hip arthroplasty. The use of a modular femoral neck and head system is one method of achieving predetermined anteversion and adjusting offset and abductor lever arm.

Besides choosing a modular implant, also the choice of material for the coupling is fundamental. Although the metal-polyethylene coupling, introduced by Charnley [5] in 1961, is currently the most commonly used, and has been performed on large number of patients with a mean follow-up of over 15 years, it has a big disadvantage: the production of polythene wear debris, which has long been known to cause loosening of the implant itself in the long term [7,8]. In an attempt to reduce the problem of wear, since the end of the 70's research has been aimed at alternative materials such as bioceramics, which are inert, biocompatible materials, characterized by hardness and strength, which have made the problem of wear negligible. However, ceramic as a coupling material has been criticized for its fragility; the risk of breakage is increased markedly if a ceramic head is inserted on a used Morse taper. Being able to change the prosthesis neck enables the ceramic-ceramic coupling to be maintained in partial revision.

The authors tested the reliability and practicality of modular necks and ceramic-ceramic couplings in hip revision arthroplasty.

Patients

Between 1990 and 2005, we performed 785 hip revision arthroplasties; 324 complete revisions, 290 acetabular revisions, 141 stem revisions, and 30 inlay replacements. The prostheses used were AnCA-Fit (Cremascoli Ortho, Italia) with a cementless titanium anatomical stem and Profemur with a tapered revision titanium stem. Both stems have a modular neck inserted by Morse taper and a hemispheric press-fit cup. There are 2 lengths of modular neck and 5 different types: straight, varus-valgus of 8°, lateral-medial, anteversion-retroversion of 8° or 15°. The ceramic head (Biolox® Forte, CeramTec, Stuttgart, Germany) has a diameter of 28 mm and is available in three lengths: short (–3.5 mm), medium (0 mm), and long (+3.5 mm). A non-straight neck was used in 61% of cases.

No neck fractures were observed. We did not see any radiographic signs of ceramic wear. No breakage occurred in the ceramic heads and none of the modular components (head-neck, neck-stem) became disassembled.
Analysis of retrieved necks confirmed the absence of corrosion.

Conclusions

Modular implants were designed because the surgeon needed to adapt the prosthesis to the anatomical characteristics of the patient, [10] both in primary and revision arthroplasty, where the joint anatomy and biomechanics can be severely affected by previous implant failure. The versatility of modular implants is helpful to the orthopedic surgeon performing revision surgery in patients with bone or soft tissue defects that can jeopardize implant stability. The higher dislocation rates of revision total hip arthroplasty are related directly to soft tissue defects and have been a major stimulus for the development of systems that provide intraoperative choices to achieve hip kinematic restoration. Being able to modify femoral anteversion, abductor lever arm and femoral offset gives the surgeon the choice of the most reliable combination and reduces the risk of joint impingement and prosthesis instability, especially in partial revisions that are more often accompanied by dislocation [3] compared with total revision.

However, doubts concerning mechanical strength and mobile neck wear are legitimate. Laboratory studies have been performed to test the fatigue strength of the modular neck. The fatigue tests performed on the Morse taper did not cause breakage at up to 20 million cycles. Also "fretting", i.e. wear produced between two surfaces caused by micromovement, was tested in the laboratory. These tests showed a negligible production of wear particles under 1 mg. per year [4]. The special oblong and conical shape of the coupling obviates micromovement between the modular stem and neck and minimizes "fretting corrosion"[2].

In partial revision removing the mobile neck enables better exposure for revising the cup, and when the stem is stable a ceramic-ceramic coupling can be maintained without increasing the risk of breaking the head [1] (Fig. 1,2,3).

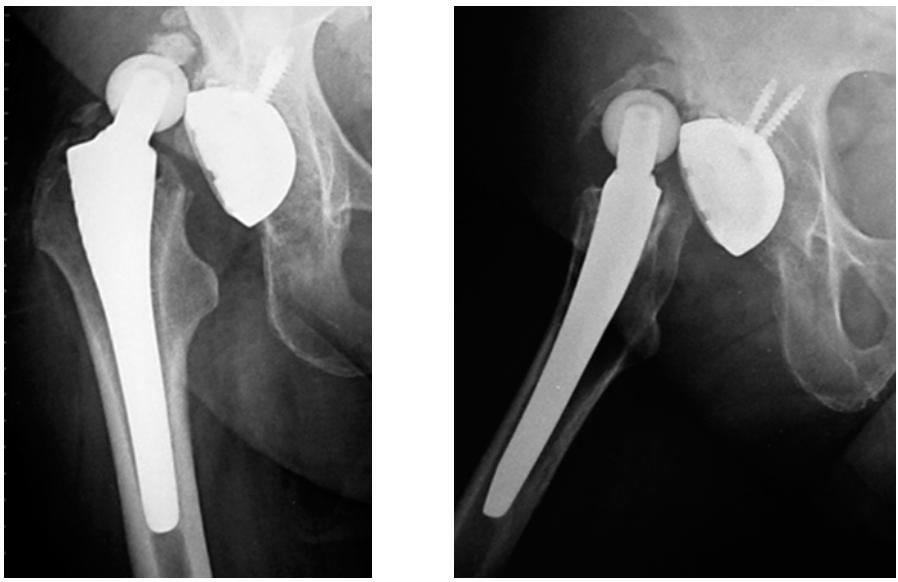

Figure 1a, b:
Cup loosening and dislocation in a 73 year-old patient.

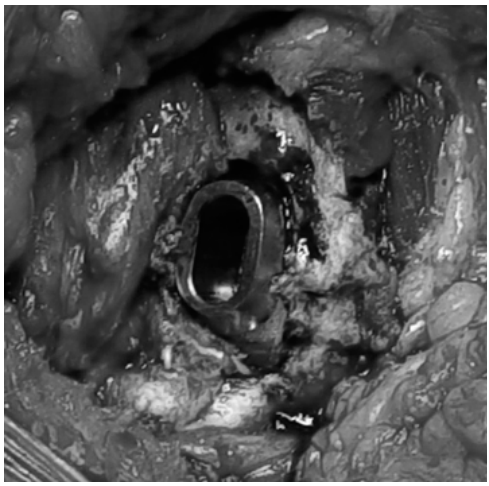

Figure 2:
Removal of the modular neck, avoiding stem revision.

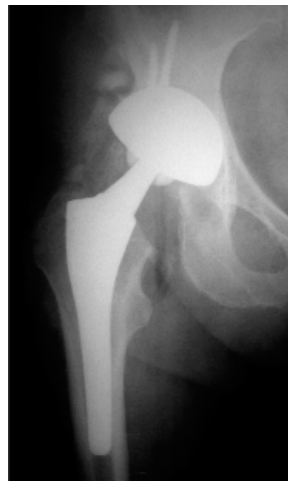

Figure 3:
Follow-up 3 years after surgery; long retroverted 8°modular neck, mantaining ceramic on ceramic coupling.

Another advantage offered by this system is that even if a ceramic femoral head is fractured after THA, the removal of the fixed femoral component during revision surgery is unnecessary, because a fractured ceramic head and a modular neck with a scratched taper are easily replaced.

The greatest criticism of modular implants is the risk of fretting corrosion of the components. Despite the modular components, fretting damage in a modular femoral neck system is not significant in in vitro tests; Viceconti reported that, in an in vitro cyclic load fretting test, a normal, stable prosthesis was likely to produce less than 10 mg/year of metal debris, and that a further production of 0.6 mg/year due to the modular neck should not have any significant effect.

Using ceramic as the coupling material was introduced to reduce the problem of wear. Metal and, above all, polyethylene debris have been, in fact, blamed for the process of aseptic loosening of hip prostheses [7,8]. In fact, the particles released act as foreign bodies and trigger a cascade macrophage reaction, which can induce, by releasing enzymes and cytokines, osteolysis, periprosthetic bone resorption and, consequently, aseptic loosening of the implant. Wear is accentuated also by the relatively poor resistance of the metal to surface scratching by bone and/or cement fragments, so-called "third-body wear". In this case the surface roughness is increased and thus so is polyethylene abrasion. Therefore, these problems have prompted the use of ceramic-polyethylene or ceramic-ceramic couplings. With the former coupling polyethylene wear is reduced because ceramic is smother and less prone to scratching [6]; with the latter coupling polyethylene debris is not produced. The biomechanical properties of the material provide a good solution to the problem of wear and reduce markedly the incidence of periprosthetic osteolysis [4]. Therefore, the deterioration of bone stock is reduced and, revision surgery is facilitated by the need to replace fewer prosthetic components.

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5.4 Experience with BIOLOX® option revision heads

T. Güttler

Introduction

The combination of modular ceramic heads with adapters or sleeves between hip taper and ceramic head offers new possibilities for the use of ceramic implants in primary and revision hip replacement. Several concepts for modular heads with sleeves to be used on tapered cones of hip stems where published and patented in the 1980's, but not introduced for ceramic implants in hip replacement.

A versatile modular sleeve / head system for total hip arthroplasty was designed by Anapliotis and Kranz, Merete Medical Berlin in the mid 1990's. Different options for neck length and offset were available for several approved taper specifications. This modular head system was initially introduced with the trademark Multiset and later Bioball. The modular Bioball heads were offered in CoCr metal alloy and ZiO_2 ceramic. In 2005 the modular ceramic Bioball heads became also available in Biolox® delta material.

Based on the experiences of the modular Bioball system and the availability of Biolox® delta Al_20_3 Matrix Composite Ceramics, Ceramtec developed the Biolox option head range for standard and XL modular neck lengths [1,2]. The basic features and THA applications of the Biolox option heads offer a modular ceramic head solution for hip revision, new possibilities of a wear couple upgrade at time of revision and additional options for primary THA.

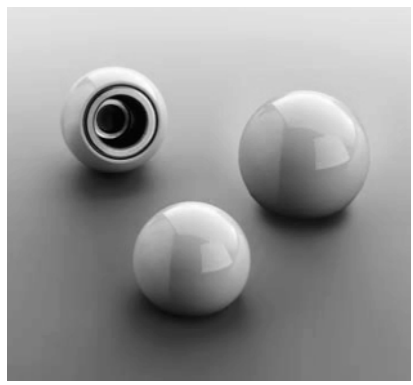

Figure 1:
Biolox option revision head implants 28 mm, 32 mm and 36 mm.

Biolox option implants are offered by different orthopaedic companies which approve the use with specific femoral stem implants and taper specifications.

Important note:

The instructions for use of Biolox option implants must always be followed. They define the use of Biolox option implants in combination with approved hip implant components.

In 2006 Biolox option implants are available for 28 mm, 32 mm and 36 mm Biolox delta heads. The taper specifications will be further extended and approved for specific hip stems. Biolox option heads can be combined with approved Biolox forte and Biolox delta acetabular cup implants and approved polyethylene implants.

Intraoperative application of Biolox option implants

The adapter sleeves of Biolox option head are made of forged titanium alloy Ti6Al4V which increase the strength of the ceramic head for taper conditions encountered during revision surgery. The Biolox option adapter sleeve levels out irregularities on the cone from damage after a head replacement. The head to be replaced must be removed using an extractor or a pestle in such a way that the cone suffers the least possible damage.

Prior to a decision for using a modular Biolox option head, the condition and compatibility of the cone of the implanted hip stem needs to be assessed. Three different cases can be identified concerning the cone conditions:

- Case 1 – a new unused cone
- Case 2 – a used cone after replacement of a prosthetic head
- Case 3 – a damaged cone

Case 1 occurs in primary application, e.g. when implanting a ceramic head of neck length XL in primary THA. Case 2 applies to the standard application for the modular Biolox option prosthetic hip heads in case of hip revision. The case 3 cone condition applies to the special application for the modular Biolox option prosthetic hip heads, where the cone damage can be of the following degrees:

- Degree 1 – No visible damage, cone shape intact
- Degree 2 – damage with visible scratches up to 0.3 mm, but no change of the cone shape (Fig. 2)
- Degree 3 – ablation of cone surfaces (beveled, leveled, crushed) or visible abrasion on the cone (Fig. 3)

Cone damages of degrees 1 and 2 are leveled out by the adapter sleeve of the Biolox option prosthetic hip heads. Any cone damage of degree 3 precludes the application of Biolox option implants.

Figure 2:
Example for a grade 2 damaged taper.

Figure 3:
Example for a grade 3 damaged taper.

The intraoperative assessment of the cone condition especially in cases of cone damage might be difficult in some cases. An additional tip for the surgeon might be how smooth the head fits on the cone during final insertion of the Biolox option head. After coupling of the sleeve with the ceramic head, the Biolox option implant must be coupled to the taper in the same way as any other modular head. This coupling should be possible in a smooth and easy way, and when turning the Biolox option implant on the taper the contact or taper-fit should not change due to the existing taper damage. If there is any doubt that the taper and coupling condition is compromised, the application of Biolox option implant is not approved.

Use of Biolox option Implants in primary hip replacement

In cases of primary hip replacement Biolox option implants generally supplement the use of Biolox ceramic implants. Beside the obvious advantage of an additional XL neck length limitations of ceramic implant handling leading to poor taper conditions are facilitated in case of an intended use of a ceramic THA solution for the patient:

- ceramic XL head
- secondary taper coupling
- unexpected taper damage
- ceramic head stock back-up

Ceramic XL head

Biolox ceramic heads are generally available in short S, medium M and long L neck lengths. Biolox option heads offer an additional XL neck length for ceramic on polyethylene or ceramic-on-ceramic THA indications. Since the Biolox option XL head design is not skirted, the free range of motion is similar to the L head design. With the distribution of S, M, L and XL heads being roughly 20%, 45%, 20%, and 15% respectively, the XL-Biolox option head can replace a significant number of XL metal heads and gain the benefit of improved wear characteristics against polyethylene, of extended range of motion compared to skirted metal XL heads, and of course in ceramic-on-ceramic articulations.

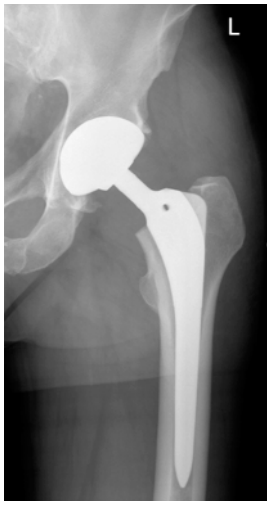

Figure 4:
Biolox option head with XL length in primary THA.

Secondary taper coupling or unexpected taper damage

Biolox option heads can be used in primary THA in any case were the taper is used or even damaged during primary hip intervention, and a ceramic head is indicated. It must be mentioned, that an unplanned intraoperative removal of a Biolox ceramic head prevents the use of a new ceramic head implant. In this case a Biolox option head is the safe ceramic solution.

Ceramic head stock back-up

In very rare cases where Biolox head implants become unsterile during surgical intervention or when a package is opened, a Biolox option head stock offers always an alternative ceramic implant selection. The aspect of an incomplete ceramic head implant stock should be also mentioned here.

Use of Biolox option implants in revision hip surgery

The primary use of Biolox option implants is the use in revision hip surgery. The Biolox option implants are primarily suitable in cases of acetabular cup or liner exchange when ceramic implants have been used, or in order to improve the wear characteristics. Other less common applications include cases of ceramic implant failures or with complications associated with immunological response to metal implant components. Different revision surgery situations are discussed as follows:

- modular head exchange
- acetabular liner revision
- acetabular cup revision
- failure of ceramic implant components
- allergy to metal implant components

Modular head exchange

As mentioned above the use of Biolox ceramic heads is only approved for use on an unused hip taper. Any exchange of any modular head to a ceramic head requires the use of an approved Biolox option head. The reasons for modular head exchanges can vary and a modular head exchange during hip revision happens more often than in primary cases. In these cases the use of a head removal instrument is recommended.

The exchange of a modular head without exchange of the acetabular cup component may be indicated in cases of recurrent dislocation. Biolox option offers a solution for the used taper after ceramic head removal, including the XL-neck length. Also, it is possible to convert the head diameter from 28 to 32 mm, or to 36 mm with appropriate cup sizes.

A special requirement for head exchange might occur in the case of a ceramic insert discovered in situ unexpectedly during surgery. This can happen because x-rays are not always sufficient to identify the material of the modular cup insert. Even in case of a proper preoperative planning the intention to exchange the modular ceramic head to a metal head might be not possible, and a Biolox option head offers a solution.

Acetabular liner revision

The exchange of an acetabular liner is generally possible without changing the modular head. In cases of dislocation, the intention of liner exchange will be to use a more constrained polyethylene liner. In cases of acetabular wear, the intention might be to upgrade the hip articulation to a ceramic-on-polyethylene or even ceramic-on-ceramic total hip replacement if the cup component allows for a ceramic liner. These options are possible with Biolox option implants. Also, a ceramic head with increased diameter and neck length can be implanted together with an acetabular liner exchange. In any case, the liner revision is facilitated with the removal of the modular head. In this case, the use of trial heads and trial cups are well suitable to verify the additional joint stability before using inserting the optimal liner and head combination.

Acetabular cup revision

The complete revision and implantation of an entire acetabular cup implant is nearly impossible without removal of the modular head. In that case, the implantation of a new ceramic Biolox head is only possible with Biolox option implants on approved stem tapers. In cases of a metal head articulation at the time of revision, this procedure could also result in wear couple upgrade. With appropriate revision cup systems a ceramic-on-ceramic THA articulation is also a possible option, if implant alignment, joint stability or any other factors do not contraindicate such a THA treatment. Note that ceramic implant liners are not available as constrained, posterior wall, asymmetric, or offset liners, etc., which are more common in hip revision surgery.

Failure of ceramic implant components

In cases of ceramic component failure the use of a metal head against polyethylene can lead to secondary complications due to worn out metal heads after ceramic implant component failure [3,4,5].

Biolox option heads offer the possibility to exchange the original ceramic head to a new ceramic head without stem revision if the taper damage conditions are still appropriate. The recommendation for the cup is either a ceramic insert (if possible) or a polyethylene insert. A ceramic liner must be always exchanged in cases of a fractured ceramic head.

Allergy to metal implant components

Since ceramic materials offer an alternative material option, the situation of an unidentified or even verified need to exchange metal hip articulation components due to immunological response to Co, Cr, Ni etc. alloy components should be mentioned. In cases where titanium implants are used, a metal head on polyethylene or a metal on metal hip articulation – with a modular cup component - could be converted to a Biolox option head either against polyethylene or ceramic cup liners. These cases are rare but the surgeon should consider the extended possibilities of Biolox option implants.

Conclusion

Biolox option heads present a valuable additional ceramic implant solution, which will be available with more approved stem implants for Biolox ceramics. Composite solutions of metal sleeves and ceramic heads offers new applications in standard THA and revision hip replacement.

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5.5 Acetabular cup revision: pitfalls and solutions

W. Mittelmeier, M. Haenle, J. Kircher, R. Bader and M. Hauschild

Introduction

Total hip arthroplasty (THA), with an estimated number of implantations of approximately 180.000 [6] per year in Germany alone, has proven to be one of the most successful operations in modern medicine. THA has helped to improve the quality of life of a huge amount of patients through out the last decades. However, epidemiological investigations have shown that a relative risk of revision operations after THA lies between 7-13% depending on the implant design and fixation technique [14]. The most common cause for implant failure seems to be the aseptic implant loosening, followed by dislocation and early or late endoprostheses associated infections [17]. Due to an even increasing number of implantations per year and the increasing expectation of life, revision operations, especially acetabular cup revisions, become a more and more important issue. The choice of implant may be based on functional, biomechanical, tribological but also economical and legal matters [18].

In the final consequence, the wear (Fig. 1) between articulating leads to an aseptic loosening of the implant components [11,13,19,22]. However, it has also been described, that the bone density decreases in the pelvis adjacent to the acetabular implant components [24], which of course might cause loosening and decreases the bone quality regarding potential revision operations.

Modern modular total hip endoprostheses consist of an acetabular cup, a liner, a femoral head and a femoral stem [1]. In case of revision it has to be distinguished between total and partial revision. A revision operation, where only articulating components are being exchanged due to mechanical wear between the femoral head and cup liner, are obviously easier to carry out and less cumbering for the patient. Therefore an early diagnosis of the wear disease is essential, which, in a number of cases, is overlooked in the early stages. This paper focuses on acetabular cup revision surgery, its pitfalls and solutions. The implant of choice for the far more challenging partial THA revision surgery hence has to meet a number of criteria, especially the possibility of combination with the remaining parts of the original endoprostheses as well as a sufficient coverage of the acetabular bone defect situation [5,15].

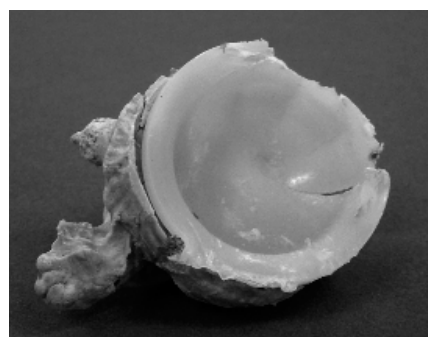


Figure 1:
Excessive wear and damage of a retrieved cemented full polyethylene-cup.

Acetabular Cup Revision

Pre-operative planning becomes even more important when performing THA revision surgery, especially when only the acetabular cup shall be exchanged. This is partly due to the possibility of combination of the endoprostheses components, which are to be left in situ. Common pitfalls in acetabular cup revision are shown in Table 1. Infection as a cause of THA revision surgery is supposed to be around 7% [9], and Perdreau-Remington et al. where able to retrieve pathogenic agents in 76% in microbiological smears from prostheses parts after revision surgery during an elongated culturing [16]. If there is any doubt that the prosthetic loosening could be associated with a septic condition, a pre-operative puncture followed by a microbiological and histological investigation should be carried out beforehand as in a number of cases a cure can only be achieved when removing the prostheses [9]. An important part when planning an acetabular revision surgery remains a detailed medical history, which must include previous irradiation and tumour diseases as possible reasons for prosthetic loosening. To clarify possible metastases a pre-operative CT-scan may be indicated. Possible allergies against either the implant or other biomaterials must be known before performing surgery. In our hospital, we favour the antero-lateral approach, where the patient is positioned in a supine position, which gives good reproducible positioning. The theatre report has to be present in advance to avoid a false estimation of the taper regarding its angulations and to guarantee that the necessary implants as well as appropriate explantation instruments are available on the day of surgery.

Common pitfalls during acetabular revision surgery
Pre-operative irradiation/ unknown metastases
Allergies
Low-grade infect
False pre-operative estimation of the taper dimensions
False pre-operative estimation of the defect situation
False estimation of the bone quality
Vascular and nerve injuries during acetabular cup fixation
Malpositioning of the centre of rotation (high, low, offset)
Malpositioning of the implants leading to consecutive impingement or dislocation
Allograft fracture

Table 1
Common pitfalls during acetabular revision surgery.

A special challenge for the surgeon is the iatrogenic dislocation of the femoral head from the acetabular cup without dissection of the muscles. This is partially due to limited intra-operative space during a mere acetabular cup revision [6].

The intention is to process towards the artificial joint without excessive bothering of the surrounding muscles and soft tissue. To be able to get a decent view on the acetabular cup, the gluteus medius may be notched, to perform a better exposition of the remaining femoral stem. An intra-operative specimen for

microbiological investigation is taken as a standard procedure. The scar tissue and the antero-lateral capsule however have to be sacrificed in order to dislocate the femoral head. As most of the proprioceptive fibres for the hip joint lie within the capsule, this may lead to a loss in propriocepction and has to be taken into account for the post-operative treatment in order to prevent joint instability. If a modular implant system was used during the primary implantation, the femoral head must be removed from the stem. This procedure will not only decrease post-operative wear, but will also enable an even better view on the acetabular cup.

The choice of implant [11] (Table 2) has to be made either regarding the defect classification which might be made according to the American Academy for Orthopaedic Surgeons (AAOS) [5] which identifies patterns and locations of bone loss (Table 3), or according to Paprosky et al. which is based on the severity of bone loss and the possibility to achieve cementless fixation [15]. A false pre-operative estimation of the defect situation and a resulting treatment may lead to an insufficient anchorage of the implant. A CT-scan of the pelvis is indicated especially for large defects or obscure circumstances: it is advised to have implants in stock for all different fixation techniques and defect sizes. Comorbidities and the remaining expectation of life of the patient however have to be considered as well during or before the surgical treatment when making the choice of implant [14].

Implants for acetabular cup revisions
• Defect covering revision implants - monobloc-systems, e.g. LOR-Cup (Zimmer) - modular-systems, e.g. metal-shell cranial extended (ESKA), MRS (Brehm) • Revision implants with additional bone graft - TCP/HA, artificial bone graft - Cancellous bone, auto-/allograft • Standard acetabular cup with/without weight bearing allograft
Fixation of the acetabular cup
• uncemented with/without special fixation-mechanisms - Fixed flap - Mouldable flap - Peg fixation ♦ Fixed ♦ Modular • Cemented
liner fixation
• Cementation of the liner • Direct clamping
Special implants as fallback options
• Socket acetabular cup • Saddle prosthesis • Tumour endoprosthesis • Partial pelvis replacement

Table 2
Possibilities regarding the choice of implant during acetabular cup revision [11].

Acetabular Defect Classification according to the AAOS:	
Type I	Segmental Defects
Type II	Cavity Defects
Type III	Combined Defects
Type IV	Pelvic Discontinuities
Type V	Arthrodesis

Table 3
Acetabular Defect Classification according to the AAOS [5].

In general we favour a treatment with an acetabular press-fit component (Fig. 2, 3). This however implies that the remaining acetabular bone stock has to be sufficient for a stable acetabular press fit. A misinterpretation regarding the quality of the remaining bone stock might lead to an instable result. To improve post-operative bone regeneration either artificial bone grafts or auto-/allografts may be used and a post-operative osteoporosis therapy should begun, if indicated. In most cases, the application of bone grafts is advised. However, allograft fractures might occur and hence the use of chips and/or autologous bone grafts is favoured. If artificial bone grafts are being used, a secondary dislocation within the joint must be avoided as they might damage the articulating parts.

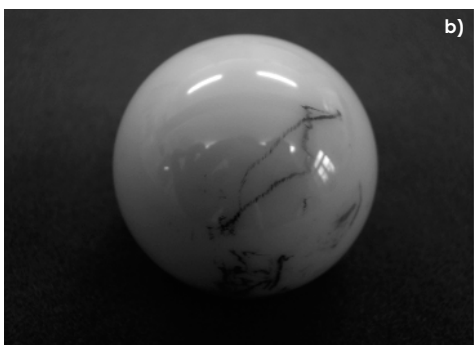


Figure 2a, b:
a) Scratched taper of a revised femoral stem.
b) Metallic deposits on a ceramic head.

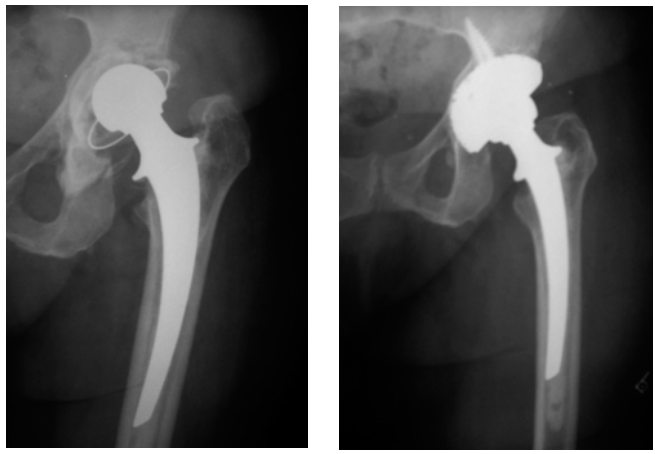


Figure 3a, b:
Pre-operative X-ray of a cavity defect D'Antonio type II. The acetabular cup revision was carried out with a large cementless primary implant.

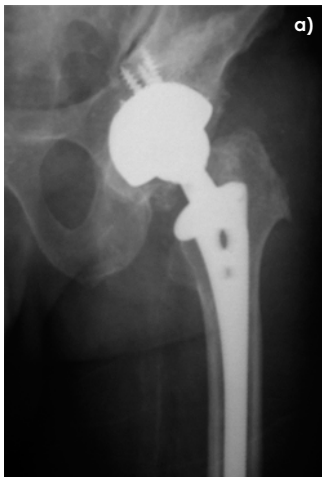
Furthermore, the containment has to be restored in order to enable post-operative weight bearing. The centre of rotation must be chosen carefully to avoid a high or low hip centre. A high hip centre might here lead to a gluteal insufficiency and comprises the risk of bony impingement. A low hip centre on the other hand may cause difficulties when reducing the hip intraoperatively and result in a high tension upon the surrounding nerves, muscles, vessels and soft tissue. An intraoperative change of the offset, i.e. hip-centre to far medial/lateral, can again lead to muscular, especially gluteal insufficiency. Another crucial factor is the positioning of the implant. Biomechanical investigations have shown that the position of the acetabular cup is a crucial parameter for the range of motion and stability against dislocation after total hip arthroplasty [2,20] and in particular after THA revision operations. An increased anteversion of the acetabular cup in combination with an anteverted femoral stem for instance is known to provoke dislocation or instability. During the primary operation the surgeon can adjust the position of the stem according to the position of the cup, but not so during acetabular cup revision with a remaining stem. To avoid a consecutive impingement (between femoral neck and cup) and dislocation 3D analysis regarding the range of motion could hence be used for the pre-operative evaluation of the necessary position of the acetabular cup.

According to the acetabular bone defect, an oval cup with a flap and pegs might be necessary. When preparing the fixation of the screws and the peg, especially careful drilling is essential as nerve or vascular injuries might occur. The soft tissue should be guarded with retractors and an intra-operative X-ray control is advised. A chronic nerve irritation, which has been present pre-operatively, might again only become visible because of intra-operative mobilisation. Due to the acetabular defect and the difficulties described regarding the prosthesis parts left in situ, intra-operative complications regarding the anatomical structures occur at a higher rate during THA revision surgery compared to primary implantation [1].

If a head-neck-stem has been used during primary implantation, a new femoral head can be mounted on the stem. The favourable tribological properties of ceramic femoral heads such as very limited wear and little osteolytic reactions are obvious [4,10].

During acetabular cup revision the metal taper may be damaged or scratched (Fig. 4a), and laboratory confirmed studies have shown that the burst strength of ceramic femoral heads is reduced when the head was mounted on a damaged metal taper [23]. This leads to a general advise to replace the damaged taper or at least not to use a ceramic femoral head. Nowadays a sleeve technology can be applied, where a metal sleeve covers the critical defect of the taper, and a ceramic head may after all be used [8]. If possible, the exchange of a modular femoral stem should be performed because of possible metallic deposits on ceramic heads (Fig. 4b) and scratches on metallic heads which can lead to increased wear and subsequent loosening of the implant [19].

A post-operative calculated antibiotic prophylaxis is administered for at least 10 days due to the reported infection rates of up to 7% as a reason for THA revision operation [17] and covers the most common pathogenic agents which are related to endoprostheses infections [9].



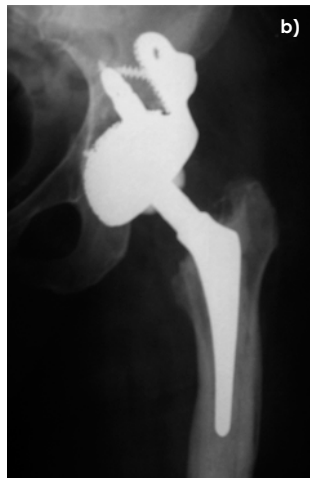


Figure 4a, b: a)Acetabular cup revision with an uncemented acetabular revision cup. b) Acetabular cup revision with an uncemented acetabular revision cup with an additional flap and peg.

Conclusion

A THA revision operation remains one of the most challenging operations in orthopaedic surgery and needs an experienced surgeon in order to guarantee best post-operative outcome and help to improve the quality of life of the patient. Especially the mere acetabular cup revision is an individual and hardly predictable situation on which the surgeon has to be able to react during the operation. Hence THA revision operations should be performed in specialized orthopaedic departments. This paper points out frequent pitfalls during acetabular revision operations and offers solutions to prevent such pitfalls intra-operatively. An explicit preoperative planning before revision surgery remains essential [1]. Clinical results however continue to be inhomogeneous and restricted comparable, as evidence based studies still lack.

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5.6 Revision strategies in total hip arthroplasty with respect to articulation materials

K. Knahr and M. Pospischill

Introduction

Revision surgery has become more and more important because of the increased number of total hip arthroplasties performed during the past three decades and their limitation of long-term survival mainly due to polyethylene wear.

The aim of this paper is to present strategies for possible revision scenarios in consideration of different articulating partners.

Revision strategy for metal/ceramic-on-polyethylene bearings

The main reason for revision of metal- or ceramic-on-polyethylene couplings is increased polyethylene wear, with subsequent osteolysis [1].
The annual wear rate of metal-on-polyethylene is 0.1 – 0.3 mm/y, the rate for ceramic-on-polyethylene is 0.05 – 0.15 mm/y [2]. Therefore, the onset of visible wear and osteolysis in ceramic-on-PE articulations usually occurs later than in metal-on-PE partners.

In case of revision there are no limitations concerning the articulating partners (Fig. 1a, b).

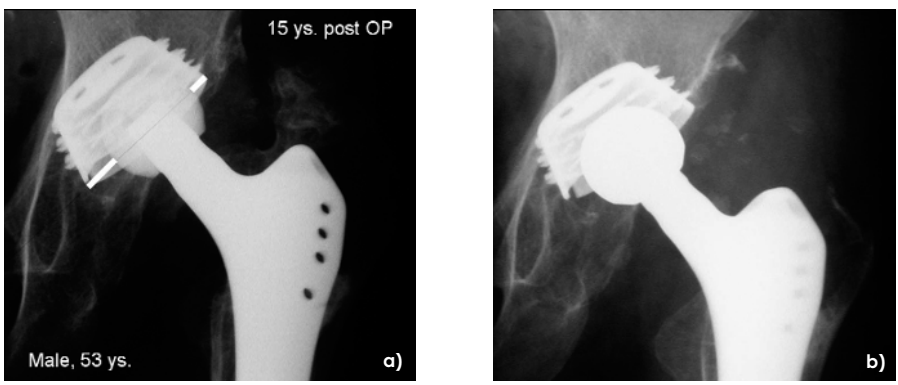

Figure 1a, b:
Exchange of polyethylene liner and ceramic head to a metal-on-crosslinked polyethylene bearing due to progressive wear.

Revision strategy for metal-on-metal bearings

Metal-on-metal bearings have been reintroduced by Weber in 1988 as an alternative to metal/ceramic-on-polyethylene bearings due to improved wear behavior of high carbon implants [3]. However, there are several reports in

literature that show hypersensitivity to metal wear particles leading to early osteolysis and aseptic loosening of components (Fig. 2) [4-6]. Clinical data suggest an association with a delayed hypersensitivity type IV to metal, mainly cobalt. It is still unclear whether the allergy to metal alloys is preexisting preoperatively or the patients became hypersensitive secondary to metal particles. As a consequence, in patients with postoperative persisting or early recurrent, load-dependent thigh pain - with or without radiographic signs of osteolytic lesions - a possible hypersensitivity to metal should be considered.

In case of revision surgery, all bearing couples except metal-on-metal are suggested.

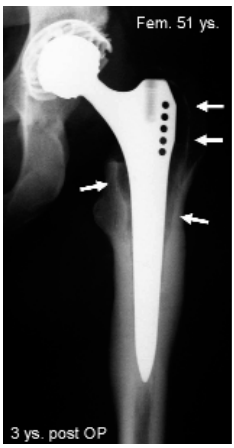

Figure 2:
Early osteolysis because of hypersensitivity to metal 3 years postoperatively.

Revision strategy for ceramic-on-ceramic bearings

As ceramic-on-ceramic bearings produce very few wear debris, revisions mainly are not caused by osteolysis and secondary loosening of the implant. The serious problems of ceramics are fracture of the material f.e. due to impingement or recurrent dislocation.

Alumina ceramic is a very hard and resistent material with excellent wear characteristics. The linear wear rate is very low and described in literature about 0.003 mm/year [7]. Nevertheless the elasticity of the material is also low and does not allow any deformation under load. High punctual stress can lead to fracture. Exact positioning of the cup is necessary to avoid edge loading at the proximal rim of the liner [8].

The revision of ceramic components is not as straightforward as of the other bearing partners and requires certain considerations. Therefore, different failure modes need different treatment scenarios.

Scenario 1: Acetabular revision

In many cases it is necessary to remove the ceramic ball head of a well fixed stem either to improve the exposure or to vary the lengh of the neck after the cup revision. It is recommended to perform cup exchange with the original ball head in place as long as possible to protect the taper. A rough removal can damage the surface structure of the taper. If a ceramic head would be used on a

damaged taper once again, high stress concentration can develop leading to a breakage of the ball. For this reason the removal should be done with special tools and under protection of a swab to avoid any scratches on the taper. In principle if the surface structure is macroscopically not damaged a new ceramic head can be used. Only the surgeon is responsible when re-using the taper of a stable stem. Manufacturers state that tapers are never to get re-used with a ceramic ball head because of the danger of damage of the taper during removal which is not in their control. If the surgeon is uncertain or unwilling to take over responsibility, he has to remove the stem which often complicates the surgical procedure.

In the last several years new concepts were developed to solve this problem. Recently, CeramTec offers a metal sleeve that can be put on the original taper to create a smooth surface where a new ceramic ball head can be attached (Fig. 3).

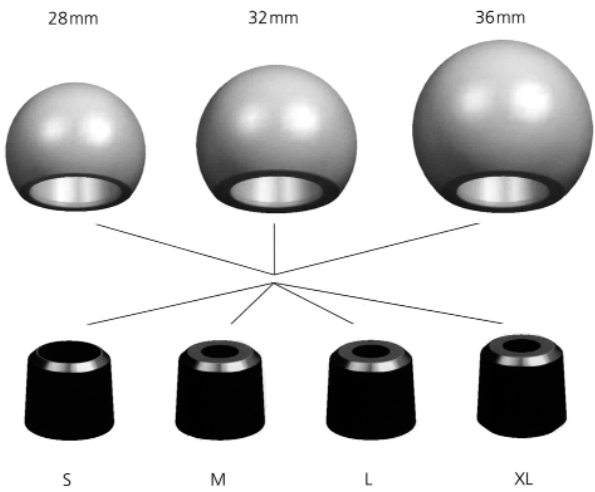

Figure 3:
Revision ball heads system by CeramTec.

Scenario 2: Exchange of the ceramic head for a longer neck size due to dislocation

Again one is faced with the possible damage of the taper during removal of the original head. This can be solved either by careful removal described above as well as using the ceramic revision ball heads with an inner metal sleeve.

Another problem is the possible limitation of neck length increase for joint stabilization. As the use of ceramic skirted balls is not advisible because of possible impingement leading to fracture, modern ceramic head systems do not exist in the sizes XL or XXL. These issues can limit the ability of ceramic heads for use in revision cases with dislocation. One solution is again the use of the revision ball heads system including an inner metal sleeve allowing longer neck length sizes (Fig. 4).

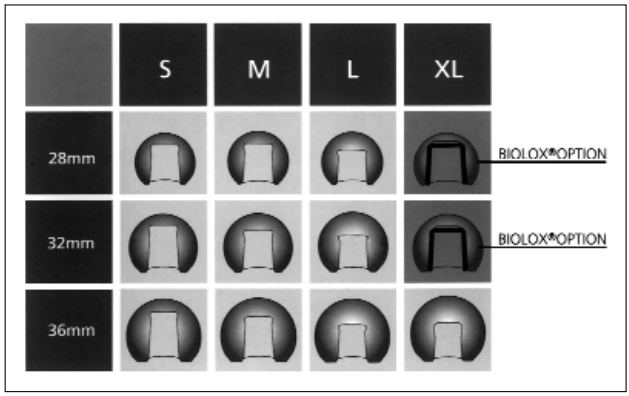

Figure 4:
Inner metal sleeves allow ceramic XL neck sizes.

Scenario 3: Fracture of the ceramic head

Mostly ceramic component fractures are either caused by a trauma of the patient or are related to dislocation or poor intraoperative handling. In case of fracture many ceramic particles of different sizes can be found during revision. Despite meticulous synovectomy and extensive joint lavage there are always small particles left. This remaining debris is harder than metal and leads to third-body-wear. Therefore it is absolutely necessary to avoid an exchange to a metal head after fracture of a ceramic articulation. Especially if a polyethylene liner is used the small ceramic wear particles get pressed into the soft poly which works like a sandpaper leading soon to massive abrasion of the metal head [9]. The one and only choice of articulation type for revision is renewal of a ceramic wear couple to reduce the risk of third-body-wear.

Scenario 4: Fracture of the ceramic liner

This can be caused either by intraoperative rim chipping due to malinsertion by the surgeon or by impingement between the rim of the liner and the taper, especially when skirted balls are used. Again, the one and only choice of articulation type is renewal of a ceramic wear couple to reduce the risk of third-body-wear.

Prevention of ceramic failure

To avoid any damage to the ceramic liner during insertion a special suction cup instrument was created [10]. It allows a simple and secure fixation within the titanium shell and can also be used to remove the liner in case of revision (Fig. 5).

It is important to avoid that any tissue gets between the shell and the liner. This could lead to breakage during impaction. The surfaces should be clean and dry. If an all-ceramic inlay with taper fixation is used, just one single blow with the impactor guarantees a secure fixation. Concerning the fixation of the ceramic ball to the taper, the same precaution should be taken.

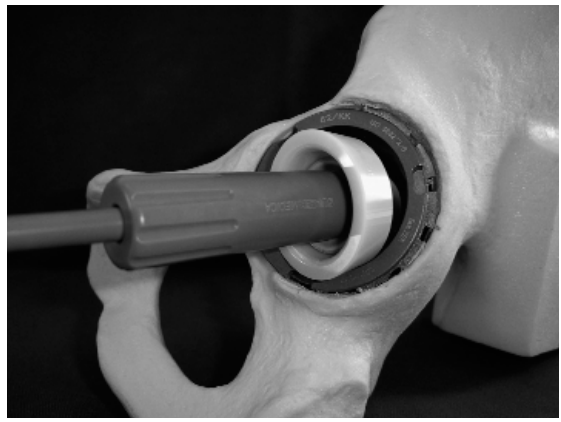

Figure 5:
The suction cup instrument.

Conclusion

Revision of a total hip arthroplasty needs comprehensive knowledge of the characteristics of the articulating materials. A wrong re-implanted wear couple can lead to early re-failure.

Selection of articulation in primary THA can be influenced by possible revision scenarios. Today the new XL-PE, metal-on-metal and ceramic-on-ceramic articulations offer excellent wear behaviors. Concerning the amount of wear, ceramic-on-ceramic seems to be the favourite. Nevertheless, a certain amount of risk for fractures has to be considered.

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SESSION 6

Tribology

6.1 Hip Joint Simulators: State of the Art

S. Affatato, W. Leardini and M. Zavalloni

Abstract

Wear and simulator testing are complicated tasks. Controlled wear testing should not be routinely done to qualify a material, but rather to elucidate wear mechanisms. What is meant by a simulator? It generally, may be described as a machine used to test a joint replacement under conditions approximating those occurring in the human body. Simulator tests, on the other hand, can be used to conduct accelerated protocols that replicate/simulate particularly extreme conditions, thereby establishing the limits of performance for the material. Simulators vary in their level of sophistication but, however, a hip joint simulator play an important role in pre-clinical validation of biomaterials used for orthopaedic implants. Simulators are necessary to perform wear tests on biomaterials prior the implantation in the human body in order to obtain quality control and to acquire further knowledge as to the tribological processes that involve joint prostheses.

Introduction

Total hip replacement (THR) is one of the most successful orthopaedic surgery in the last ten years. The biomaterials of hip joint prosthesis are metal or ceramic in femoral head, and metal, ceramic or UHMWPE in acetabular cup. Material selection and component design are important factors in the performance and durability of total joint replacements. Wear of total hip prosthesis is a significant clinical problem, because the wear of the implant products can cause adverse tissue reaction that may lead to massive bone loss around the implant and consequently loosening of the fixation. The need for systematic study of wear is evident in order to improve the knowledge of the tribology characteristic of a hip prosthesis. The study of wear rate typical of joint pairing constitutes an important aspect in pre-clinical validation of a prosthesis [1]. Generally, two categories of laboratory tests are conducted: wear screening device (quick tests) that provide information exclusively on the intrinsic features of the materials studied, and those conducted on joint simulators, in which real prostheses are tested in an environment that simulates physiological conditions [2]. A wear-screening device basically uses a very simple specimen configuration. This categories of tests are quick and provide information exclusively on the intrinsic features of the materials studied, without reproducing either the features of the shape of the implant, or the environment with which it will have to interact. Simulators are more complex and vary in their level of sophistication to reproduce with major accuracy the in vivo conditions [3]. The simulators differ between them from a lot of parameters: the number of channels, loading condition (physiological or simplify), movements, biaxial or tree-degree of freedom, configuration of the femoral head within the acetabular component anatomical or not.

Controlled bench wear testing should be used to develop an understanding of wear mechanisms and the influence of environmental, design, and material

parameters on wear behaviour. Replicating the specific conditions occurring in a hip or knee joint, simulator testing can then be used to test specific design and material combinations. In order to obtain realistic results, a wear test could be performed to reproduce in vivo working conditions [4,5]. The degree of reliability of these tests depends on the accuracy in recreating in vitro the conditions of a prosthetic implant in the human body.

Joint simulator tests have been developed to simulate the biomechanics of human joints in a controlled condition. Results from simulator testing can provide confirmation of the material's performance for a given geometric design under a variety of operating conditions.

Since 2000, the International Organizations for Standardization (ISO) developed an international procedure in order to obtain comparable results between the laboratories. These international recommendations suggested the specifications and the methods to assess the wear and as to conduct a wear tests.

A spontaneous question is: these international recommendations (ISO 14242-Part 1,2) are followed from the scientist in the world?

In the follows will take in examination the known hip joint simulators.

Different Simulators Design

In the last years, a lot of simulators design, were developed in order to achieve similarity between the simulation and in-vivo conditions. At this regard, a report of the most known simulators available in literature. The characteristics of the major hip joint simulators are shown in Table 1.

AUTHOR	SIMULATOR	STATION	CLASSIFI-CATION	MOTION SIMULATED	WEAR RATE	POSIZION-HEAD
Bragdon et al. (2003)	AMTI	12	3-axis	FE(±25°), AA(±9°), IN-EX(±20°)	4.8 ± 1.1 mg/Mc	anatomical
Saikko (2005)	HUT-4	12	2-axis	FE(46°), AA(12°)	8.2 mg/Mc	anatomical
Smith (2001)	Mark II Durham	5	2-axis	FE(+30°/-15°), IN-EX (±10°)	50.32 ± 7.07 mm^3/Mc	anatomical
Nevelos (2001)	Leeds PA II	6	2-axis	FE(+30°/-15°), IN-EX (±10°)	0.11± 0.04 mm^3/Mc	anatomical
Barbour (2000)	PROSIM Limited	10	2-axis	BI-AX (±30°)	42 ± 1 mm^3/Mc	anatomical
McKellop (2004)	EW08 MMED	16	2-axis	FE(±22.5°) AA(±22.5°)	0.4 mm^3/Mc	No anatomical
Clarke (2005)	SW	12	2-axis	BI-AX (±23°)	0.032 ± 0.028 mg/Mc	No anatomical
Affatato (2006)	SW	12	2-axis	BI-AX (±23°)	0.17 mg/Mc	No anatomical

FE = flexion-extension, AA = abduction-adduction, IN-EX = internal-external rotation, Bi-AX = biaxial rocking, Mc = million cycles

Table 1:
Main characteristics between different simulators design.

AMTI – Bragdon CR & Harris HW [6]

The AMTI-Boston Hip Simulator, developed by William H. Harris, simulates hip motion with simultaneous loading in a physiologic environment (Fig. 1). The simulator provides rotation about 3 axes in the sagittal plane, abduction /adduction plane and about the vertical (femoral) axis, and loading profiles which replicate walking or stair climbing etc. The twelve stations Hip Simulator (AMTI, Boston) allows friction/wear tests of twelve joints simultaneously. The system operates with four degrees of freedom (load and three motions), and the left and right banks of the machine can be operated under a different set of motions and loading. The acetabular cup flexes up to ±25° from vertical, the approximate anatomic range, while abduction/adduction motion of up to ±9° is provided, each motion separately controlled. The femoral ball is rotated under separate control of up to ±20°(Fig. 3b). Any loading cycle between zero and 4500 N can be applied, including the Paul [7] or Bergman [8] loading profiles at a frequency up to 2 Hz.

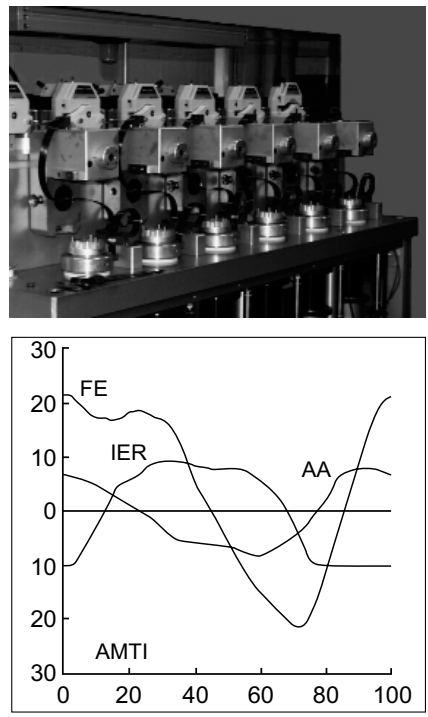
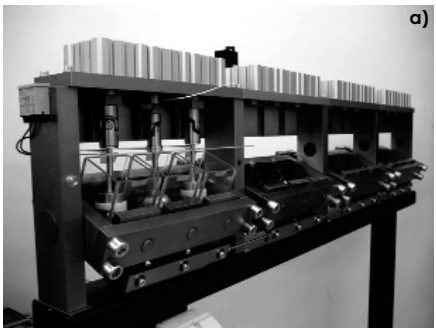


Figure 1:
AMTI simulator.

HUT-4 – Saikko V. [9]

In the 12-station HUT-4 simulator (Helsinki University) (Fig. 2), the prosthesis is in the anatomical position and self-centring. The electromechanical motion consist of flexion-extension (FE) and abduction-adduction (AA) of the femoral component. The excursions of the FE and AA motions are 46° and 12° respectively, in accordance with biomechanical studies of gait cycles. The prosthesis is mounted in anatomical position. In particular, the cup is inclined at 45° with respect to the neck axis. The load actuator is pneumatic and the load direction is along the neck axis.



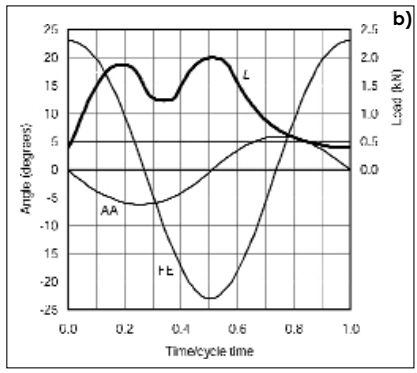
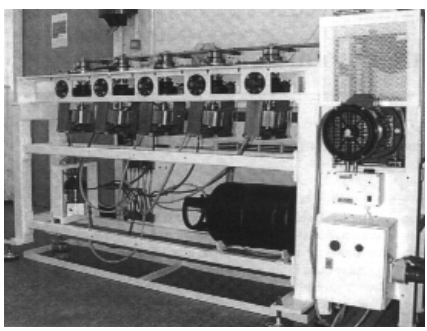


Figure 2a-c:
a: Two-axis, twelve-station hip joint simulator HUT-4; b: Close-up of HUT-4 hip joint simulator and c: measured variation of flexion-extension (FE) ,abduction-adduction (AA) angles and load waveform.

Mark II – Smith SL & Unsworth A. [10]

The Mark II Durham hip joint simulator (Durham University) (Fig. 3) is a five stations machine were the joint are mounted anatomically and subjected to a dynamic loading cycle with independent two-axis motion. The simulator apply an approximate sinusoidal motion through +30° to -15° in the flexion/extension plane and +10° to -10° in the internal/external. The load actuator can perform a Paul's curve or a square one (Fig. 3a-d).



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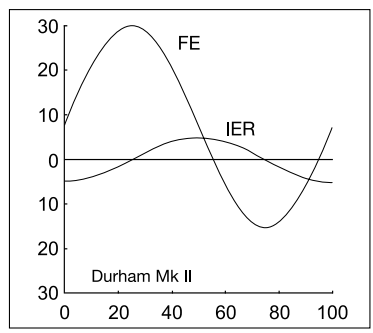

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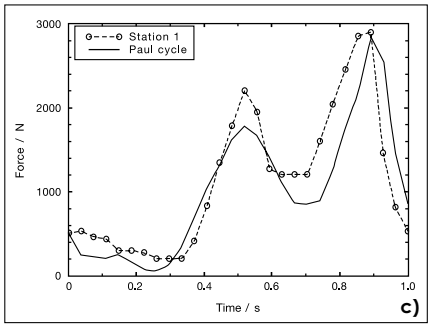


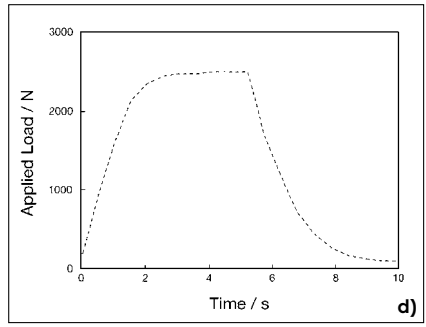
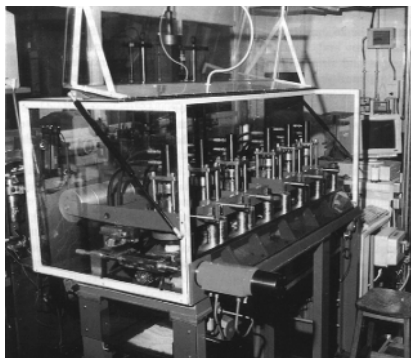
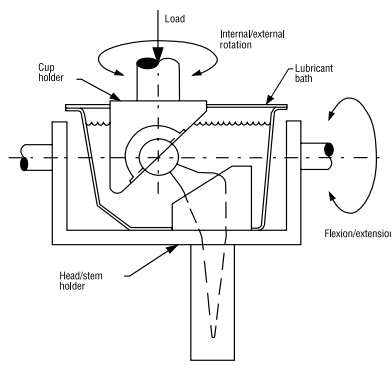


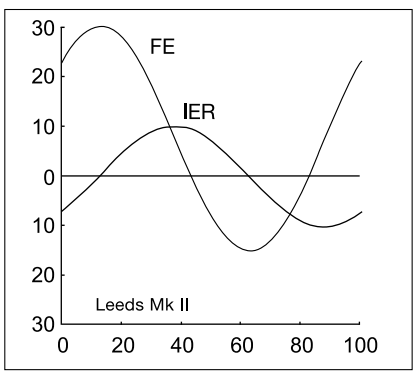
Figure 3a-d:
Durham MK II.

Leeds PA II – Fisher J. [11]

The Leeds PA II hip joint simulator (University of Leeds) (Fig. 4) was is a six stations. The load is applied in vertical axis and the simulator can control, independently, the Flexion-Extension and Internal-External rotations. With simplified cycles to generate a multidirectional motion between the femoral head and the acetabular cup. The joint bearing are mounted in the anatomical position with both the femoral stem and the acetabular cup cemented into metallic holders.







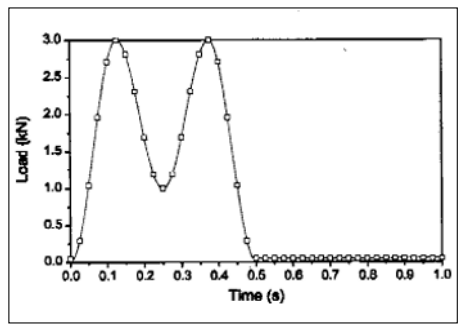
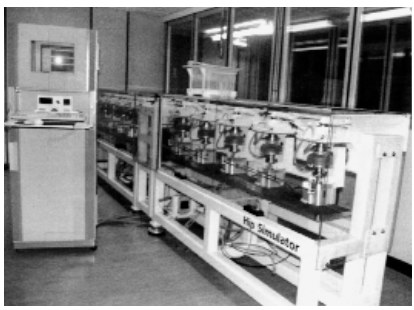
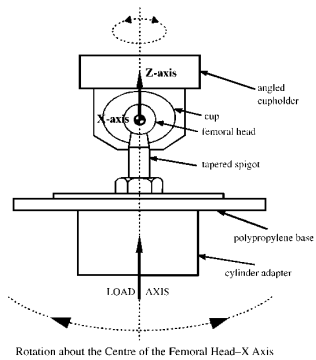


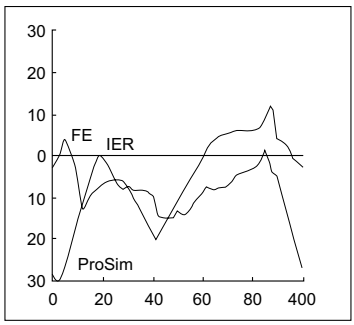
Figure 4a-d:
Leeds MK II.

ProSim Limited – Dowson D [12,13]

The ProSim Limited hip joint simulator has 10 station (University of Leeds) (Fig. 5). In each station, the cup is mounted in the anatomical position above the femoral head inclined at an angle of 35° with respect to the horizontal plane. This position replicate the inclination of the cup in the pelvis at 45° to the vertical and the resultant load vector 10° medially. Each station has two degree of freedom and the range of motion vary between –30° to +30°. The load and motion kinematics follows the Paul's studies.







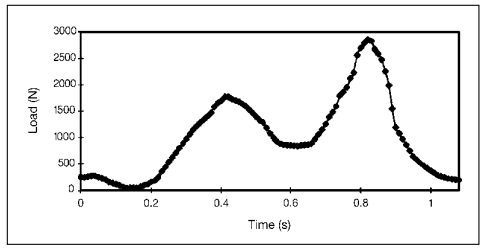
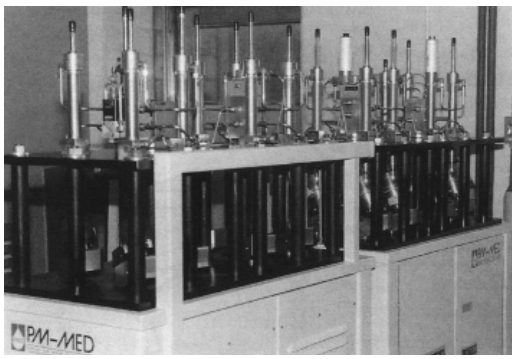


Figure 5a-d:
ProSim.

MATCO – Medley JB & McKellop H [14]

The MATCO hip simulator (model EW08 MMED) is configured in two bank of eight channel each (Fig. 6). The cups and the heads are mounted in not anatomical position. This simulator involves a symmetrical shift of the cup over a stationary head through a range of about 45° (±22.5°) in both sagittal and frontal planes with no rotation in the transverse plane. Usually the imposed load follows a Paul's curve with a peak load of 2.1 kN.



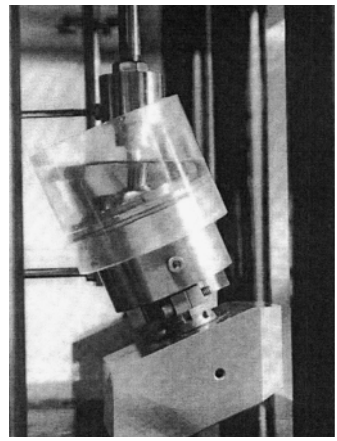
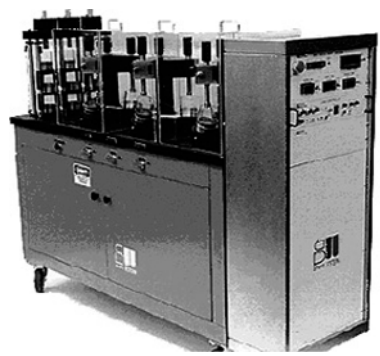


Figure 6:
MATCO.

Shore Western-12 station [15,16]

The Shore Western Hip joint simulator is a 12 station machine (Fig. 7). In each station the implants are mounted in non-anatomical position and the heads alignment is provided by a ball bearing on the head holder. The acetabular cups are mounted onto the simulator with an inclination of 23° with the respect to the horizontal plane and the cup holder can contain even the lubricant used during tests. The load applied is sinusoidal with a maximum peak of 2 kN and its direction is overlapping on the vertical axis. The test frequency is usually set at 1 Hz.



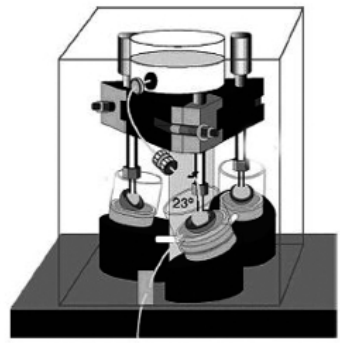


Figure 7:
Shore Western.

Wear Test

A typical wear tests is conducted using a joint simulator.

Usually cups are fixed to a particular holder mounted on a bearing block that allows the motion and maintain the natural angle between cup and hip joint load axis. The femoral heads are mounted using self-aligning connection components. The stations are filled with lubricant (typically sterile bovine calf

serum diluted with deionized water plus 0.2% sodium azide) in order to wet completely the specimen's contact surfaces.

In old machines, before the international recommendation, the implants were mounted in non anatomical position (upside down); in this case unfavourable effect of the three-body wear phenomena are possible and so is usually applied a test procedure that includes periodic washing and cleaning of the specimens. Various methods are applied for quantitative wear evaluation [17]. The wear tests are stopped periodically (typically every 500,000 cycles) and the wear is evaluated with gravimetric, volumetric or profilometric methods. The components are removed from their holders and cleaned and after a drying procedure they are weighed. The cups are cleaned using a special detergent to remove dust and possible particles debris in an ultrasonic bath.

Major indications about the weighing procedures are given from the ISO 14242-2. Wear data of the simulators above introduced are shown in Table 2.

AUTHOR	SIMULATOR	BEARING	WEAR RATE
Bragdon et al. (2003)	AMTI (anatomical)	CoCr-UHMWPE cross-linked	4.8 ± 1.1 (mg/Mc)
Saikko (2005)	HUT-4 (anatomical)	CoCr-UHMWPE	15.5 (mg/Mc)
Saikko (2005)	HUT-4 (anatomical)	CoCr-CoCr	0.89 (mg/Mc)
Smith (2001)	Mark II Durham (anatomical)	Zirconia-UHMWPE	50.32 ± 7.07 (mm^3/Mc)
Nevelos (2001)	Leeds MK II (anatomical)	Alumina-Alumina	0.11± 0.04 (mm^3/Mc)
Barbour (2000)	PROSIM Limited (anatomical)	Zirconia-UHMWPE	42 ± 1 (mm^3/Mc)
Barbour (2000)	PROSIM Limited (anatomical)	CoCr-UHMWPE	47 ± 4 (mm^3/Mc)
McKellop (2004)	EW08 MMED NO (anatomical)	CoCr-CoCr	1.2 (mm^3/ Mc)
Clarke (2005)	SW (upside-down)	Alumina-Alumina	0.032 ± 0.028 (mg/Mc)
Affatato (2006)	SW (upside-down)	CoCr-CoCr	0.17 (mg/Mc)

Table 2:
Wear rate from different simulators design.

Conclusions

In conclusion, the use of expensive laboratory tests requires an understanding of the limitations of each test. Wear and simulator testing are complicated tasks because of the lack of understanding of the basic wear mechanisms under a variety of operating conditions. Controlled wear testing should not be routinely done to qualify a material, but rather to elucidate wear mechanisms. For now, confidence in the interpretation of wear testing data derives from successful correlation of bench test wear surfaces with retrieved implant surfaces in terms of

surface texture and wear debris size and shape. One of the critical issues in wear and joint simulator testing is how to extrapolate short-term testing results to long-term projections. This requires a solid understanding of the relationship between material structures, properties, and wear mechanisms. A carefully designed parameter study is needed to systematically examine the influence of speed, loading cycles, and motion directions on a material's behaviour and the resulting wear phenomena. Material selection and component design are important factors in the performance and durability of total joint replacements. The role of wear testing and joint simulation studies is often unclear, however, in terms of discriminating the effect of materials and design on performance. Controlled bench wear testing should be used to develop an understanding of wear mechanisms and the influence of environmental, design, and material parameters on wear behaviour. Replicating the specific conditions occurring in a hip joint, simulator testing can then be used to test specific design and material combinations. The elements of a wear system include the contact surfaces, lubricant, load, articulating surface speeds, motions, surface roughness, and temperature. The general conditions existing at the contact interface may not control wear as much as the specific load conditions existing at the asperities on the contact surfaces. Unfortunately, conditions at asperities are difficult to measure.

Joint simulator tests have been developed to simulate the biomechanics of human joints in a controlled condition. Results from simulator testing can provide confirmation of the material's performance for a given geometric design under a variety of operating conditions. Different simulators design provide different wear results as explained in Table 2 and in this sense, it is impossible to compare wear results obtained using different simulators even if testing the same prostheses because at the moment each one use an internal protocol and don't follow the ISO standards. Future developments on this matter, in our opinion, robin-test and a consensus conference should be helpful to define a common protocol for the THR simulation. should be carried out taking in account the need for the labs in the world to use the same simulation parameters in order to make the results comparable between them.

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6.2 Highly Crosslinked Ultra High Molecular Weight Polyethylene- (UHMWPE-) Acetabular Liners in combination with 28mm BIOLOX® heads

C. Hendrich, N. Wollmerstedt, A. Ince, F. Mahlmeister, S. Göbel and U. Nöth

In the current practice highly crosslinked UHMWPE liners are used mainly in combination with metal femoral heads. The current study demonstrates the 5-year results of highly crosslinked UHMWPE (Longevity®) acetabular liners in combination with 28mm alumina (BIOLOX®) heads. In comparison with a historical control group linear wear rates were significantly reduced. The combination of highly crosslinked UHMWPE with alumina heads may therefore be useful in further reducing wear.

Introduction

In total hip replacement one of the most promising developments during the last years was the introduction of new types of polyethylene (PE) [2]. The use of irradiation in combination with heat treatment results in highly cross-linked polyethylenes with no measurable wear under in vitro conditions [6]. The clinical results are limited to short-sterm studies yet which were performed in combination with metal femoral heads. Already in the 80ies one study with irradiated PE in combination with alumina femoral heads was performed showing reduced wear rates [7]. The effect of the combination of the new highly crosslinked PE with alumina heads was not investigated, yet.

Material und Methods

The linear wear rates of two groups of patients with primary total hip arthroplasty was investigated. In both groups Harris-Galante type II and III acetabular implants (Zimmer, Warsaw, USA were used in combination with 28 mm alumina (BIOLOX®) heads (CeramTec, Plochingen Germany). In group 1 (58 patients) highly crosslinked PE (Longevity®) and in group 2 (99 patients) conventional, gamma-in-air irradiated PE was used – Figure 1. Different cemented and cementless stems were implanted. Linear wear was measured by digital wear measurement ("Hip Analysis Suite – University of Chicago, Chicago, USA) [5]. We measured the linear wear and documented the age, gender, BMI and activity of the lower extremity with an electronic pedometer StepWatch (CymaTech, Mountlake Terrace, USA).

Group1 included 52% females, the mean age was 56 years (SD 10, range 32-74) with a BMI of 28 (SD 5, range 19-40). The mean activity was documented with 6242 cycles per day. The primary diagnoses were osteoarthritis in 74%, developmental dysplasia (DDH) in 12%, avascular necrosis (AVN) in 3% and miscellaneous in 10% of the patients.

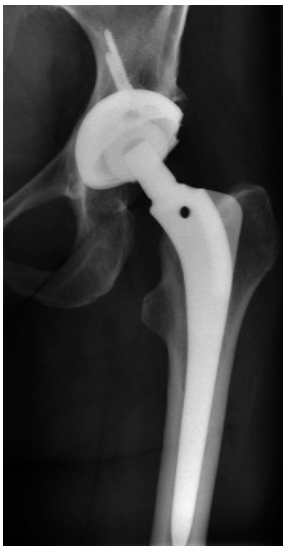

Figure 1:
Total hip replacement using the Harris-Galante cup with a highly crosslinked PE liner in combination with a 28mm BIOLOX® femoral head.

Group 2 consisted of 53% females with a mean age of 61 years (SD 9, range 41-82), with a BMI of 28 (SD4, range 20-40). The mean activity was 5400 cycles per day. The primary diagnosis was osteoarthritis in 74%, DDH in 12% and AVN in 3% and in 10% of the patients miscellaneous diagnoses.

A multivariate analysis of covariance was performed to compare the annual wear rate of both groups. The daily activity was not used for the statistical analysis because only 52 patients of group 2 had complete data.

The data of the latest follow-up were used to calculate a linear regression model to demonstrate the influence of the follow-up time on the wear rate.

Results

In the analysis of covariance (Table 1), which was not influenced by the BMI and age, clearly different linear wear was documented. The wear of group 1 (Longevity + 28mm BIOLOX® heads) was reduced also at the different times of follow-up. The gender of group 2 (conventional PE + 28mm BIOLOX® heads) showed a significant effect on the wear whereas females had a lower wear rate than males.

		Covariates	
dependent variable	explained variance (corr. R^2)	factor variables (independent variables)	p-value
annual linear wear	0,291	sex	<0,001
		BMI	0,318
		age	0,454
		patient group	<0,001
		follow-up time	<0,001
		patient group and follow-up time	<0,001

Table 1:
Multivariate analysis of covariance.

The regression analysis were all significant and the explained variance (corr. R^2) was 18% for group 1 and 10% for group 2. To illustrate the decrease of wear rate over time the regression for the linear wear rate over time are depicted in Figure 2 and Figure 3. Also the 95% confidence intervals are shown. In group 1 (Longevity + 28mm BIOLOX® heads) the 0.1 mm/year wear rate is achieved at 53 months. In group 2 (conventional PE + 28mm BIOLOX® heads) the 0.1 mm/year wear rate is calculated at 129 months.

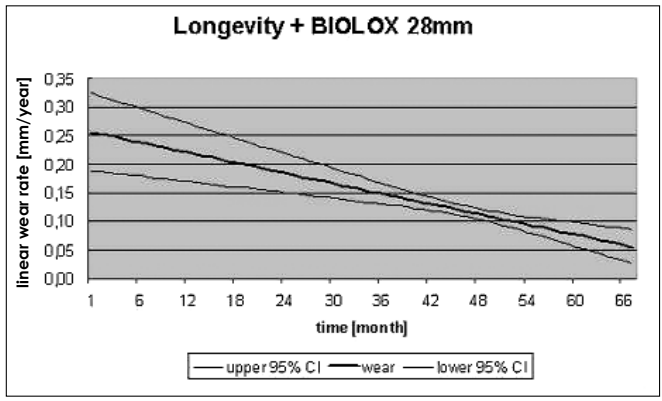

Figure 2:
Regression analysis of the linear wear rate of highly crosslinked PE in combination with 28mm BIOLOX® heads over time.

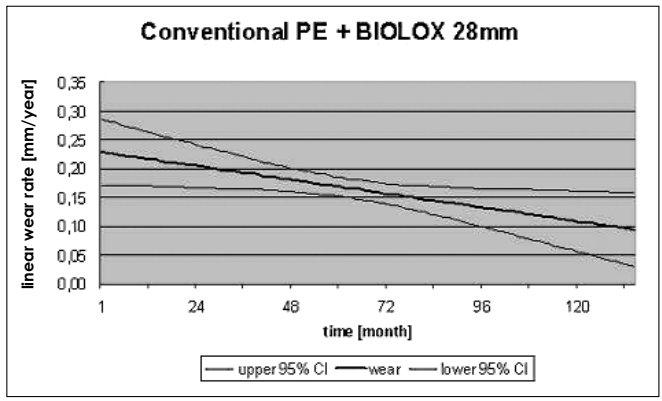

Figure 3:
Regression analysis of the linear wear rate of conventional PE in combination with 28mm BIOLOX® heads over time.

Discussion

The aim of this study was to measure the wear of highly crosslinked UHMWPE in combination with 28mm BIOLOX® heads. The study design was prospective and the digital measurement system of Martell was used [5]. However one definite weakness of this study is the historical control group. The strengths of this study are the high number of patients, the use of similar actebular components and heads in all patients and the measurement of activity.

Our data showed a significantly reduced wear rate of highly crosslinked UHMWPE in combination with BIOLOX® heads compared to conventional PE after 5 years of follow-up. Meanwhile some study on short- and mid-term results for different highly crosslinked UHMWPE are available. After follow-up times of 2 years the crosslinked PE showed reduced wear rates compared to conventional ones [1,3,4]. However all studies so far used metal femoral heads. Our patients were less than 60 years with a moderate activity level. In contrast the group with the conventional PE was significantly older and showed less activity. We demonstrated that the mean linear wear rates declined over a 5-year period. The regression analysis showed a signifiantly earlier reduction of wear compared with the group of conventional PE.

While our study suggests that the use of highly crosslinked UHMWPE and BIOLOX® heads will reduce linear wear it should not be overlooked that this new combination still creates a measurable amount of wear even after 5 years. In vitro investigations which did not show any wear after 20 million cycles are not consistent with this in vivo finding. If the reduced wear rate during the first 5 years will not increase in future the combination of highly crosslinked PE with BIOLOX® heads is a promising wear couple for young and active patients.

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6.3 Wear of Highly Crosslinked Polyethylene against Cobalt Chrome and Ceramic femoral heads

J. Fisher, L. M. Jennings and A. L. Galvin

Abstract

There is increasing interest in the use of highly cross-linked polyethylene with large diameter heads in the hip. This study investigated the wear characteristics of size 36 mm ceramic and cobalt chrome femoral heads articulating against highly cross-linked polyethylene inserts using a physiological hip simulator. The steady state wear rate of the ceramic femoral heads articulating against highly cross-linked inserts was found to be 50% lower than that of cobalt chrome femoral heads.

Introduction

There is increasing interest in the coupling of highly cross-linked polyethylene with large diameter heads in the hip, due to the reported lower wear characteristics of highly cross-linked polyethylene compared to conventional polyethylene [1,2,6]. Further, clinical experience has demonstrated an advantage of alumina over metallic femoral heads with a reduction in wear being reported for conventional polyethylene on ceramic heads compared to metallic heads [3]. This differentiation has also been demonstrated in in vitro physiological simulator studies. The wear rates of ceramic and cobalt chrome heads on conventional polyethylene were 26 mm^3/million cycles and 35 mm^3/million cycles respectively for size 28 mm hip prostheses tested in the Leeds Prosim Physiological Anatomical Hip Joint Simulator [4,7]. There are limited clinical reports of ceramic femoral heads articulating against cross-linked polyethylene, although in a 17 year study by Wroblewski, no further penetration of cross-linked polyethylene articulating against 22.225 mm alumina ceramic was observed after the first two years [8].

The aim of this study was to determine the wear of large (size 36 mm) highly cross-linked polyethylene inserts against ceramic and cobalt chrome femoral heads using a physiological hip simulator and test conditions.

Materials and Methods

Size 36 mm Biolox® Forte alumina (CeramTec AG, Germany) and cobalt chrome (Durasul®, Zimmer, Switzerland) femoral heads were coupled with highly cross-linked polyethylene inserts (Durasul® Alpha, Zimmer, Switzerland) in the ten station Leeds Prosim Physiological Anatomical Hip Joint Simulator. Five sets of components for each material were studied, four were tested in articulating stations to determine creep plus wear and one was loaded with no articulation to determine creep.

The test conditions were a physiological walking cycle with a twin peak Paul type loading curve with a peak load of 3kN and a minimum swing phase load of 100N. Two independently controlled motions of +30°/-15° flexion-extension and ±10° internal/external rotation were applied. The simulator was run at 1Hz.

The simulator was run for a total of 7 million cycles and the lubricant changed every 330,000 cycles. The lubricant used was new born calf serum (Harlan Sera-Lab Ltd, Loughborough, UK) diluted to 25%, with 0.1% sodium azide added to retard bacterial growth. This corresponded to a serum protein concentration of 15.45 g/l. The change in volume of the polyethylene inserts was determined geometrically, being placed in a controlled environment for a minimum of 48 hours before measuring, using a Kemco (Kemco 400 3D, Keeley Measurement Company, UK) co-ordinate measuring machine to map the insert surface. The change in volume was subsequently calculated using bespoke software (Tribology Solutions Ltd, Pontefract, UK) and the mean volume change rates over the periods 0 - 7, 1 - 7 and 2 - 7 million cycles were calculated.

A contacting Form Talysurf (Taylor Hobson Limited, Leicester, UK) surface measuring machine was used to characterise the bearing surfaces at the start and end of the test.

Results

The mean change in volume of the articulating stations is shown in Figure 1. One of the highly cross-linked polyethylene inserts fractured at the fixation interface early in the test and was excluded from the analysis. The failed polyethylene insert was articulating against a ceramic head. The volume change during the first million cycles was twice as high for the ceramic/cross-linked polyethylene bearing combination compared to the cobalt chrome/cross-linked polyethylene bearing combination. This elevated volume change in the first million cycles of the ceramic/cross-linked polyethylene bearing combinations was attributed to creep. After the first million cycles the change in volume was linear for the cobalt chrome/cross-linked polyethylene bearing combinations, indicating that they had reached their steady state. In contrast, the ceramic/cross-linked polyethylene bearing combinations did not reach their steady state until 2 million

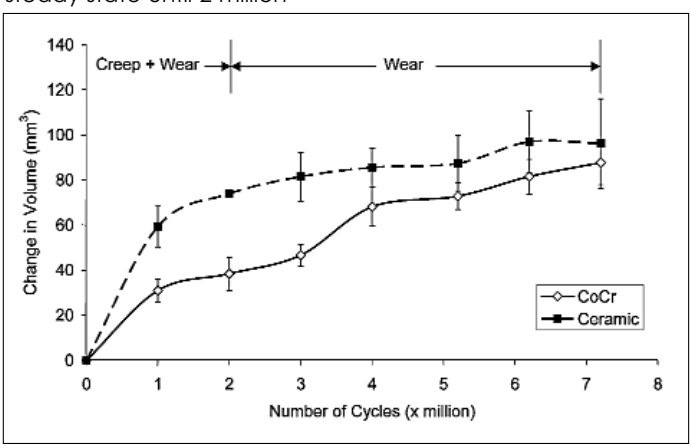

Figure 1: Mean Change in Volume of the Articulating Stations at 7 Million Cycles.

cycles. The creep only stations also demonstrated this behaviour. This indicated that the volume change was due to both creep and wear in the first million cycles for the cobablt chrome/cross-linked polyethylene bearing combinations and until 2 million cycles for the ceramic/cross-linked polyethylene bearing combinations. After these periods the volume change was due to wear.

The mean volume change rates over the periods 0 - 7, 1 - 7 and 2 - 7 million cycles are shown in Figure 2. The mean volume change rates over the full duration of the test, which comprised of creep and wear, were similar for the ceramic and cobalt chrome heads against highly cross-linked polyethylene combinations. The rate of volume change of the cobalt chrome/cross-linked polyethylene bearing combination did not change substantially over the period 1-7 and 2-7 million cycles, being 9.2 and 9.5 mm^3/million cycles respectively and representing the wear rate of this combination. In contrast the rate of volume change of the ceramic/cross-linked polyethylene bearing combinations decreased, resulting in a wear rate of 4.3 mm^3/million cycles when calculated over 2-7 million cycles. Comparing the results over the period 2 to 7 million cycles, which represented the steady state wear rate for both sets of components, the wear rate of the ceramic/cross-linked polyethylene bearing combination was statistically significantly lower than that of the cobalt chrome/cross-linked polyethylene bearing combination ($p < 0.01$).

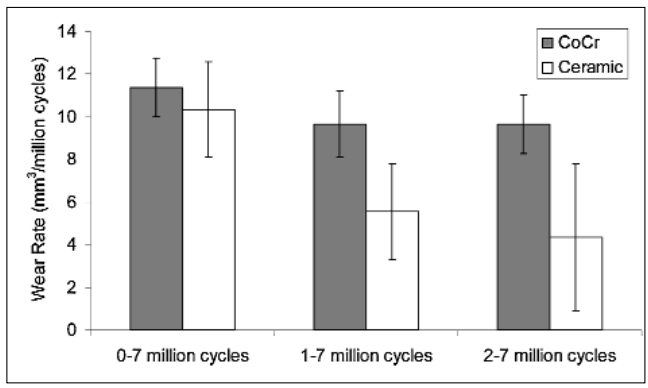

Figure 2:
Mean Wear Rates with 95% Confidence Limits.

The overall surface roughness (R_a) of the ceramic and cobalt chrome femoral heads were similar at the start of the test at 0.004 µm and 0.006 µm respectively. At the end of the test the overall surface roughness increased to 0.015 µm and 0.009 µm for the ceramic and cobalt chrome femoral heads respectively. The overall surface roughness R_a of all the highly cross-linked inserts substantially reduced from 1.070 µm to 0.232 µm during the test due to the removal of machine markings. There was no difference between the ceramic and cobalt chrome groups in terms of insert roughness ($p > 0.66$ at end of test).

Discussion

The volume change of the ceramic/cross-linked polyethylene bearing combinations during the first two million cycles of the hip simulator test was twice that of the cobalt chrome/cross-linked polyethylene bearing combinations due to increased creep. This may be due to poorer conductivity of the ceramic heads and the resulting higher temperature. After 2 million cycles a steady state wear

rate was reached for the ceramic components, with a wear rate of 4.3 mm^3/million cycles. This was over a 50% reduction compared to the wear rate of the cobalt chrome/cross-linked polyethylene bearing combinations at 9.5 mm^3/million cycles. It is expected that the functional biological activity of the ceramic/cross-linked polyethylene bearing combination will be lower than the cobalt chrome/cross-linked combination due to the lower steady state wear rate. A study using size 28 mm cobalt chrome heads articulating against highly cross-linked polyethylene on the same simulator and using the same test conditions reported a steady state wear rate of 4.6 mm^3/million cycles [5]. This wear rate was determined after 1 million cycles, which removed the contribution of the initial creep deformation. Further, a loss of machine markings of the highly cross-linked acetabular cups was observed, which is consistent with this study.

The clinical implications of this study relate to the measurement of wear, which is routinely assessed using penetration measured from radiographs. However, penetration is a measure of both wear and creep. This means that although the penetration of polyethylene inserts coupled with metal and ceramic femoral heads may be similar, the actual wear is likely to be lower with the ceramic heads due to their elevated creep.

Conclusion

This study has shown the steady state wear rate of ceramic femoral heads articulating against highly cross-linked inserts to be 50% lower than that of cobalt chrome femoral heads.

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6.4 US perspective on hip simulator wear testing of BIOLOX® delta in 'severe' test modes

I. C. Clarke, D. Green, P. Williams, T. Donaldson and G. Pezzotti

Abstract

A ceramic on ceramic (COC) simulator wear study was run with 36mm Biolox® implants under 'severe' microseparation test mode. The implants included the zirconia-toughened alumina (ZTA: Biolox® delta, 'd') with alumina used as the historical control (Biolox® forte, 'f'). The four combinations (ball-cup: dd, df, fd and ff) were run simultaneously in a hip simulator to 5 million cycles duration (5Mc). The femoral balls were 36mm diameter and four material pairings were run with pre-set ball/cup diametral clearances. All combinations demonstrated stripe wear phenomenon on both balls and cups. The stripes began immediately in the run-in phase (100,000 cycles) as well-defined, narrow scars that gradually expanded over the duration of the study. For the cups, there was a narrow superior stripe region along the rim that expanded circumferentially with test duration. The ff combination showed the greatest stripe expansion that also expanded rapidly into the main wear zone. The appearance of such narrow stripes in run-in phase was comparable to prior microseparation simulator studies and short-term ceramic retrieval studies. The gradual expansion of our simulator stripes compared well to our long-term ceramic retrievals with 15 to 22 year use in-vivo.

Wear rates for all 36mm COC combinations were very low even under our severe microseparation test conditions. Our ff pairings demonstrated 'Average' wear rate of 1.5 mm^3/Mc. Clinical wear rates for contemporary alumina THR retrievals ranged from 0.1 to 3.6 mm^3/year, so clearly our simulator wear rates were in mid-clinical range for alumina implants. The general trend showed that ff pairs had the highest THR wear rates and dd pairs had the lowest. Overall wear rates were ranked as follows: ff >> (df ≥ fd) > dd. Under our microseparation test condition, the 'Average' wear rates for our fd and df hybrid pairings were > 3-fold lower than with the historical control (ff). The 'Average' wear for the dd pairing was 6-fold lower than control and 2-fold lower than the hybrids (fd, df). It was interesting that the delta ceramic wore preferentially over the forte ceramic in the hybrid pairings, possibly due to the slightly higher hardness of the pure alumina. Comparing this study with 36mm diameter ceramic balls to prior microseparation COC studies with 28mm diameters, there was little discernable difference in wear rates. Thus the effects of the 36mm versus 28mm ball size, if any, will likely be of small significance clinically.

At the two sites analyzed (pole and stripe), monoclinic transformations were detected in all delta implants. The monoclinic phase for delta balls increased with test duration to 20% and 27% at the pole and stripe, respectively. The delta cups revealed only 15% monoclinic but likely this lower value was due to difficulties of laser access to inside of the intact cups. The wear debris for all combinations was similar in sizing, aspect ratio and circular shape factor at 0.5 and 1.1Mc durations. Particle size appeared to be just slightly larger for the hybrid delta combinations at 1.1Mc duration. Raman spectroscopy, surface roughness and debris studies are continuing.

Overall the ZTA ceramic combinations in microseparation simulator studies consistently showed lower wear than the alumina used as historical control. This was in contradistinction to ytrria-stabilized zirconia balls that showed increased wear compared to the control. Thus the wear performance of ZTA implants in the laboratory was quite different to zirconia implants and appeared superior to the alumina as the historical control. The superior strength and wear resistance of ZTA ceramics may become advantageous in sub-optimal clinical cases that may have had the risk of implant fracture or abnormally high wear.

Introduction

Development of Alumina-based Ceramics

Pure alumina ceramic has dominated the history of ceramic hip implants since the pioneering days of Drs. Boutin, Griss, Mittelmeier and Salzer [1]. Alumina's notable strengths lie in its exceptional inertness, stability, hardness and wear resistance. However it is also a brittle material and subject to a small but persistent history of fracture [2]. By today's standards the fracture risk would appear to be less than 0.01% and mainly associated with ball diameters 28mm and smaller [3].

The French ceramic-on-ceramic (COC) designs (Ceraver Inc, Roissy, France) were introduced by Boutin in 1970 and have been well documented by Sedel and colleagues [4]. The German ceramic designs made by Feldmuhle Inc (now CeramTec, Plochingen, Germany) were introduced by Mittelmeier in 1973 and now represent the most widely studied alumina total hip replacement (THR). Typical ceramic wear rates have been described as < 10µm in successful cases [5-7]. However a dichotomy of wear performance emerged with these pioneering COC designs. In retrieval studies, Plitz and Griss described a problem case of "Avalanche" wear with an alumina ball that had eroded 0.9 mm even although the socket was judged to be positioned correctly [8]. This case at 3 years follow-up showed massive destruction covering an area of 650 mm^2, which was almost two thirds of the ball's surface (Fig. 1).

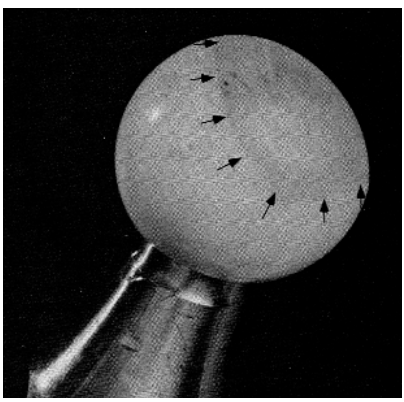

Figure 1:
Example of an 'Avalanche' wear case with an alumina ball retrieved at 3 years follow-up. The socket was judged to be positioned correctly [8]. The gross surface destruction covered almost two thirds of the ball (arrows) and represented linear wear of 0.9 mm.

Several other retrieval studies have referred to such complex 'high wear' cases (see review by Clarke et al [9]). For example, a retrieval study of 4 Mittelmeier THR described one case with ultra-low wear, amounting to only 10µm on ball and

65µm on cup (13 years use; female 72 years old, low-angle cup)[10]. In contrast their retrieval case with the highest linear wear revealed erosion of 325µm and 785µm in ball and cup, respectively (5 years use; female 42 years old, steep-angle cup). Thus these 2 cases revealed that 12-fold to 30-fold differences in wear could be found in such COC retrievals. We note here that these were all monoblock ceramic designs with sub-optimal fixation features.

One of the most complete COC retrieval studies incorporated 11 Ceraver cases from the 1977-1988 era and 11 Biolox® cases (Mittelmeier THR) from the 1980-96 era [11]. While the average wear was 355 um for the series, linear wear extended to an astounding 3 mm in one case (Fig. 1). The series wear-rate averaged 56µm/year with the 'mild' wear rates at < 12µm/year and the 'severe' cases at > 160µm/year for balls, with the cups averaging higher at 180µm/year. The latter values were comparable to the range found for the UHMWPE cups in use at that time [12]. All ceramic retrievals were the monoblock cup designs, well known for problematic loosening and abandoned in the early 1990's [1]. Thus six of the main risk factors appeared to be combinations of inferior alumina ceramic, monoblock ceramic cups, a steep cup angle (> 500 in 50% of cases), neck-socket impingement, inadequate fixation concepts and a migrating, tilting ceramic cup (77% of cases).

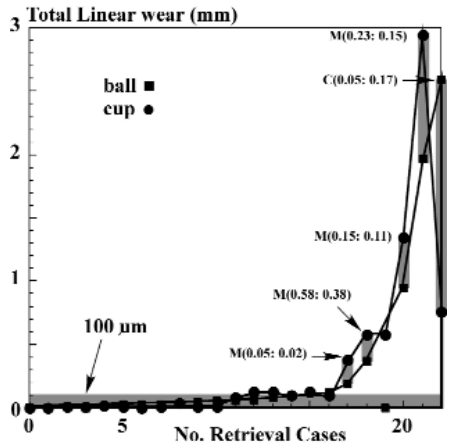

Figure 2:
Survey of linear wear (redrawn from data in Nevelos et al [10], ball-cup pairs and total linear wear indicated). Included were 11 retrievals each of Ceraver (C) and Mittelmeier (M) types of COC bearing. With linear wear magnitude ranked from left to right, the majority had undergone < 100µm erosion. However the 'severe' cases had wear-rates > 160µm/year for balls and 180µm/year or cups.

Thus in overview, while alumina ceramic has had a notable history spanning 36 years and the incidence of fracture has been quite rare, maybe as low as 1 in 25,000, continuing reports of catastrophic fractures have been disquieting to many surgeons. The 2nd observation was that not all ceramic cases produced low wear and when implant conditions were sub-standard, the resulting ceramic wear could be as high as any polyethylene cup [12]. These two limitations set the stage for alternative ceramic implants.

In 1985 zirconia ceramic was introduced as a high-strength alternative to alumina, In particular, the Prozyr™ balls (St. Gobain Desmarquest, France) dominated the market for zirconia total hip replacements, While Prozyr™ was used with considerable enthusiasm, a history of disquieting clinical reports showed a complex performance involving uncertain metastability under the hydrothermally challenging conditions found in vivo. Finally, late manufacturing changes and subsequent fracture problems resulted in Prozyr™ being taken off the market circa 2000-2001 [13].

In 2000, a mixed alumina-zirconia ceramic was introduced under the trade name Biolox® delta [14]. On the micro-structural level, the zirconia-toughened alumina (ZTA) contained Al_2O_3 (75 vol.%), ZrO_2 (24 vol.%) and mixed oxides (1 vol. % CrO_2 and SrO). Briefly, the salient features can be summarized as follows: (i) no porosity seen in the composite microstructure; (ii) the size of the alumina and zirconia grains was typically of the order < 1.0 and 0.3µm, respectively and (iii) a smaller fraction of platelet-shaped elongated grains of strontium hexaluminate were included in the microstructure with aspect ratio typically 3 to 6. This zirconia-toughened alumina (ZTA: Biolox® delta) showed strength and reliability characteristics that had the potential to double the strength of Biolox® forte implants (Table 1) while the ZTA hardness was offset slightly lower than that of pure alumina. Thus the composite ceramic offered considerable strength improvements for use in the very demanding applications of today's total hip replacements.

Property	Units	Biolox® forte	Biolox® delta	*Ratio
Flexural Strength	MPa	580	1150	x2.0
Weibull's Modulus	(reliability)	(5)	(13)	x2.6
Fracture toughness	$MPa.m^{0.5}$	4.3	8.5	x2.0
Ball 'burst' strength	KN	50-60	95-110	x1.9
Hardness	HV0.5, HV1	2300	1975	x0.9

Table 1:
Mechanical characteristics with Biolox® delta (28mm femoral balls) shown approximately double that of Biolox® forte [14].
*Ratio shows the advantage of Biolox® delta ceramic relative to Biolox® forte.

Retrieval and Laboratory Wear Analyses

The wear properties of alumina-zirconia composites was first reported by Kaddick and Pfaff using ring-on-flat specimen geometry [15]. This was followed by a hip simulator study with three ZTA (alumina 75%; zirconia 24%) ball and cup combinations. Overall wear to 10Mc duration averaged 0.03 mm^3/Mc with the delta cups contributing 60% [16]. This was a standard simulator study with no microseparation test mode thus these ZTA wear rates appeared similar to the standard alumina simulator studies [9].

A recent COC retrieval study re-focused our attention on the incidence of "stripe" wear in the pioneering monoblock cups [17]. This was followed by a simulator study using the microseparation test mode to produce stripe wear in the laboratory [18]. Later microseparation simulator studies pointed out that this test mode was essential to differentiate between ceramic materials exhibiting ultra-low wear rates [19,20]. In 'microseparation' test mode, the alumina COC bearing could produce average wear-rates of 1.84-2.2 mm^3/Mc compared to typical wear rate of 0.05 mm^3/Mc or even less with the standard test mode, i.e. MSX produced > 40-fold increase in wear! The average wear-rates for delta-delta and delta-forte combinations in the simulator study were 0.16 and 0.61 mm^3/Mc, respectively (Table 2). Compared to prior microseparation studies with Biolox® forte, the delta-forte THR reduced the wear by 3-fold and the delta-delta THR by 12-fold [21].

Key:
d-f = delta ball on forte cup
d-d = delta ball and cup,
*Ratio = higher wear of delta-forte compared to delta-delta combination
RI = run-in phase,
SS= steady state phase,
'Average' = overall wear rate (0-5Mc).

THR	RI (0-1Mc)	SS (1-5Mc)	'Average' (0-5Mc)
d-f	0.99	0.51	0.61
d-d	0.32	0.12	0.16
*Ratio	x3	x4.2	x3.8

Table 2:
THR wear-rates (mm^3/Mc) in microseparation simulator study using zirconia-toughened alumina (ZTA) balls with both alumina and ZTA cups [20].

Insley et al [19] studied two types of ZTA materials for aging and wear performance. The N-ZTA type had composition 25% zirconia with remainder alumina whereas the C-ZTA had 24% zirconia, 1% mixed oxides and remainder alumina. The XRD studies revealed that the N-ZTA contained only the tetragonal phase of zirconia whereas the C-ZTA contained up to 35% monoclinic phase. After aging of both ceramics by autoclave for 5 hours at 134ºC or 1 year's emersion in Ringer's solution, there was no further detectable change in phase content. The C-ZTA material showed the least wear, an approximately 2.5-fold reduction compared to alumina (Table 3).

Table 3:
THR wear-rates (mm^3/Mc) with 2 types of ZTA compared to alumina (Al) in microseparation simulator study [19].
*Ratio = higher wear of alumina relative to ZTA.

THR	Wear-rate	*Ratio
Al-Al	2.25	ref
N-ZTA	1.7	x1.3
C-ZTA	0.9	x2.5

Thus while the standard simulator studies of ZTA ceramics showed no difference when compared to alumina, the microseparation simulator studies clearly showed that ZTA materials offered a 2 to 12-fold wear reduction under this more severe test mode (Tables 2, 3). There was also the consideration of the zirconia phases in the ZTA composites, given the generally unsatisfactory clinical performance of femoral balls made from pure ytrria-stabilized zirconia. In particular one simulator study reported up to 35% monoclinic in ZTA ceramic [19]. In addition, up to this point the simulator studies had involved either 28mm or 32mm diameter ZTA balls [16,19,20]. However the driving force in orthopedics today is use of larger ball diameters ad can readily be seen in this 11th Annual Bioceramics Symposium. Thus for our study, we investigated the behavior of Biolox® delta (d) and Biolox® forte (f) combinations using the 36mm ball diameter. The relative wear performance of four ceramic THR combinations (ball-cup: dd, df, fd, ff) was studied to five million cycles duration using our 'severe' microseparation test mode. Our analytical methods included wear data, roughness measurements, SEM, XRD, confocal Raman microscopy and debris analysis.

Methods

The 36mm diameter ceramic balls and cups of alumina (Biolox® forte) and zirconia-toughened alumina (Biolox® delta) were provided by CeramTec AG

(Plochingen, Germany) with pairings matched to average 70 µm diametral clearance with no outliers greater than +8 µm from the mean (Table 4). These were tested anatomically in a 12-station orbital hip simulator (Shore Western Manufacturing, Monrovia, California) customized for micro-separation with 23° biaxial oscillation (Fig. 3a and Table 5: MSX cup angle 50° to horizontal). Maximum displacement was achieved during the unloaded swing-phase of normal walking and maximum dynamic loading in the Paul curve was 2.0kN at a gait frequency of 1.0Hz. The lubricant was alpha-calf serum (Hyclone®, Ogden, Utah) diluted to a protein concentration of 10mg/ml. The serum test volume was 300ml, replaced at every event and stored frozen for later debris analysis. EDTA was added to reduce calcium films and/or precipitates (20ml of EDTA per liter of serum). Adding distilled, filtered water compensated for serum evaporation.

THR	ff	fd	df	dd
1	69	71	70	73
2	68	74	78	67
3	70	66	68	76
Average	69	70	72	72

Table 4:
Summary of diametral clearances for the four sets of ceramic THR (N=3 each) run in this microseparation study.

Simulator	Leeds Mk II	SWM-orbital
Ball diameter	28mm	36mm
Biolox® forte (ff)	0	N=3
Biolox® delta (dd)	N=3	N=3
Biolox® combi (df)	N=3	N=3
Biolox® combi (fd)	0	N=3
Simulator type	Leeds Mk II	SWM
Microseparation	200-500 µm	500-1500 µm
Test stations (#)	(6)	(12)
Peak load	NA	2kN
Cup inclination	45°	50°
Flexion arc	45°	46° (*orbital)
Rotation arc	20°	46° (*orbital)
Lubricant	Bovine serum	Alpha-calf serum
Dilution	25%	10%
Proteins	15.5 mg/ml	10 mg/ml
Data intervals		100,000 cycles RI
and serum replenished	330,000 cycles	500,000 cycles SS
Test duration	5 million cycles	5 million cycles

Table 5:
Comparison of microseparation test modes from Leeds University[20] and Loma Linda University [30].
- Simulator with cam orbiting about an axis of ±23°.
- NA = not available in paper
- RI = run-in wear phase
- SS = steady-state wear phase

After cleaning and weighing, balls were marked with degree locations from the pole (0°) to the equator (90°) to compare growth of stripe wear at each event (Fig. 3b). Ink was used as a surface stain for purposes of wear identification.

This method consistently revealed surface disruption in the stripe regions. However the less worn polar and transition areas did not retain any of the dye. The inked areas were inspected at every event and recorded by digital-photography. The polar and transition wear regions in combination with stripe wear (Fig. 3b) were then studied by reflected light microscopy and scanning electron microscopy (Phillips LV-FEG SEM). Wear trends were quantified by linear regression. Run-in wear was assessed with 10-wear events between 0 and 1Mc duration and steady-state with 10-wear events between 1 and 5Mc duration. The definition of 'Average' wear rates from 0 to 5Mc duration were used as a simple index to compare published simulator wear-rates and clinical wear [20-22].

Figure 3a:
Schematic of femoral ball showing major sites used to measure and compare data from the roughness, Raman spectroscopy, XRD, RLM and SEM studies.

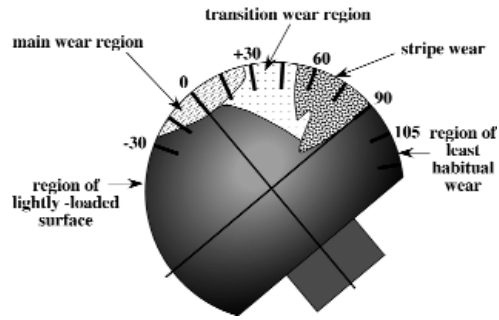

Figure 3b:
Delta ball in microseparation test mode distracting from a delta liner inclined at 50° to the horizontal in hip simulator.

The delta implants were assessed (Fig. 4) for monoclinic content using confocal Raman Spectroscopy (1.1Mc and 5.0Mc) and by X-ray diffraction (3.0Mc). With the Raman method, the optical microscope and video monitor enabled mapping of the zirconia balls and a computer-controlled stage provided high-precision displacements along both x and y-axes. Raman spectra were collected with a triple monochromatic spectrometer (T-64000, ISA Jovin-Ivon/Horiba Group, Tokyo, Japan) equipped with a charge-coupled detector (high-resolution CCD camera). Details of the calibration procedures have been reported elsewhere [23]. Ball measurements were taken at the pole (0°) and through the scar sites, typically 65-90° relative to the pole (Fig. 3b). Cup measurements were taken at the pole (0°) and the equatorial scar site adjacent to cup bevel, typically in the middle of the scar area.

The serum solutions containing the wear debris were digested in hydrochloric acid, diluted with alcohol, and centrifuged. Additional washings were performed with acetic acid and alcohol. The resulting purified debris was extracted using polycarbonate filters and studied by SEM [24].

HE175 Analysis techniques		
T_	Reflected-light microscopy stripe wear	(attempted)
T1	Weight-loss wear rates	every event
T2	Digital photography stripe wear	every event
T3	Raman spectroscopy phase transformation	1.1, 5Mc
T4	X-ray diffraction phase transformation	1.1, 3, 5Mc
T5	SEM wear scars	5Mc
T6	Profiling Surface roughness	1.1, 5Mc
T7	Profiling diametral clearance	5Mc

Figure 4:
Summary of analytical techniques used in this study of Biolox® forte and Biolox® delta implants.

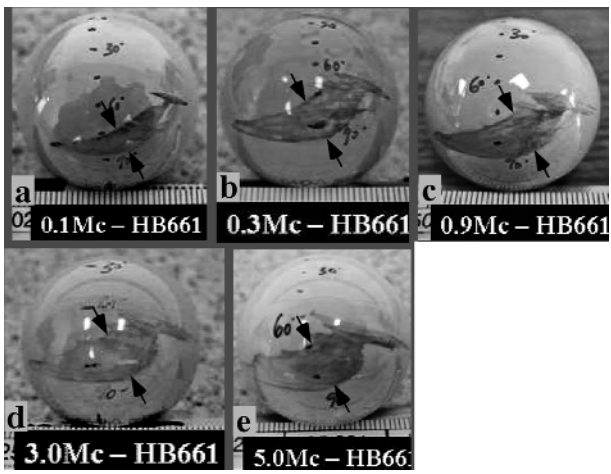

Figure 5a-e:
Appearance of narrow stripe on delta balls (df-combination) growing broader in longitudinal direction (arrowed) as test extended from 0.1 to 5Mc duration. Noted that initially two distinct stripe markings corresponded to heel-strike and toe-off kinetics in the simulator. Here the staining with ink aided visualization of stripe wear whereas main-wear and transition regions did not retain the dye.

Results

The microseparation test mode provided stripe wear phenomenon on all delta and forte combinations within 100,000 cycles on both balls and cups (Fig. 6). For the balls, two well defined, stripe regions developed, the thin inferior stripe having a 75-90° location relative to the pole and an emerging thin, superior stripe locating slightly higher on the ball dome, approximately 45-60° location. The stripes initiated narrower at the 45° site and broader at the 75-90° site. These stripes elongated over the course of the study (0.9 to 5.0Mc) and coalesced to form a broad stripe spanning a 45-90° arc. Final scar areas for the stripe wear on ff-balls ranged from 150 to 350 mm^2 whereas the delta stripes had noticeably smaller areas.

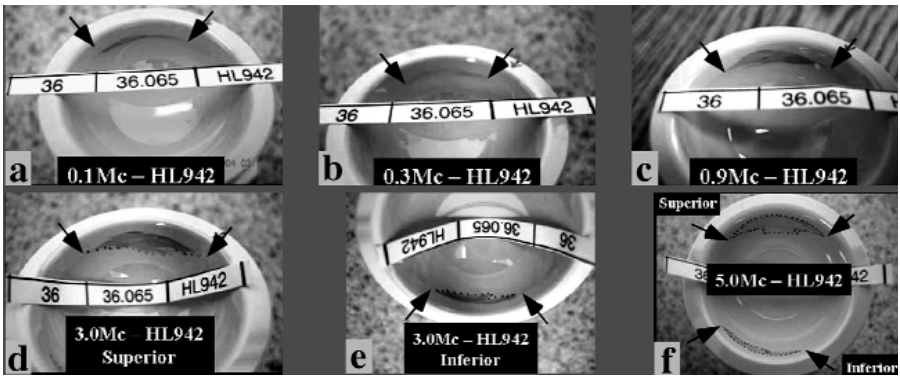

Figure 6a-f:
Appearance of superior narrow stripe on delta cups (fd-combination) growing broader in longitudinal direction (arrowed) and extending circumferentially as test continued from 0.1 to 5Mc duration. An inferior cup stripe appeared by 3Mc duration (Fig. e).

For the ff and dd cups, the narrow stripe began with an approximately 10-20° circumferential wear arc along the superior cup rim (Fig. 6). With the hybrid fd and df cups, it was double that size (20-50° arc) and the stripes gradually expanded along the circumference of the cup between 0.9 and 5.0Mc duration. The ff combination showed the greatest stripe expansion to a maximum of 150° rim arc and was seen also to expand radially into the cup's main-wear zone. With fd and dd cup combinations, an additional stripe formed on the inferior rim of the cup at 3.0Mc duration (Figs. 6e, f). This was a narrow, well-defined stripe that expanded circumferentially along the rim as the duration increased. Additional visual observations were that a) no corresponding inferior stripes were noted on the balls and b) inferior stripes were not seen on any forte cups.

Wear rates for all COC combinations were very low even under our 'severe' microseparation test condition. The highest wear rates in this study occurred during the run-in phase, the THR combinations ff, df, fd and dd averaging 4.9, 0.97, 0.89 and 0.47 mm^3/Mc, respectively. Over 1 to 5Mc duration, the steady-state wear rates averaged 1.07, 0.51, 0.49 and 0.23 mm^3/Mc, respectively. Our ff pairings demonstrated 'Average' wear rate of 1.5 mm^3/Mc (Fig. 7). The run-in, steady state and 'average' wear-rates consistently showed that the ff pairs had the highest THR wear rates and the dd pairs the lowest. Thus the run-in, steady-state and overall 'Average' wear rankings were as follows:

$$ff >> df \geq fd > dd$$

Under our microseparation test condition, the 'Average' wear rates for our fd and df hybrid pairings approximated > 3-fold reduction compared to the historical control (Fig. 7). The 'Average' for our dd pairing was > 6-fold lower than the control and 2-fold lower than the hybrids fd and df. It was also interesting that whether in ball or cup, the delta ceramic implant wore preferentially higher than its mating forte implant in each hybrid pairing.

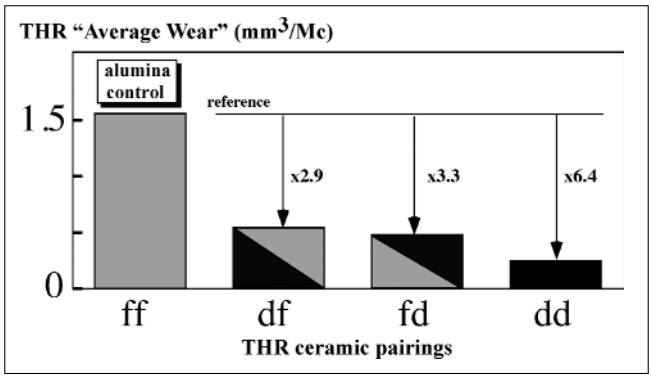

Figure 7: Volumetric wear rates for 36mm diameter forte (f; gray color) and delta (d; black color) implants at 5 Mc duration. Relative to the alumina control, the delta hybrid combinations averaged 3-fold wear reduction and the all-delta averaged 6-fold wear reduction.

Phase transformations from zirconia tetragonal to monoclinic were detected in all delta implants (two sites analyzed = pole, stripe). The monoclinic phase for delta balls was always greater at the stripe region than at the polar region (Fig. 8) and increased with time. For delta balls there was a 56% increase in polar monoclinic between 1 and 5Mc duration and a 20% increase in monoclinic in the stripe regions over same duration. Thus the polar monoclinic represented only 54% of that in the stripe region at 1Mc duration but almost 80% by the 5Mc duration. We also noted that the delta cup transformation trends were slightly lower with less distinct trending. This may have represented the technical difficulties of imaging these intact hemispherical cups.

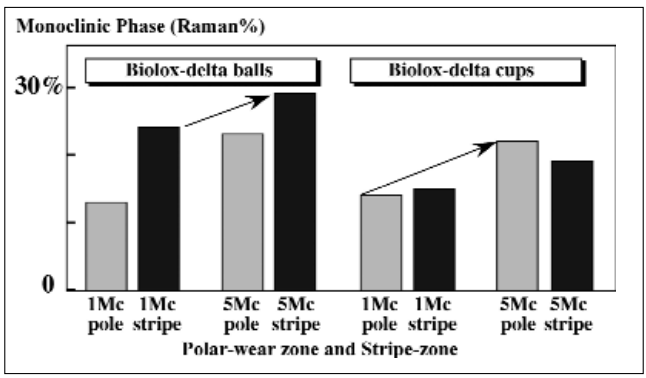

Figure 8: Percentage of monoclinic phase detected in zirconia grains by confocal Ramam spectroscopy in delta balls and cups. Comparisons shown for main wear zone (at pole) and stripe wear (near equator) after 1.1 and 5 Mc test duration. Trend (arrowed) at pole and stripe wear was for monoclinic increasing with test duration.

Wear mapping by SEM demonstrated increased wear damage from the polar region down into the stripe wear zone (Fig. 3b). Transiting across the polar region (-60° to +30°) revealed lightly polished surfaces with the main feature being the smaller zirconia grains (Figs. 9a, b) with a few scratches evident and occasional small pits. Approaching 30° in the transition region, the surfaces became quite smooth and pits became more common (Fig. 9c). In the stripe regions there were many pits of larger size and now the shape of alumina grains became delineated in the remaining smooth areas of the surface (Figs. 9d, e). At the equator and beyond, the surfaces became less disrupted signifying a milder form of wear (Fig. 9f). Maximum roughness measured at 1Mc duration was < 40μm and these studies are continuing.

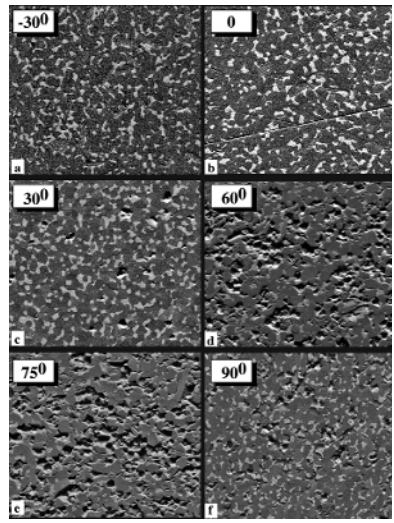

Figure 9a-f:
SEM mapping (all x5,000 original magnification) of progression of surface roughness from lightly worn surface (-30°) across the pole (0°) into the transition zone (30°) and down to the stripe wear region (60°) encroaching onto the equatorial region (90°) as follows:
a) zirconia (light crystals) visualized in darker alumina matrix in lightly loaded region at –30° site (Fig. 3) with no porosity evident.
b) At polar region with a few scratches visible and no porosity.
c) At +30° site (Fig. 3) scratches polished out and some porosity now evident due to erosion of smaller zirconia crystals.
d) At +60° considerable surface porosity evident in middle of stripe region.
e) At +75° considerable surface porosity in stripe region.
f) At +90° reduced surface porosity having left the stripe wear.

The ceramic debris characterized at 0.5 and 1.1Mc varied from very small globular polygonal shape to large sharp-edged fragments that had been chipped off the surface by the violence of the micro-separation test mode (Fig. 10). Thus the large angular fragments were probably created by the impact of edge loading during the microseparation mode and the small globular debris likely produced in the main and transitional wear zones. During the run-in wear phase (0.5Mc duration), comparison of average equivalent circular diameter (ECD) between pairs (Fig. 11) revealed the following:

1. Overall, the pairings ff, dd and df were similar
2. THR fd ECD was 2.5-fold greater than other THRs during run-in.
3. In detailed comparison, ff < (dd, df) < fd

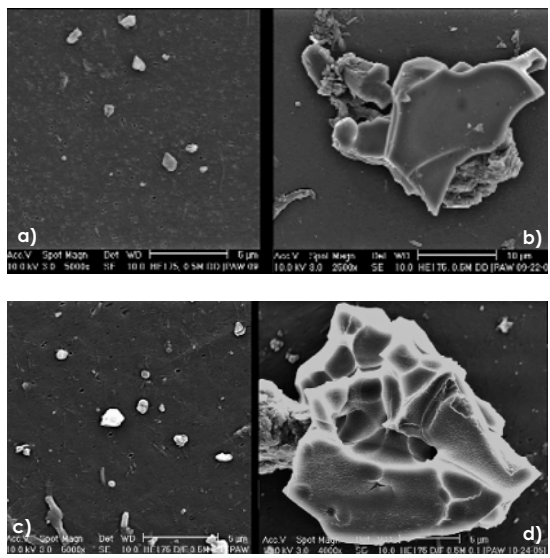

Figure 10a-d:
Purified and filtered debris from delta-delta (dd) study at 0.5Mc of run-in wear phase.
a) Debris from dd simulation, small polygonal and globular particles, appearance was representative of all dd and ff combinations. EDXA labeled the particles as 'alumina' i.e. no zirconia identification.
b) A larger, sharp-edged fragment from dd simulation. EDXA labeled this as 'alumina' with no zirconia identification.
c) Debris from df combination, appearance was representative of all hybrid combination. EDXA labeled this as 'alumina' with no zirconia identification.
d) Larger sharp-edged fragment from the df combination, with some alumina grains outlined within the structure. EDXA labeled this as 'alumina'.

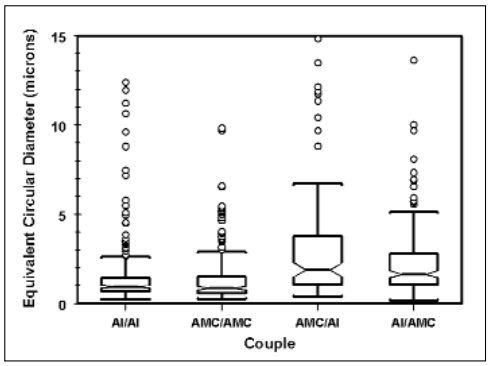

Figure 11:
Box plot of equivalent circle diameter (ECD) comparisons of debris collected from serum at 1.1Mc duration.

There was no difference in aspect ratio and circular shape factors (CSF) parameters across the combinations analyzed and over the two events (Tables 6, 7). Into the steady-state wear phase (1.1Mc) the equivalent circle diameter (ECD) data indicated the following trends:

1. ff = dd
2. (df, fd) > (ff, dd)

Thus wear debris for all combinations was similar after 0.5 and 1.1Mc durations. Particle sizes appeared slightly higher for the hybrid delta combinations at 1.1Mc duration. Overall the delta material showed a wider distribution but the mean values were not that different. The wear debris morphology is still under investigation.

Parameter	dd	ff	df	fd
# of particles	260	592	307	239
ECD	1.24 ± 1.72 [0.76]	0.79 ± 1.11 [0.49]	1.57 ± 3.35 [0.75]	4.29 ± 4.07 [2.98]
Aspect Ratio	1.61 ± 0.44 [1.51]	1.56 ± 0.38 [1.50]	1.56 ± 0.43 [1.45]	1.69 ± 0.58 [1.58]
CSF	0.79 ± 0.10 [0.80]	0.79 ± 0.09 [0.80]	0.77 ± 0.10 [0.78]	0.74 ± 0.11 [0.76]

Table 6:
Descriptive statistics for wear debris the four groups at 0.5Mc. Shown are the mean ± std. and [median].

Parameter	dd	ff	df	fd
# of particles	216	236	122	185
ECD	1.43 ± 1.51 [0.87]	1.51 ± 1.87 [0.95]	3.35 ± 3.91 [1.89]	2.69 ± 3.81 [1.65]
Aspect Ratio	1.58 ± 0.39 [1.50]	1.59 ± 0.44 [1.51]	1.60 ± 0.40 [1.47]	1.62 ± 0.45 [1.52]
CSF	0.77 ± 0.08 [0.78]	0.77 ± 0.09 [0.78]	0.77 ± 0.09 [0.79]	0.77 ± 0.09 [0.77]

Table 7:
Descriptive statistics for the four groups at 1.1Mc. Shown are the mean ± std. and [median].

Discussion

The phenomenon of 'stripe' wear has been recognized on both ceramic femoral balls and acetabular cups since the early 1970's [8]. Such stripe wear was seen visually, generally as a less-polished, lunar shape on the femoral ball and a circumferential stripe adjacent to the cup bevel. Stripe wear has been attributed to many phenomena including poor quality ceramics, negative clearance between ball and cup, vertically inclined or migrating/tilting cups and recently as a result of cup rim-wear while flexed at 90° [22]. Clarke et al [25] suggested that this was also likely to be partly the natural consequence of using a rigid cup material as opposed to the much more flexible polyethylene, i.e. a stress concentration effect created by the rim of CoCr and alumina cups.

Our microseparation mode clearly demonstrated the stripe wear phenomenon at the first measurement interval of the run-in phase (100,000 cycles). The appearance of narrow stripes appeared comparable to prior microseparation simulator studies and also short-term ceramic retrieval studies. On the balls, there were generally 2 well-defined narrow stripes initiated, basically corresponding to the two impact effects of the Paul gait cycle, i.e. heel-strike and toe-off. For dd and df combinations, an additional inferior stripe became visible at 3.0Mc duration. Such stripe effects appeared very similar to other descriptions in microseparation simulator studies and short-term retrieval studies [17,20,22]. Also the gradual expansion of stripe wear with test duration fitted with the larger stripe areas seen in our ceramic retrievals at 15 to 22 years of follow-up [26].

We noted also that simulator wear rates were very low for all Biolox® combinations, even under our severe microseparation test conditions. Our ff pairings demonstrated an 'Average' wear rate of 1.5 mm^3/Mc. Clinical wear rates have been reported for contemporary alumina retrievals to be in the range 0.1 to 3.6 mm^3/year [22]. Clearly our simulator data were mid-clinical range. Previous microseparation, simulator studies of ZTA ceramics showed 'Average' wear- rates (at 5Mc duration) of 0.16 and 0.61 mm^3/Mc for dd and df combinations, respectively [20] and 0.4 mm^3/Mc for a 'ZTA/forte' combination [19]. Our 'Average' wear rates were similar at 0.24 and 0.5 mm^3/Mc for dd and df combinations, respectively. Comparing this study with 36mm diameter ceramic balls and two prior microseparation COC studies with 28mm diameters, there was little discernable difference in wear rates. Thus the effects of the larger balls if present will likely be of little clinical significance. Previous microseparation simulator studies also noted that wear with a forte ball and cup created 2.5 to 3-fold more wear than with a ZTA ball and forte cup (Fig. 10) [19,20]. In the present study with four combinations run simultaneously in our simulator, we noted that wear with a forte ball and cup averaged 2.9, 3.3 and 6-fold more than our df, fd and dd combinations, respectively. Therefore these microseparation studies appear to show excellent agreement with each other and also fitted the known clinical performance of COC alumina THR. Thus the wear of 36mm ball diameters in our study appeared quite comparable to that in prior microseparation studies with the 28mm diameter ball. It was also interesting that the delta ceramic wore preferentially over the forte ceramic in the hybrid pairings (df, fd). This may reflect on the hardness of alumina being a more protective mechanism when bearing on a ZTA implant of slightly reduced hardness (Table 1).

The increased monoclinic content from 1 to 5Mc duration was an expected trend. This is the well-known, transformation-toughening phenomenon of the

tetragonal zirconia crystal. With zirconia grains exposed to both hydrothermal stress and abrasive wear on the articular surface, it was expected that the monoclinic phase would increase with time. For the delta balls, the monoclinic averaged 20% and 27% at the pole and stripe, respectively, perhaps in line with the 35% monoclinic reported previously in ZTA studies [19]. However the zirconia-toughened alumina is a very different ceramic from the yttria-stabilized zirconia that was abandoned circa 2001 [13]. A good example of this difference in ceramic behaviour can be seen in a microseparation simulator study comparing effects of femoral balls of alumina, zirconia and ZTA running with Biolox® forte cups (Fig. 12) [19]. With zirconia balls, the wear rates increased 2.5-fold above the control alumina combination; with ZTA balls the wear rates decreased 3-fold below the control alumina combination. These very different trends supported the ZTA combination as the superior ceramic.

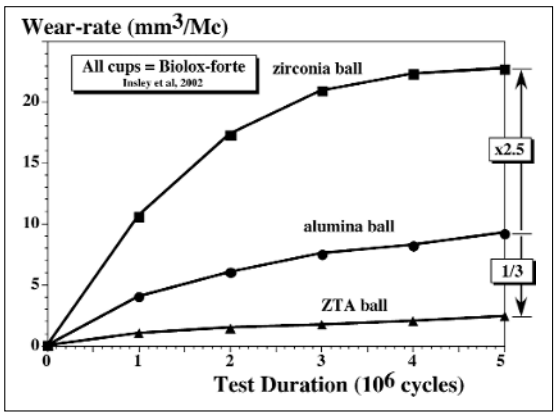

Figure 12:
Comparison for wear trending in microseparation test mode with varied types of ceramic balls running on Biolox® forte cups (redrawn from Insley [19]).

Prior simulator studies in 'standard' mode produced alumina wear rates of 0.004-0.05 mm^3/Mc [16,31]. In contrast the microseparation test mode produced alumina wear-rates averaging 2 mm^3/Mc. Thus the 'microseparation' mode appeared quite 'severe' in that it produced wear rates elevated > 40 times compared to the 'standard' simulator wear methods. The size and shape of the larger debris fragments in our study also illustrated that a very severe damage mechanism was operating. Such a test mode appeared beneficial to us since we have had concerns regarding the serum lubricant being unphysiologically protective of metal and ceramic bearing surfaces in simulator studies [27-29]. The repeated impact of a ceramic cup rim onto a femoral ball during the microseparation mode clearly obviates any concerns we would have about 'protective biofilm' effects. Therefore the MSX mode may represent a more realistic wear test to differentiate between different ceramic materials.

The impact 'violence' and greatly increased wear rates of the microseparation test mode may have aided our understanding of the gross wear reported in some retrieval cases (Fig. 2). The implications of a mobile ceramic cup impacting onto the femoral ball during gait activities clearly could dramatically affect the alumina wear-rates in-vivo. At the present time, all such reports of 'Avalanche' wear have come from retrieval studies of the pioneering cups, which were notorious for loosening, migrating and tilting. With the advent of the superior metal-backed, ceramic cups in 1989, it is possible that the risk of 'Avalanche' wear with alumina has been avoided? However in this regard it

would appear that the ZTA ceramic offers superior protection to adverse stripe wear seen with alumina implants.

Thus in overview, the ZTA ceramic provides a doubling of the strength properties over pure alumina due to its unique 'zirconia-toughening' mechanism. The consequence of the zirconia content is that the hydrothermal stressing of the zirconia grains exposed at the articular surface will result in their transformation to monoclinic and erosion from the surface. Thus the main articulating surface will be the surrounding alumina matrix. However internally, the ZTA ceramic still retains its superior strength characteristics. So overall it would appear that the hard alumina phase will continue to provide the ideal bearing surface while the zirconia phase will contribute to increased strength and toughness internally.

Conclusions

1. Our microseparation wear study with the alumina THR (Biolox® forte; 36mm dia.) produced wear rates that were of the order 1-2 mm^3/Mc. This was 20 to 40 fold higher than in the standard simulator test mode (0.05 mm^3/Mc).
2. Our microseparation simulation study generated stripe wear on all ceramic components (Biolox® forte, Biolox® delta). This was characterized by a narrow stripe on the ball that expanded with test duration. The corresponding cup stripe was on the superior rim adjacent to the bevel. Such stripe wear produced roughness less than 40µm at 1Mc duration. These findings were comparable to other simulator and retrieval studies of alumina and ZTA implants.
3. The new ceramic Biolox® delta consistently produced wear-rates that were 3 to 6 fold lower than the control alumina THR (Biolox® forte) during run-in, steady-state and overall-average trends. This was a much superior performance compared to zirconia balls that revealed wear higher than the control alumina in the same type of microseparation test.
4. Transformation of the zirconia grains was detected in all Biolox® delta implants and increased with test duration. Monoclinic transformation was highest (27%) at the stripe wear sites on the delta balls due to the severity of the microseparation wear process.
5. Monoclinic phase transformations were least in the delta liners (15%), likely due to the difficulties of imaging the concave surfaces of intact cups.
6. The wear debris for all Biolox® forte and Biolox® delta combinations was similar in aspect ratio and circular shape factor at 0.5 and 1.1Mc durations. Particle size (ECD) appeared slightly higher for the hybrid delta combinations at 1.1Mc duration.
7. Our results with 36mm THR (Biolox® forte, Biolox® delta) appeared very similar to data from previous microseparation wear studies and retrieval studies (28mm THR). Thus we did not detect any performance difference between 28mm and 36mm ball diameters.

Acknowledgements

We are grateful to Moran Innovations (Yuciapa, CA) and Shore Western Manufacturing (Monrovia CA) for the microseparation fixtures. The ceramic implants and financial support for this study were provided by CeramTec Inc.

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6.5 Comparison of polythene liners with alumina liners in hydroxyapatite hip arthroplasty

J. M. Buchanan

Introduction and Aims

Wear debris contributes to the development of granulomatous debris disease and loosening.

This is a comparison between polythene liners and alumina liners in Hydroxyapatite Hip Arthroplasty (HA). Cemented implants used in hip arthroplasty often loosen after ten or more years of use. This is partly mechanical but also associated with debris disease. Wear particles from the bearing surface and also from the cement bone interface are forced into the periprosthetic membrane. Particulate plastic is taken up by macrophages creating an aggressive granulation tissue which destroys the bone; debris disease. If loosening is to be reduced the production of plastic debris should be eliminated Fixation has to be secure, preferably without cement. A physiological and mechanical seal between the implant and the bone would be ideal to prevent the formation of a periprosthetic membrane into which any debris might be forced. Will HA bonding achieve this goal?

Furlong prostheses which are fully coated with HA have been shown to achieve this. This has been demonstrated by several authors with a maximum follow up of nearly 20 years and with minimal evidence of aseptic loosening [1,2, 3,4,12].

Devane[6] compared polythene wear in metal backed acetabula. Patients were in two groups, cemented and uncemented. Polythene wear was seen in both groups but was greater in the uncemented hips.

Røkkum[13] described excessive polythene wear and osteolysis requiring revision in eighteen hips from a series of 100 HA coated hips. Six more similar operations were planned.

Yoon[17] studied 96 hips with ceramic/ceramic bearings with mean follow up of ninety two months and found femoral osteolysis in 22%. Half of these were expansile lesions in Gruens zones 1 and 7 [10]. Histology and scanning electron microscopy showed ceramic debris in macrophages. The average size of the particles was 0.71µ. They concluded that ceramic wear particles could stimulate a foreign body response and cause periprosthetic osteolysis.

Sedel[14] has a long term experience with alumina/alumina couples with very few failures.

Volumetric reduction of wear debris should reduce the incidence of debris disease. Different bearing couples are used in hip arthroplasty Early surgery used metal on metal. Later implants pioneered by Charnley[5] used metal on polythene. However, the metal was abrasive and caused wear on the polythene. Alternative bearing surfaces have been introduced over the years in an attempt to reduce wear with ceramic on polythene, ceramic on ceramic and metal on metal.

Greenwald and Garino[9] demonstrated considerable reduction in wear particularly with alumina/alumina bearings.

Method

This study is purely clinical study, comparing the results of alumina on polythene with alumina on alumina. This is not randomised. Patients are selected for alumina liners if life expectancy is 20 years or more. Patient's weight or life style is not considered.

Since May, 1988 patients have been treated with a fully coated Furlong Hydroxyapatite ceramic coated (HAC) prosthesis. Some 2399 hips have been inserted with 1899 ultra high molecular weight polythene liners and 500 alumina liners. All the hips had Biolox Forte heads. Patients are assessed pre-operatively and post-operatively at three months, six months and a year. They are then assessed annually using the Harris Hip Score (HHS) [11] and plain X-rays with a maximum follow up of 18 years.

Where possible post-mortem histology is carried out (Professor Archie Malcolm [4]). Undecalcified sections of the implants are examined. They show bony osseo-integration within the first three months. Specimens at seven and eight years after implantation show that much of the Hydroxyapatite has been replaced with bone but with no intervening fibrous tissue.

Results

Since 1988 2399 hips have been inserted into 1,769 patients. There are 703 men and 1066 women in the series. The age range varies from 18 to 93 with a mean age of 61.9 years.

Pre-operative Harris Hip Scores are shown in Table 1 and demonstrate that the patients were experiencing significant symptoms pre-operatively.

Harris Hip Score	< 10	10+	20+	30+	40+	50+	60+	70+
Number of hips	355	466	709	450	199	75	21	16

Table 1:
Pre-operative Harris Hip Score.

The post-operative Harris Hip Scores demonstrate that the majority of patients have done well following their surgery. However, medical and other joint problems may reduce the Harris Hip Score because overall function is not good although the hips are working well. See Table 2.

Harris Hip Score	< 40	40+	50+	60+	70+	80+	90+
Number of hips	88	28	60	206	538	527	779

Table 2:
Post-operative Harris Hip Score.

Follow up periods are shown in Table 3.

Table 3:
Follow-up Period.

Years	< 1-4	5-9	10-17
Number of hips	1223	714	362

There are 920 patients/hips with Harris Hip Scores of less than 80. Medical and other musculo-skeletal problems may affect general function and will lower the HHS despite a well functioning hip.

Patients with problems, particularly relating to their HA hip arthroplasty, represent a relatively small number. Aseptic loosening has been seen in 11 components (six acetabular cups and five femoral stems). There have been three fractured ceramic liners and four fractured ceramic heads. Four patients have had periprosthetic fractures around the femoral stem. Six patients have deep infections. Seven acetabula have been revised for malpositioning causing repeated dislocation. These 35 revised cases represent 1.45% of the 2399 hips.

Serious problems associated with acetabular liners are few in number and do not affect the overall HHS assessment

HHS confirms that the HAC hip surgery is successful with a failure rate of 1.2%

In the polythene group there are 93 hips where there is obvious eccentricity of the head in the acetabulum. The polythene must be wearing but X-rays have not shown any significant osteolysis yet.

Some patients exhibit a small scallop in the calcar beside the femoral stem but they have no complaints.

Revision of worn liners has been performed in five hips when X-rays suggested that the plastic was getting dangerously thin. None of these patients had any symptoms.

One patient completely destroyed the polythene liner damaging the titanium shell The whole acetabulum had to be revised. A second patient had loosening of the acetabulum associated with some osteolysis and at operation there was also osteolysis around the top of the femoral component although it was still stable and bonded to the femur. This case represents the only patient with osteolysis and loosening associated with polythene wear.

Osteolysis was found in the posterior calcar region in one other hip.

In the alumina group there has been no obvious wear and no osteolysis. However 3 ceramic liners have broken. These were noted where weight had been taken on an unsupported ceramic lip.

The surface finish of the Biolox Forte heads is extremely smooth with surface roughness of Ra=0.05µm. Wear of the polythene will be related to the surface toughness of the material and to the possible, or probable, inclusion of third bodies

Discussion and Conclusions

Hydroxyapatite

HAC hip surgery appears to be a successful procedure when assessed clinically [2,3,4]. Patients in general seem to recover quickly from the procedure and regain normal activities within a period of several weeks. Many of these patients return to labouring jobs and many of them are active playing racquet sports and golf.

Osseo-integration of Hydroxyapatite coated implants to the host bone secures the implants. Bony bonding secures the implant bur also creates a seal around the prosthesis which prevents the ingress of any particulate material into the bony periprosthetic tissues. In HA arthroplasty, there is no fibrous membrane. The Hydroxyapatite will be substituted by a process of osteoclastic and osteoblastic activity. However, the bone substituting the HA is laid down against the metal with no intervening fibrous tissue leading to a Perfect Fit [4]. In consequence aseptic loosening is rare and has been seen in only 11 components in this series of 2399 hips using 4798 individual components

In this 18 year series there are 362 hips that have been followed up for more than 10 years with good results. Patients who have required revisional procedures are not particularly those that have been in the series for a long time.

Polythene Liners

In the polythene group (1899 hips) problems of polyethylene wear are reduced by using an alumina femoral head which is less abrasive than a metal head [13]. However, wear has been seen in 93 hips with obvious eccentricity of the head in the plastic liner. It is probable that very many more have some wear. Only two hips have had associated osteolysis both of which have been revised. Only one of these had loosening of the acetabulum.

At operation, insertion of a hooded polythene liner is relatively simple and minor degrees of mal-orientation can be controlled by turning the hood to a better stabilising position.

When the whole acetabulum is made of plastic, wear is not a mechanical problem but can cause debris disease. Polythene liners are relatively thin especially in the smaller sizes and a thin plastic liner might wear out completely and catastrophically.

Wear of a polythene liner, even with a ceramic head, must progress and significant wear has been observed after 10 years.

Alumina Liners

Inserting an un-hooded ceramic liner is more demanding. There is no hood to prevent dislocation and the whole acetabulum has to be accurately orientated. If there is a problem the ceramic liner can only be removed by smashing it.

Patients with a life expectancy of more than 20 years require alternative bearings which will not cause osteolysis from their wear products. In this series alumina on alumina has been used (500 hips). No osteolysis has been seen but there have been failures of three ceramic liners. Alumina liners have not been seen to wear on plain X-ray examination [7,16]. Stripe wear has been seen when revising a head and acetabulum for dislocation. This is probably related to poor orientation of the cup with the head load bearing on the rim. It is probable that additionally there is cyclical loading and unloading as the head lifts off during the swing phase of walking.

Literature suggests that alumina wear debris can cause osteolysis [17] but this has not been encountered in this series.

Conclusion

Alumina/alumina bearings will give good service for a long time and that they should be used for patients with a life expectancy of more than 20 years. With further follow-up it may become evident that more ceramic/polythene couples

are failing in which case the threshold for routinely using ceramic/ceramic couples may be changed to patients with a life expectancy of 25 years or more. Alumina on polythene will ultimately wear out but, if the patient's life expectancy is limited, use of this couple would be justified on grounds of easier surgery and cost.

There is a small risk of fracture with alumina/alumina which has to be balanced against a much greater risk of progressive wear in the ceramic/polythene couple. The newer Biolox Delta material should further reduce the incidence of ceramic component failure.

HA fixation works.
Ceramic heads and polythene liners are satisfactory for short to mid-term use.
Ceramic heads and ceramic liners should give satisfactory long term results.
Long term follow up on these cohorts of patients is essential.

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6.6 Edge Loading and Squeaking in Third Generation Ceramic-on-ceramic Bearings

W. L. Walter, W. K. Walter and M. A. Tuke

Alumina ceramic-on-ceramic bearings perform exceptionally well under standard hip simulator conditions but in vivo some retrieved bearings have shown an unusual pattern of wear. Stripe wear is the term used to describe the long, narrow area of damage seen on some femoral heads retrieved from alumina ceramic-on-ceramic hip bearing couples (Fig.1). This unusual shape is the result of line contact between the head and the edge of the liner. Stripe wear has been reported in first and second-generation alumina bearings and has been associated with steep cup angles, young patients, and revision surgery [1].

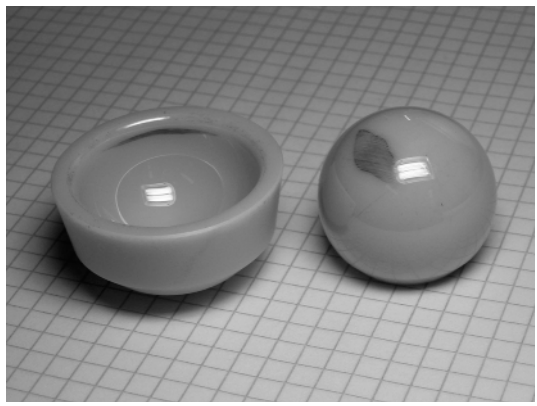

Figure 1:
This 3rd generation alumina ceramic bearing (biolox forte) was retrieved from a female patient and shows the typical pattern of posterior edge loading wear. There is a narrow stripe of wear on the posterior rim of the acetabular liner and a broader stripe of wear on the ceramic head. The wear has been coloured with a graphite pencil for the photograph.

We studied 16 bearings retrieved from a series of cementless hip arthroplasties with third generation alumina ceramic-on-ceramic bearings in order to characterise the mechanism of stripe wear formation [2]. None of these bearings were retrieved for bearing failure. The average wear volume was 0.4mm^3 per year in the heads and 0.3mm^3 per year in the liners. Mapping of wear stripes on the heads and liners showed that the majority do not occur with normal walking; instead they probably occur with edge loading when the hip is flexed such as with rising from a chair or with climbing a high step.

The mean volumetric wear rates of ceramic-on-ceramic bearings in this study of 0.7mm^3 per year (running-in) are roughly one order of magnitude less than metal-on-metal bearings and two orders of magnitude less than standard polyethylene bearings [3,6].

Post-operative audible squeaking of a hip replacement is a complication that is almost as old as hip replacements themselves being reported as early as the 1950's in the Judet acrylic hemiarthroplasty [7]. In the modern era of total hip replacements it is more commonly a complication of hard-on-hard bearing

surfaces. A case of squeaking was reported in a mismatched couple where a zirconia ceramic head was coupled with an alumina ceramic cup [8] but the phenomenon remains unreported in properly matched modern ceramic bearings. Transient squeaking in metal-on-metal resurfacing hip replacements has been reported with an incidence of 3.9% [9]. Audible squeaking in modern total hip replacements with ceramic-on-ceramic bearings is a rare problem.

In our series, patients with squeaking hips are younger, heavier and taller than patients with silent hips. The hips started squeaking after an average of 14 months. To date all bearings retrieved from squeaking hips have signs of edge loading wear.

We studied acetabular component orientation in 17 squeaking hips and compared them to 17 matched controls [10]. Ninety four percent of control hips were in an ideal range of 25°+/-10° anteversion and 45° +/-10° inclination but only 35% of squeaking hips were in this range (p=0.0003).

Eight hips squeak with bending. Four hips squeak with walking and 5 hips squeak after prolonged periods of walking. Hips that squeaked with walking had acetabular components that were more anteverted (40°) than hips that squeaked with bending (19°) (p=0.001) or prolonged walking (18°) (p=0.020). Even though malpositioned acetabular components are more likely to squeak, not all malpositioned acetabular components squeak. Furthermore perfectly positioned acetabular components can still squeak. In our experience it is surgically impossible to place the acetabular component in the ideal position every time due to variations in pelvic positioning on the operating table, variations in pelvic anatomy and pelvic movements and even differences in the definitions of ideal acetabular component position.

As with most other problems in joint replacement surgery there are patient factors, implant design factors (yet to be defined) and surgical technique factors that determine which hips will squeak and which will not.

Our findings regarding edge loading wear and squeaking have implications for testing of hip prostheses. Studies that use standard hip simulators to reproduce the forces of normal walking and conclude that 1 million cycles equals a year of in vivo service are far from realistic. Hip simulator studies must include edge loading if they are to give an indication of in vivo performance of new bearings.

Overall, we are very happy with the performance of these bearings and continue to use them as our bearing of choice. We now diligently check the hip on the table for impingement and infolding anterosuperior capsule and we are looking for more accurate ways to position the acetabular component.

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SESSION 7

Tricks and tips: how to manage the implantation of ceramic implants

7.1 Tricks and tips in every day utilization of ceramic on ceramic coupling

R. Giacometti Ceroni, L. Zagra and M. Corbella

Introduction

The problem of the wear in THA is well known [1,2]. Ceramic can reduce the wear at the lowest rate thanks to its hardness, surface finishing, and wettability which means better lubrication at the liner-head junction. Moreover it is an inert material with very high biotelarability and no production of ions [3].

The first ceramic implant was implanted by P. Boutin in 1970 [4], while new designs and use in wide number of cases were developed by H. Mittelmeier since 1974 [5]. The main problems with the first generation of alumina implants were linked to old type of ceramic with low purity and density and large grain size distribution, but also to inadequate designs, such as the "skirt heads", and to the missing ongrowth of the bone onto the ceramic surface. Not reliable stems were also employed in that time. All these problems caused in the past the high risk of ceramic fracture and a great number of loosening of the components.
At the present, the long experiences and the evolution of the designs and materials (Biolox Forte® and Delta®), have made the ceramic a safe and a very low wear material [3,6,7]. Nevertheless some problems are reported: stiffness of ceramic and the risk of fracture, becoming lower and lower but not zero.

Our experience with ceramic material started in 1978 with ceramic/ polyethylene. It was a large and positive experience (more than 4000 cases in the first 20 years), and ten years ago we started to implant ceramic-ceramic devices in younger patients (about 1300 hips). At the beginning we employed 28 mm heads with ceramic-polyethylene sandwich liners too. Since 2001 36 mm heads have been used as the first choice implant: at the actual state of art 36 mm can be utilized with cups of 52 mm of diameter or more while in the smaller cups 32 mm heads are employed [8]. In the older patients we now implant 36 or 32 mm heads coupled with highly cross-linked polyethylene.

With this paper we report our experience along these years. The aim is to identify tricks and tips for minimizing the risks of failure in every day surgical practice.

Tricks and tips

Correct indication

The first tip is to respect the correct indication. Ceramic-ceramic is the coupling with the lowest wear so it is indicated in the younger and more active patients, but it is more expensive and less forgiving (elevated rim liners are not available and there are fewer different neck lengths).

In very old patients the risk of dislocation is higher and ceramic-ceramic can be a disadvantage having less options.

The implant should be stable with correct muscle tension to avoid initial microseparation and eventually a damage of the liner rim. Therefore, old patients and patients showing a palsy of the pelvic muscles should be considered at risk.

As the more frequent mechanism that leads to liner (or head) breakage is the impingement (neck of the stem to the rim of the cup), great attention to the orientation of the components must be played. Avoid an excessive antiversion or retroversion, a vertical or horizontal cup, but also an incorrect antiverted or retroverted stem. That is the reason why in cases in which the orientation of the acetabular component can show particular difficulties (such as in severe DDH or hard post-trauma arthritis), the indication for ceramic-ceramic must be carefully evaluated and the use of modular stems or necks can be useful.

Surgical technique

The use of ceramic requires a precise surgical technique paying attention also to small details.

The metal back of the cup must be adequately prepared before introducing the liner, particularly in case of 5° 43' of liner cone angle, to avoid a wrong sticking during the insertion or late breakage or disassembling of the liner:

- Absolutely do not damage the metal back during implantation, not only inside, but mainly on the rim (the proper device to handle the cup should be used) (Fig. 1 a,b,c,d).

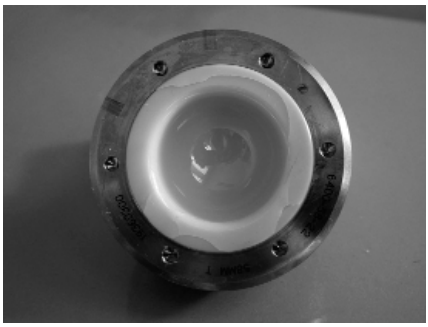

Figure 1a

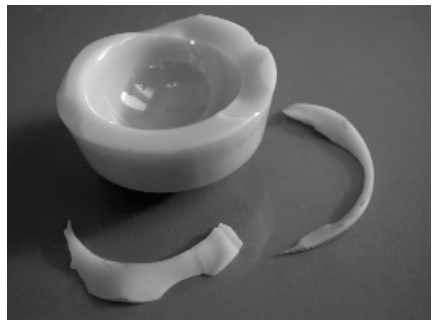

Figure 1b

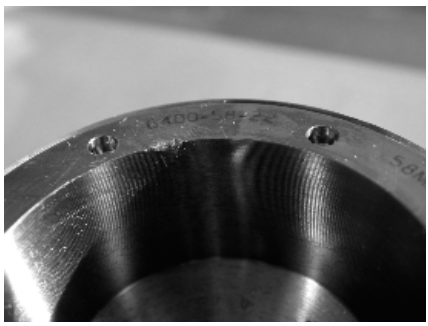

Figure 1c

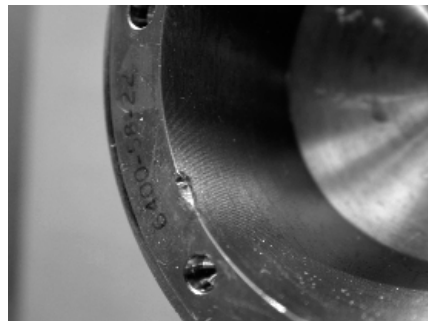

Figure 1d

- It is, generally, better not to use additional screws, but if necessary pay attention they do not protrude from the holes inside the cup.
- Remove all the soft tissues just around the cup to avoid an interposition between metal back and liner.
- Wash and remove blood and fat tissue from the metal back.
- Lock the liner by gently hammer onto a plastic impactor it in the correct axis.
- Check the full integrity of the ceramic liner. And check it again.

Do not use ceramic heads with not certified cones or with cone adapters because the risk of head fracture is high.

The Morse cone of the stem must be respected with great care in order to avoid the breakage or the loosening of the head:

- Perform the reduction test of the prosthesis with plastic test heads and, once the final head has been implanted, avoid to change the head with another one of different neck length, especially with smaller diameter heads or short necks.
- Clean the cone not leaving blood or fat fragments before impacting the head.
- Grip the head on the cone by a movement of screwing; it is better not to hammer the head.

Revision

In case of partial revision the features of the artrhoplasty to revise should be known before starting the operation: the coupling, the head diameter, the Morse cone size. When the head is changed with a ceramic one on a stable stem, it is better to use revision heads, but if the Morse cone is macroscopically damaged, the employment of revision heads is mandatory. In order to avoid damage of the cone during the surgery, it is better to leave the old head on the stem and to change it at the end of the operation.

To remove the head or the liner, also during a primary THA in case of need, great care must be applied: a sharp blow to the head with a device that cannot scratch the cone of the stem (with a plastic tip for example) and a very sharp one on the rim of the cup to remove the liner. The effect on the shell is the same as to take out the cigarettes from the box by knocking on the bottom.

The most important trick is to check very carefully during the procedure and at the end of the operation that every component is in order and assembled in a correct way: no damages of the metal back or of the liner, no scratches on the cone.

A ceramic fracture must be suspected when the patient refers a click in the joint after a period without symptoms. In case of head breakage the diagnosis is easy, while in case of liner at the beginning the X-rays may be nearly normal and must be repeated (Fig. 2 a,b,c,d). A CT can be useful. The ceramic fracture must be considered as an emergency. The patient must lye supine and stay immobile until the operation is not carried out, to avoid formation and dissemination of dangerous small ceramic particles.

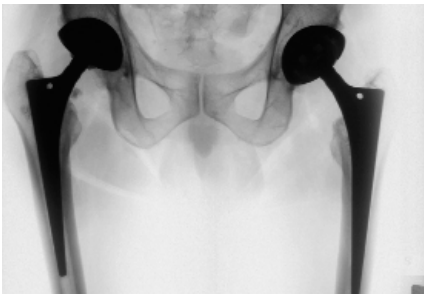

Figure 2a

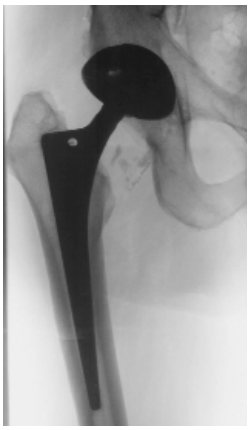

Figure 2b

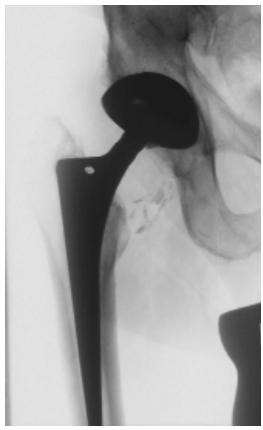

Figure 2c

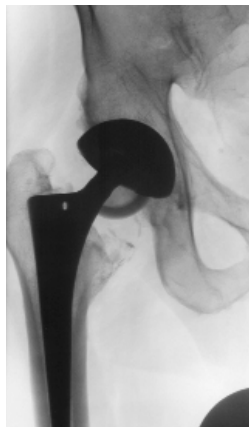

Figure 2d

Conclusions

Ceramic-ceramic coupling has the great advantage of a very low wear. Although it is less forgiving and more expensive, so the indication must be correct: younger and more active patients.

An accurate surgical technique and a precise orientation of the components are mandatory for avoiding complications such as the alumina fracture.

The most important trick is to check at every step of the operation the integrity and the correct assembling of the components and not to damage the metal back of the cup nor the Morse cone of the stem.

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7.2 Neck Modularity and CE/CE systems

P. Gaffurini and S. Bertoglio

Introduction

We cannot speak about long term results by presenting a follow-up of only 18 months in the following paper.

We will explain you in the following abstract the philosophy of our implant. We would like to show you how important the modularity as the special subject of the prosthesis characteristics is; we will present also the instruments and the ceramic-ceramic connection. To get good long-term results and a high survival rate we think it's important to do accurate pre-operative planning to reconstruct anatomical and biomechanical balance of the hip.

Including the elements mentioned above combined with material of the last generation we are sure to obtain best results for our patients for the future.

For all new prosthesis, so as for new materials there is a "surgical learning curve". So we leaved the sandwich-system for the acetabular insert, changing to the innovative ceramic Biolox Delta with the 36 diameter reducing the invasiv surgical access with new instruments.

Preoperative planning

Pauwels, Charnley and last but not least Maurice E.Müller always pointed out the importance of preoperative planning in hip surgery.

Starting surgery by drawing will help us to reconstruct as exact as possible the rotating centre of the hip respecting muscular forces on the articulation due to an minute recostruction of the lever arm.

We think that we could avoid many intraoperative so as postoperative problems by good preoperative planning. Respecting the anatomical situation of any hip gives us the chance to reconstruct exactly the articulation, giving at the new, artificial hip best prognosis for long term result and survival.

How to do preoperative planning

We use classic anterior-posterior Xray of the hip in charge.

The lever arm "K" is determined by the rotating centre "D" and the line "M", connecting the major trochanter and the muscular insertion of pelvic muscles. (Fig. 1)

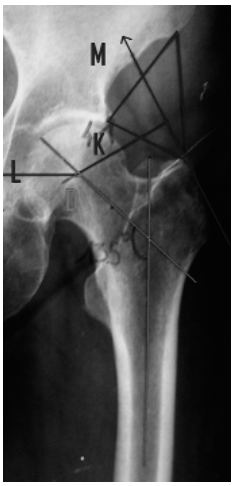


Figure 1

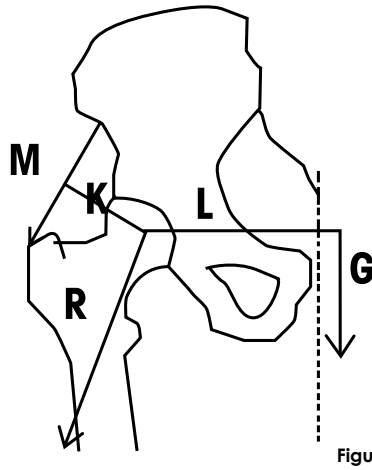


Figure 2

Due to Pauwels we planned the forces of the hip out of the weight "G" multiplied by "L" and divided by "K". (Fig. 2)

Closer we get defining the rotating centre of the hip, the offset and the exact positioning of our prosthesis, better we reach to reconstruct the anatomical and biomechanical situation of our hip. This fact is important if you have a healthy, even more important if you're confrontated with hip arthroplasty on controlateral side.

$$\frac{G \times L}{K} = R$$

The better L1/K1 is similar to L2 /K2, the better the lever arms are equal. So we get a biomechanical correctly reconstructed hip. (Fig. 3,4)

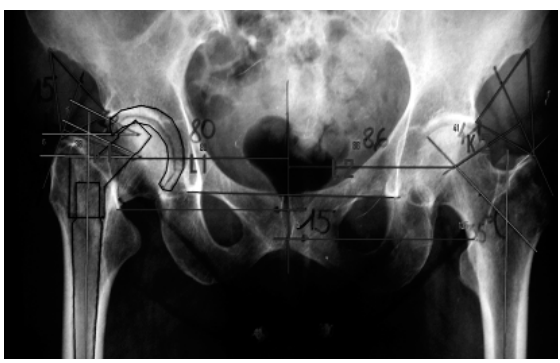


Figure 3: Preoperative planning and shorted limb of 15 mm: L1/K1 < L2/K2.

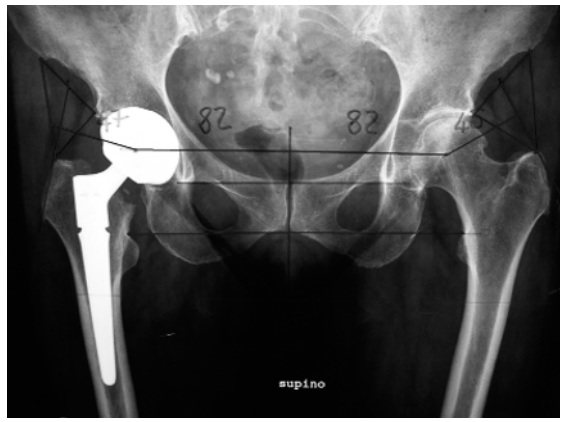


Figure 4:
Postoperatve X-Ray: L1/K1 = L2/K2.

The extra- and endomedullary part of the prosthesis

By our experience with custom made prosthesis we found that primary prosthetic stability is only given by anatomical design with good proximal metyphysical or conical meta-epiphysical contact as shown in our implant. The extramedullary part of our prosthesis defined ante- and retroversion of the neck and consequently the (long or short) offset so as the varus or valgus position. At the end we will have the ideal positionning of our implant. (Fig. 5)

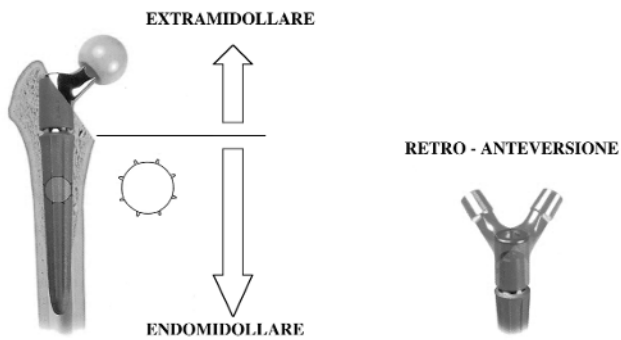


Figure 5

Material and Methods

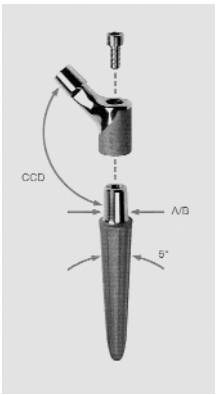
Why do we use a modular stem

According to our philosophy during preoperative planning we choosed the Modulus® stem (LIMA-Lto) for our hip. With this implant we can reconstruct the hip in the best anatomical and biomechanical way due to an anatomical primary prosthetic design which offers in the same time all the possibilities like a custom made prosthesis.

The primary material is Titanium.

The endomedullary part gives us an excellent primary stability due to radial/longitudinal leaves. We can choose the diameter starting by 13 mm; very important by operating upon displastic hip.

In the extramedullary part you can choose between the CCD angle of 135° and 125° with an offset until +5mm. So you have the possibility of lateralisation and positioning of the extramedullary part in retro- or anteversion (Fig. 6).



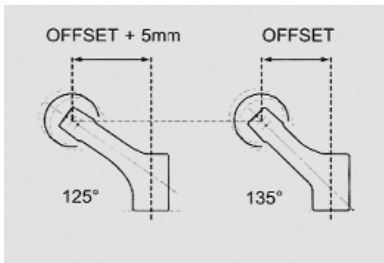


Figure 6

Modularity is given by the "MORSE" stem. In contradistinction to other prosthetic designs the extramedullary part is not only formed by the prosthetic neck, a factor which in our experience reduces the formation of débris as other complications of modular interface.

The acetabulum

For five years we used a ceramic-ceramic sytem of the sandwich-type. We found ceramic rupture and disinsertion in contact with poliethylen.

The LIMA-Lto gives us the possibility to choose a press-fit system called DELTA® in Titanium (Plasma-Spray) covered by Hydroxyapatite; combined with the 36mm ceramic inlay BIOLOX DELTA® (Fig. 7,8).

Figure 7

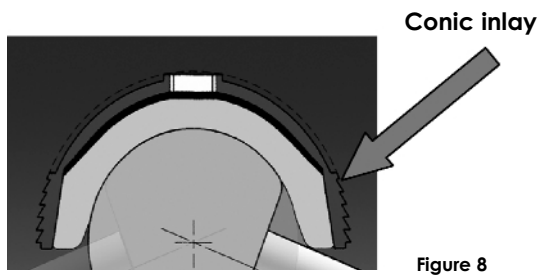


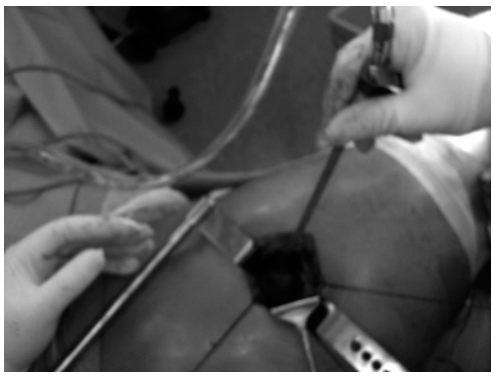
Figure 8

With the DELTA® System we have the CE insert in direct contact with the completely closed metal back; there is no friction between materials causing ruptures or growth of débris.

Surgical technique

We use postero-lateral access in patient with lateral position.

In the first few years we used a 20 – 25 cm incision to have a good view on the minor trochanter ("D"-distance). Now, due to the new instruments of the Modulus®, we can choose the major trochanter as our point of reference. (Fig. 9)



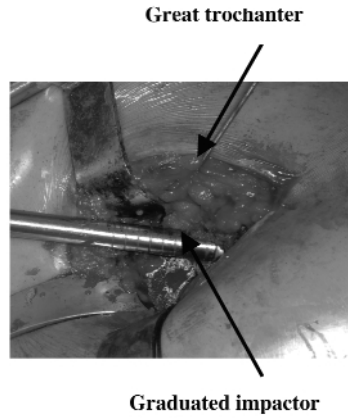
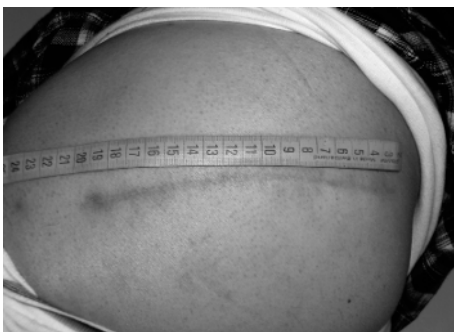


Figure 9

This fact reduces the incision to 8-10 cm with the disinsertion of the piriformis muscle, maintaining the posterior capsule of the hip joint. (Fig. 10)



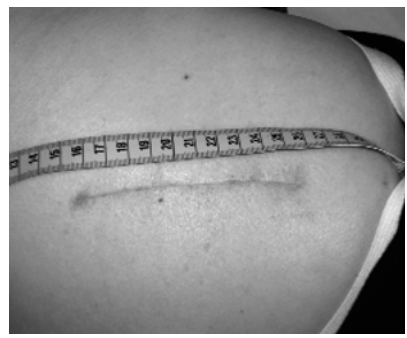


Figure 10

With this new technique we reduced drastically intraoperative blood loss and postoperative pain, obtaining faster postoperative mobilisation with full charge from the early first p.o. day, having wather therapy in the fifth p.o. day and dimission 10 days after surgery.

As point of reference of the stem we take the Koehler figure using a curved rasp.

Problems and complications

We operated upon 103 patients with osteoarthritis of the hip during the last 18 months. In the follow-up there was no postoperative dislocation of the prosthesis, no neurological problems, no intraoperative fractures. We got an operating time by 60 - 90 minutes. Initially we conferm some cases of varus positioning of the stem, an error which can leed to a painful hip also as to aseptic loosening. We resolved the problem by lateralisation of the place of entrance of the femur medullary canal. The better exhibition of the major trochanter by lateral positioning of the patient on the table also reduced varus implantation.

We had septic loosening, resolved by primary replacement with the Modulus® implant and the Delta® CE-CE.

The new curved femur rasp so as the curved impactor facilitates the femoral approach preventing impingement with the major trochanter. (Fig. 11)

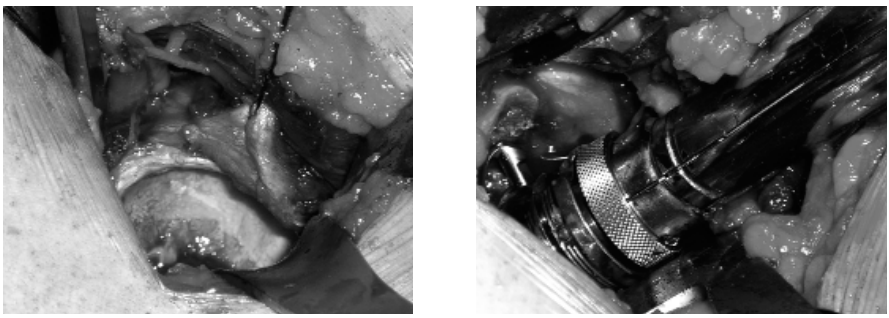


Figure 11

Conclusions

First results are very encouraging. We absolutely need more time of follow up to give clear results.

The new modular stem of the Modulus® prosthesis (LIMA Lto) combined the advantage of a good primary stability with a modular implant system. It allows us to reconstruct accurately hip anatomy by the modular extramedullary part of the system. Preoperative planning (center of rotation, forces etc.) gives us the ideal positioning of the stem, the extramedullary part and the acetabulum. The combination CE-CE with the head diameter 36 shows in first results better stability and ROM.

The future will show if we are right. We will go on analysing our results improving anatomical reconstruction of the hip by the modular system.

The positioning of the stem in a CE-CE system is essential to prevent growth of débris and aseptic lossening.

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7.3 Off-set and ceramic on ceramic bearing

A. Toni, F. Traina, A. Cervinini, M. De Fine and B. Bordini

Introduction

Alumina prostheses has shown excellent clinical long term results [4], these results have been achieved because of the low wear rate of alumina [1,2,5] due to its very high Young's modulus, that leads to an excellent compression strength. On the other side, alumina has a poor bending strength that could lead to ceramic fracture. Under normal physiologic conditions alumina fatigue limit is not reached, thus the rate of clinical failure of ceramic heads is very low: 0.004% [10]. Otherwise, when a ceramic prosthesis is under non physiologic conditions, such has head subluxation or neck-liner impingement, the risk of ceramic failure rises, especially for the ceramic liner [1].

To prevent non physiologic stresses on ceramic bearing surfaces, the surgical technique should be particularly accurate, avoiding possible causes of implant dislocation, and also providing an optimal balancing of soft tissues. To achieve these goals, an effective preoperative planning is mandatory [3], besides, a modular stem could be helpful during surgery [6,7].

Aim of this study is to present our results with modular neck ceramic prostheses, and particularly evaluating the importance of a modular prosthesis in restoring a correct hip offset, leg length and hip soft tissues balancing. Besides, we will address the problem of ceramic liner fractures, its correlation with stem modularity, and we will provide guidelines for its early clinical recognition.

Materials and methods

Part 1: Modular Neck Prostheses

Between January 1995 and December 2005, 2897 primary surgeries were performed with a modular neck stem and ceramic bearing surfaces. Among these, 2484 Anca Fit (Wright Medical Technology, Arlington, Tenn, USA) until December 2004, and 413 APTA (Adler Ortho, Bologna, Italy) since January 2005, were implanted. Both prostheses have a titanium alloy (Ti6A14V), anatomically shaped stem. Modularity consist in a modular neck coupled with the stem by a taper Morse. The modular necks have different length and five different shapes. Modular necks in conjunction with modular heads allow a lengthening of the implant and several different options in terms of offset (Fig. 1). All the THA implanted had ceramic bearing surfaces (Biolox®, Forte, CeramTec, Stuttgart, D).

Part 2: early clinical diagnosis of ceramic liner fracture

Between January 1994 and December 2004, 3041 modern ceramic prostheses have been implanted in our institution. Among these, 660 present a monoblock stem and 2381 a modular neck stem. Reviewing the causes of implant revision surgery, we have found 10 liner fractures (0.32 percent). In four of the latter, the only relevant early clinical sign was a hip noise perceivable

during walking. Since then, evaluating at clinical follow up 554 patients, we have found 10 patients (1.8%) presenting a noise that could be related to the THA. In the latter patients, a CT scan to evaluate impingement or instability of the prosthesis, and a needle aspirate for synovial fluid examination were performed. The harvested synovial fluid was analyzed following a protocol to isolate non organic particles [8], and then a Cambridge Stereoscan 200 electron microscope operated at 10KV was employed to inspected them. These analyses were performed in the attempt to detect ceramic fragments.

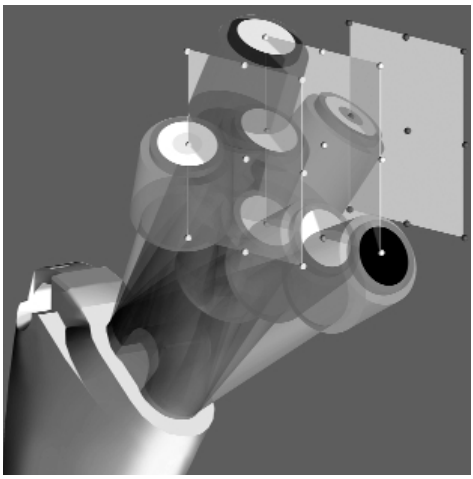

Figure 1:
Modular necks in the APTA stem implant. Modularity allows 3 different implants offsets and 3 different implant length on to 3 different planes: one anterior (antivertion), one neutral and posterior (retrovertion).

Results

None of the 2897 modular neck prostheses implanted went to revision for a modular neck failure, the overall survival rate at 10 years is 97.8% (C.I. 96.5-99.5%).

Reviewing the 10 liner fractures, we have found 7 fractures with the monoblock stem (7 on 660, 1.1%) and only 3 with the modular neck stem (3 on 2381, 0.1%); this means that a liner fracture is 8.4 times more frequent with monoblock stem in comparison with modular neck stem.

SEM analysis showed that fragment dimensions (>2µm) and shapes were not compatible with wear, but with an early stage of liner fracture. When fragments dimensions were bigger then 5µm a macroscopic liner fracture was then found at revision surgery. While, when fragments were smaller then 5µm and the CT scan showed a prosthesis impingement, a liner metal staining and a femoral neck mark were found at revision surgery.

Discussion and conclusion

The purpose of this study was to present our long term results with a modular neck ceramic prostheses, and to present guidelines for early recognition of clinical signs of ceramic liner fractures.

Modular necks prostheses with ceramic bearing surfaces have shown a very good long term survival (97.8%). Modularity allows a wide range of solutions, by modular neck trials, during surgery, it is possible to check the implant stability and if it is the case to change the final neck design, always in the attempt, at the same time, to achieve the best possible leg length and femoral offset (Fig. 2). Besides, modular necks have shown to be safe (none out of 2897 implants failed for a neck failure) and to decrease dramatically (8.4 times) the risk of ceramic liner fracture.

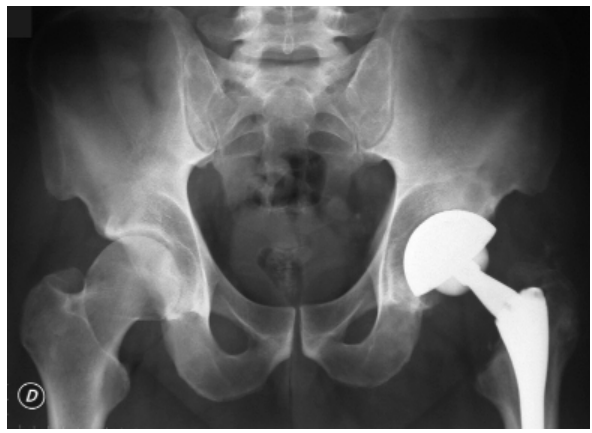

Figure 2:
X-ray of a APTA stem at 1 year follow up. The femoral offset is perfectly restored by stem modularity, the head is a 36mm ceramic head for an optimal hip stability.

Finally, we have found a possible correlation between ceramic liner fracture and an audible hip noise at clinical examination. In our experience, after an accurate differential diagnosis with a snapping hip, a CT scan and a needle aspirate could be helpful for a early recognition of a ceramic liner chipping/ fracture, before a wide spreading of ceramic fragments in the periarticular space.

At authors knowledge there aren't published studies correlating hip noise with ceramic liner fractures, however Walter WL et al. [9] correlate stripe wear of ceramic head with edge loading and hip squeaking at clinical examination.

In conclusion, modular neck prostheses with ceramic bearing surfaces are safe and effective; a noisy ceramic THA could be an early clinical sign of liner chipping/fracture or head stripe wear.

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7.4 Ceramic on ceramic cementless total hip arthroplasty in arthritis following congenital hip disease: an algorithm of the surgical treatment

R. Binazzi, A. Bondi, A. Manca, L. Marchesini and M. Delcogliano

Introduction

The prevalence of Congenital Hip Disease (CDH) in Europe is ranging between 2% and 3%. There are, though, 3 regions where it reaches 4-5%: Bohemia (Cech Republic), Upper Palatinate (Germany) and Emilia Romagna (Italy).

The Rizzoli Institute of Bologna, capital of Emilia Romagna, is traditionally the Orthopaedic Hospital treating these large number of patients of northern Italy.

Thus, in a previous series of cementless Hip implants [1] published by us in 1994 the prevalence of CDH arthritis was 32%, that is one patient out of three undergoing THA in our department showed some degree of CDH, from minimal alteration to congenital iliac dislocation. In these cases, Total Hip Replacement for degenerative arthritis can be technically difficult. In fact, the Hip anatomy can be severely altered and component placement (especially the cup) is always complicate.Based on our experience, we have classified our cases in 3 groups according to their anatomo – pathologic picture which has determined the indication to a specific surgical procedure: Group A, B and C.

First of all, we must say that femoral anatomical features, differently from acetabulum, tend not to vary with the severity of the disease and are fairly uniform. The main features of Dysplastic arthritis of the hip are:

1) FEMUR a straight and narrow femoral canal with a more or less severe anteversion (usually about 20°-25°; that is around 10° more than normal). Regarding to length, in our experience, dysplasic femora are generally hypoplasic (and then shorter than normal)) or normal, rarely hyper-plasic. With these features a straight stem is necessary, cemented or (better) cementless allowing the correction of the anteverted neck.
2) ACETABULUM = we have maintained the 3 groups of Hartofilakidis [2] with more attention to the acetabular morphology, designing an algoritm of the surgical treatment.
   A) Group A ("DYSPLASIA" of HARTOFILAKIDIS) (Fig. 1a-d) the acetabulum is small, the antero-lateral wall is deficient, sometimes absent, the medial wall is usually not too thick creating problems for placing the cup.

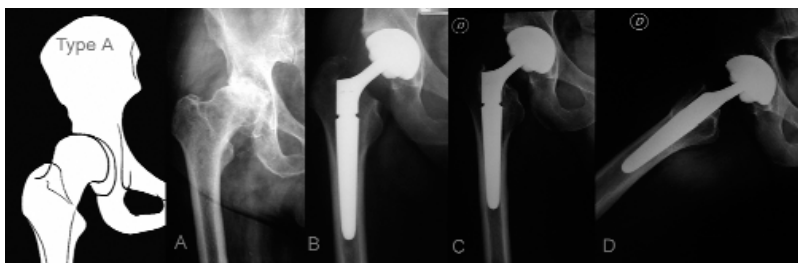

Figure1a-d:
Type A. Total Hip Arthroplasty with conical stem and a 32 mm ceramic-on-ceramic articulation.

The rotation center is practically normal.

In this case a cementless cup must be implanted, of small dimension (usually never langer than 48-50 mm), trying to medialize the cup as much as possible but being careful not to perforate the Lamina Quadrilatera.
Medialization gives a better coverage and improves the lever arm of Pelvi-Trochanteric muscles.

The cup should be placed with 10°-15° of anteversion but this depends also from the surgical approach that we use; with a postero-lateral approach, anteversion is more important than with antero-lateral. Reaming has to be directed to the posterior wall (ileo-ischiatic).

Regarding the articulating surface, we implant liners with ceramic-on-ceramic or metal-on-metal joint and head of big dimensions (32 mm or more) that are very important 1) to help correcting the limited range of motion, very common in dysplastic arthritis, 2) to reduce the post-operative dislocation rate. In these cases, grafting the acetabular roof (according to Harris) is seldom necessary.

B) Group B: ("LOW DISLOCATION" of HARTOFILAKIDIS) (Fig.2)
The head subluxation has determined a chronic hyper-pression on the acetabular roof which is almost completely absent. Thus the head has produced a large, flat and anteverse surface that is composed by the PALEO (inferiorly) and the NEO-acetabulum (superiorly).
Also the anterior wall is usually absent, while the postero-medial wall is very thick with a sclerotic neo - acetabulum.

The rotation centre is displaced proximally up to 4 cm. In these cases we have two surgical options:

1) what we call "cotile nel cotile" ("cotyle inside the cotyle") that is creating a "hole" inside this large acetabular surface to host a small cup approximately of 42-46 mm, reaming the postero-medial wall, which is usually very thick (Fig. 2a-c).

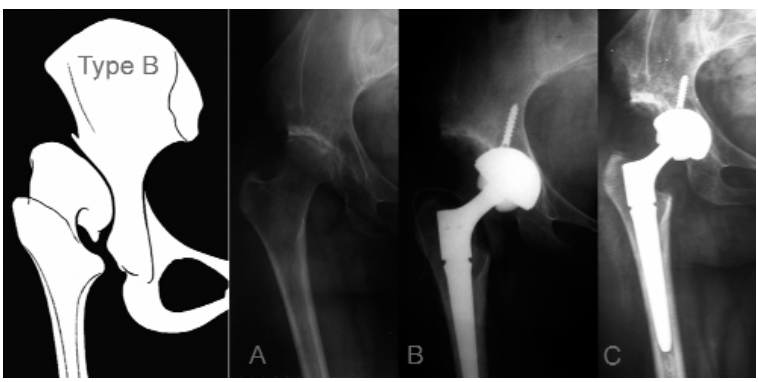

Figure 2a-c:
Type B. Total Hip Arthroplasty with "cotyle-inside-the-cotyle" technique.

This is our favourite technique, because is relatively simple and allows to get a good immediate mechanical fixation.
An alternative is

2) the use of a very large cup ("JUMBO-CUP") reaming the large surface up to 54-58 mm. Usually with this technique an antero-lateral bone graft is necessary, since the cup can be un-covered for more than 25%.
   In both cases since this patients are normally fairly young, we use ceramic-on-ceramic inserts (32 or 36 mm heads) for the same reasons described above.
   C) Group C ("HIGH DISLOCATION" of HARTOFILAKIDIS) (Fig. 3a-d)
   The acetabulum is of minimal dimension, never in contact with the femoral head.

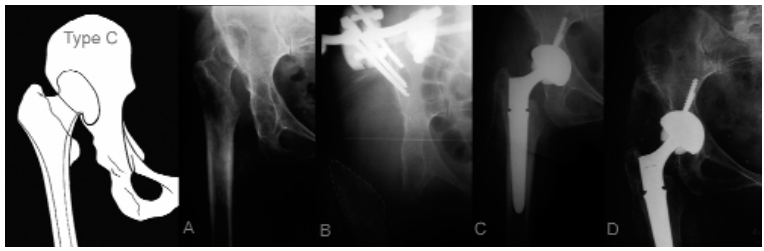

Figure 3a-c:
Type C. Two-Stage Lowering and Total Hip Arthoplasty. In B the progressive lowering with external fixator followed by THA.

There is a severe hypoplasia of all walls, so the Paleo-acetabulum is flat or even convex. The head can be in contact with the iliac wing ("ILIAC" Dislocation) with the formation of a NEO-Acetabulum, usually sclerotic, or is inside the Glutei muscles ("GLUTEAL" Dislocation). The first one is usually painful, the latter not. Both have an important joint instability and severe shorthening of the affected limb. The centre of rotation is always displaced upwards of more than 5 cm.

The PALEO-Acetabulum is always undergoing a disuse osteoporosis.
In High Dislocation several different techniques have been described.

First of all, Some Author in the past (one of them in our Hospital) [3] advocated the possibility of placing the cup into the neo- acetabulum: results were very disappointing for a series of reasons, as the beck of correction of the limb shortening, the post-operative severe Trendelemburg, and the high rate of early cup loosening.
Thus, this technique was abandoned.

Today, all Authors report about the necessity of implanting the cup in to the PALEO- acetabulum. This can be accomplished in two different ways:

1) with a one-stage procedure of femoral shortening consisting in transversal osteotomy in the trochanteric area removing a cylinder of bone, the height of which depends on the head upwards displacement.

Infact, it is well known that with a femoral lowering of more than 3,5- 4 cm, the possibility of having a sciatic nerve lesion is high. Thus, if the head displacement is for instance of 6 cm, we have to shorten the femur of 2-2,5 cm in order to be tranquil.

Then we have to implant a long stem (usually a Wagner- like tapered stem), allowing also to correct neck antiversion.

This procedure has some advantages (mainly the single procedure, then the proximal femoral derotation) but a great disadvantage for most (if not all) our patients: it does not correct leg length inequality completely, leaving the necessity of a heel pad. This usually represents the very first complaint of our patients and the main reason for undergoing surgery, more than pain and limited range of motion. Another problem is a certain technical difficulty of the operation, requiring a specific competence.

Never the less, this technique is by far the most used one, particularly in US.
The other procedure is a 2) two stage lowering and total Hip Arthroplasty, consisting in a first operation to free the proximal femoral epiphysis (Adductor tenotomy, proximal release of Glutei muscles, Z-lengthening of Psoas, then femoral head resection) and to apply an External Fixator that enables us to lower the femur progressively, about 2 mm/day.

Intra- operatively we can perform a lowering of about 3 cm, so the remaining discrepancy is usually eliminated in 2-3 weeks, during which the patients remains in the Hospital.

When the femoral epiphysis has reached the Paleo- acetabulum we remove the EF and we perform the Hip Arthroplasty with a primary implant.

In these cases we have always used a cementless cup, usually 44 mm with metal on metal (28 mm) and recently ceramic-on–ceramic (32 mm) articulation.

The Implant

In the last 13 years we have used in Dysplastic Arthritis a straight conical cementless stem with a cementless press-fit cup initially with metal-on-metal liner and in the last 3 years, with a ceramic-on-ceramic insert (Fig. 4).

This implant has many important advantages and no real drawback.

Figure 4:
The new Delta ceramic allowing a 32 mm head in a 42 mm cup.

The stem is easy to implant and allows a simple correction of neck anteversion, normally a problem with stems of different design. Beside, the cone shape eliminates any anterior thigh pain.

The cup is over-dimensioned of about 1 mm compared to the acetabular reamer in order to increase press-fit but the key-point is the new Delta ceramic insert, which has two more important advantages: 1) it can be used with cups having an outer diameter of even 42 mm, extremely useful for dysplastic cases, having very small acetabula; 2) the internal diameter of the liner is 32 or 36 mm with great range of motion improvement and reduction of dislocation rate.

Conclusions

Based on our large experience with THA in dysplastic arthritis we can summarize our conclusions as follows:

1) The main technical problem is always the cup placement, both for the bad bone quality and for the walls deficiency.
2) Cup should be medialized as much as possible in order to improve the abductors level arm. It is important, though, not to perforate the Lamina Quadrilatera, because it might favour a late intra-pelvic migration.
3) Usually the best bone mechanically is found in the posterior ileo-ischiatic area.
4) We have to try always to place the cup inside the Paleo-Acetabulum, both for biomechanical (restoration of rotation centre) and cosmetic (correction of leg length discrepancy) reasons.
5) In our experience, Harris roof autograft is seldom necessary. We perform this procedure only when more than 25-30% of the cup is not covered. Extreme care must be taken in recenting the iliac wall otherwise the graft does not fuse.
6) We had no particular problem with the femoral component using cementless cone stems which allow an easy correction of femoral neck anteversion [4].
7) Dysplastic patients are generally young since joint degeneration occurs early. Thus we tried to avoid using PE liners that do not guarantee a long life. Until a few years ago we have applied metal-on-metal inserts with excellent results. With the availability of Delta ceramic we would have an alternative to metal-on-metal without the theoretical risks connected to Co-Cr ions release. Moreover, with 32 or 36 mm ceramic heads we could obtain an excellent range of motion and decrease the dislocation rate.
8) Patients of Group 3 ("High Dislocation") showed the worst clinico-functional results and this was very easy to foresee, considering the sometimes dramatic pre-operative conditions. Nevertheless this group of patients showed a very high subjective satisfaction.

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7.5 32mm alumina on alumina hip replacement for femoral neck fracture

G. Solarino, A. Piazzolla, N. Tartaglia, L. Scialpi and G. B. Solarino

Summary

Hip replacement is considered the best option for treatment of displaced intracapsular fracture of the femoral neck (FFN). The size of the femoral head is an important factor that influences the outcome when a total hip arthroplasty (THA) is performed: implants with a 28mm femoral head are prone to dislocate more than ones with a 32mm. Obviously a large head coupled to a polyethylene inlay can lead to more wear, osteolysis and failure of the implant. Ceramic provides less friction and minimal wear even with larger heads.

31 THAs were performed for displaced intracapsular FFN, using a 32mm alumina-alumina coupling: at an average follow-up of 64 months, 29 have been reviewed clinically and radiologically. None of the implants had been revised for any reason, none of the cups were considered failed, no dislocations and no breakage of the ceramic components have been recorded. One anatomic cementless stem was probably loose radiologically.

Introduction

FFN are very common in the orthopaedic practice; when an intracapsular lesion occurs, it may be treated by either reduction and internal fixation which preserves the femoral head or by replacement of the femoral head with an arthroplasty, both operations seeking to return the patient to preinjury function as quickly as possible. Considering the very much higher failure rate after internal fixation -leading to increased suffering for these patients- primary arthroplasty stands out as the best method for displaced FFN [12].

When a THA is performed, surgeon must consider dislocation of the implant as a possible complications, claimed to be more frequent after a fracture of the hip, with the posterior surgical approach, in elderly patients, when soft-tissue laxity is present [6].

A report from the Norwegian Arthroplasty Register underlines as the femoral head size is a risk factor for total hip luxation, the 28 mm heads leading to revision significantly more often than 32 mm ones and 26 mm heads more often than 30 mm heads. Preoperative diagnosis, i.e. femoral neck fracture, was also an important factor affecting the revision rate due to luxation [4].

Aim of this retrospective work is thus to evaluate the results of 31 THAs performed for displaced FFN, using a 32mm alumina-alumina coupling.

Material and methods

From march 1996 to september 2005, 31 intracapsular fracture of the upper femur, classified as groups III and IV according to Garden, were treated with an

alumina-alumina hip replacement in 28 females and 3 males. The median age of patients at the time of surgery was 64 years (range 47-75 years). All the operations were primary procedures (none treated with internal fixation previously), performed via an Hardinge approach.

The press-fit cup, hammered in a 2 mm underreamed acetabulum, consisted of a pure titanium core with a titanium alloy mesh: its shape is grossly hemispherical (polar flattening and circumferential gutters, Triradius Cup), with one hole on its apex for the liner, inserted by a conical sleeving; it was always combined with a 32 mm alumina femoral head.

Two additional screw fixation were used in 14 cases, in the two further holes of the shell. The mean cup inclination was 44°85' post-operatively.

Three different stems were used: a cemented collared smooth anodized Ti stem in 14 cases (43.4%), two cementless (one anatomical and one straight HA-coated) Ti stems in 17 cases (56.6%). All of them have a morse cone 12-14.

Results

At an average follow-up of 64 months (range 6-120 months), 29 hips (93.5%) have been clinically and radiologically reviewed, being two patients died meanwhile for causes unrelated to the operation (i.e. malignant tumor). None of the implants have undergone a revision for any reason, but one cementless anatomical stem has showed radiological signs of impending failure (i.e. sinking of 2mm and pedestal formation) with no clinical worries. All the cups, all the cemented stems and all the straight press-fit stems were well fixed at the latest follow-up (Fig. 1). The mean Harris Hip Score was 96.7 (range 85-100) .

None of the implants had any dislocation and none of the ceramic components broke out. Ceramic wear was undetectable.

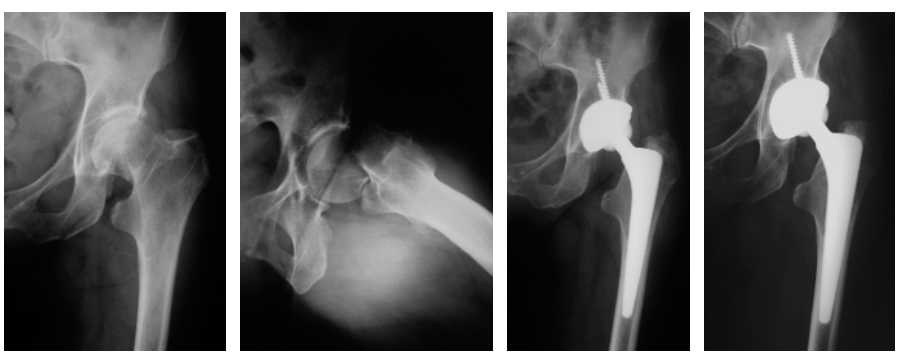

Figure 1:
Cementless THA preoperatively, at 12 and 44 months postoperatively.

Discussion

In the treatment of a displaced intracapsular FFN, surgeon should consider reduction and internal fixation or hip replacement as the surgical options; the former has a reduced length of surgery, operative blood loss, need for blood

transfusion and risk of deep wound infection, but arthroplasty has a lower re-operation rate [9]. The lesion being often a direct result of osteoporosis, the risk of higher failure must be taken in mind especially in active elderly patients [5], or in patients with chronic diseases [8]: re-operations are reported to be needed in 2 - 8% using THA, and in 14 - 53% after internal fixation [12] and at a 4-years follow-up evaluation, complication and reoperation rates are ten times lower using THA [3]. Therefore nowadays no doubt exists that total joint arthroplasty is the most clinically effective and most durable procedure in these situations [14], and it stands out as the best method even if the accumulated costs of each method during the first 2 years after the fracture are evaluated [11].

Disagreement may arise about the optimal management of patients between sixty and eighty years old [1], and even more for young active patients, but it has to be considered that if internal fixation is unsuccessful and revision to a THA is required, the risk of early complications is higher and hip function may be poorer than if the arthroplasty had been performed as a primary procedure [10].

When a THA is performed, risk of dislocation should be accounted: it is higher both after a fracture of the hip and in elderly patients, because of the poor muscular strength and the attempt to regain the pre-injury full range of motion [4,6].

Bystrom S et al. [4], in a retrospective work on 42,987 primary operations, have shown as the femoral head size was an important risk factor for prosthesis luxation: 22 mm head performed equally well or better than the 28 mm heads, but 28 mm heads led to revision four times more often than 32 mm ones.

Heads larger than 28mm can be used if we move to hard on hard couplings: ceramic-on-ceramic are attractive alternative bearing surfaces that have been reported to eliminate or reduce problems related to polyethylene wear debris. Because of its sliding characteristics (lower frictional torque, better wettability, less reactive wear particles than polyethylene), it is possible to increase the femoral head diameter, according to the Low Frictional Torque Arthroplasty theory.

A 32 mm head grants a 8°-10° wider range of movement than the one possible with a 28 mm head; furthermore its very low wear avoids the penetration of the head in the liner, as with a polyethylene one, allowing this optimal range of movement to be long-lasting. When a liner wears, the centre of rotation migrates centrally and/or cranially, and the deeper the head, the more restricted the range of movements becomes (7° are lost for each millimetre of penetration) and in fact sometimes late dislocation can be the first clinical sign of wear [6].

Our data confirm that a ceramic on ceramic 32mm coupling can protect the hip from dislocation, postoperatively and at a mid-term follow-up.

We don't report any fracture of the components: it can be explained with the precise manufacture and contact surface geometry, including optimal clearance (cup, liner, head and stems are manufactured by one industry in our series) and because using a 32 mm heads, resistance to the fracture is also increased. Santavirta S [13] has stated that for the currently available ceramic products, the component fracture risk is almost nonexistent, as shown in clinical investigations at 4 and 5 years even with a 28 mm head [2,15].

Further advantages on both strength and articularity are obtained if the diameter is even larger: rate of dislocation, in the first three months after operation, are 0.88% for 36 mm and 4.64% for 28 mm respectively; these percentages become 0% (0 cases out of 16) versus 10% (3 cases out of 30) in patients operated for femoral neck fracture [16].

Finally, we don't report any failure of the cup, when a tilting of 2° or more and/or a penetration of 2mm or more is considered on the AP pelvis X-ray (Fig. 2). It is believed that the titanium shell acts as a shock absorber between the high rigidity of the alumina and the probably porotic bone, solving the problem of the socket fixation reported when a cup of bulky alumina was cemented into the acetabulum [7].

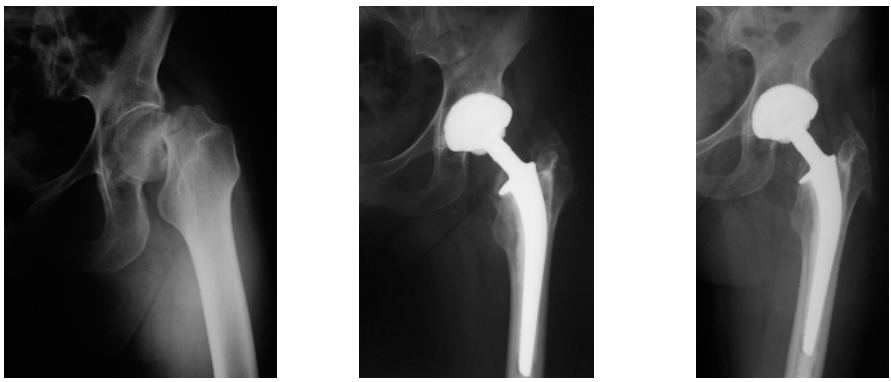

Figure 2:
Hybrid THA preoperatively, postoperatively and at 9 years of follow-up.

Conclusions

Total hip arthroplasty stands out as the best method for intracapsular displaced fracture of the femoral neck. Ceramic on ceramic is the best coupling from a tribological point of view: friction and wear are minimal even with heads larger than 28 and 22.2mm. A ball of 32mm or more allows to respect sir John Charnley's Theory and to gain a wider range of movement of the artificial joint, that remains during the years, protecting the hip from early or late dislocation.

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7.6 Is there really a "safe zone" for the placement of total hip components?

K.-H. Widmer

The term "safe-zone" has been introduced in 1978 by Lewinnek et al. [6] based on the clinical observation that less dislocation did occur when the acetabular cup was placed within 30 to 50° of abduction and 5 to 25° of anteversion. Although dislocation of a total hip is a multifactorial event component positioning and soft tissue tension have been identified as being the most important factors [1,2,3,4]. There are two leading mechanisms that induce dislocation. These are impingement between stem and cup and insufficient soft tissue tension.

Impingement most often occurs between neck and cup but also between the femoral and the pelvic bone. All forms of impingement produce some form of a hinge mechanism that drives the head of prosthesis out of the socket when the arc of movement exceeds the specific limits of the total hip prosthesis or the patient's morphology. This kind of dislocation is linked to malpositioned total hip components or reduced offset.

On the other hand insufficient soft tissue tension is developed when the preoperative femoral offset is not restored after total hip arthroplasty or when the function of the soft tissue is harmed either by failed reinsertion or due to neurological disorders. Obviously, this cause of dislocation can only slightly be addressed by component positioning.

There has been increasing interest in component positioning in recent years for two reasons. First, computer-assisted navigation allowed for a more precise component orientation during surgery and and secondly, hard-on-hard articulating surfaces are getting more popular in all countries. Both of these hard-on-hard bearings, i.e. ceramic-on-ceramic and metal-on-metal, require a more precise positioning of the components not only because of the risk of dislocation but also because of specific risks that are directly linked to cup-to-neck impingement. In metal-on-metal articulation this is the amount of wear, which increases dramatically when cup-to-neck impingement does occur. Whereas in ceramic-on-ceramic articulations impingement leads to microcracks and chipping of ceramic material from the liner's rim. This material may get into the articulating surfaces resulting in third body wear. Furthermore, in both types of articulation, i.e. in metal and ceramic, each impingement is intrinsically tied to subluxation which produces rim loading on the opposite side leading to more or less damage of the highly polished articulating surfaces.

Hence, in extending Lewinnek's definition the safe-zone for component positioning should be considered not only as the range without dislocation alone but also as the range that allows a regular and undisturbed function of the entire prosthesis without impingement.

But how can such a safe-zone be achieved? In fact, the performance of a total hip prosthesis with respect to range of movement not only depends on component positioning but also on the prosthesis design. It is the technical range of motion that mainly characterizes the design-dependent performance of a total hip prosthesis system. The larger the technical range of motion is the larger

is the safe-zone that can be reached [1,5,9,7]. Therefore, a modern hip prosthesis should at least reach 120 to 130° in its technical range of motion. It should be noted that increasing the head diameter linearly does not result in a linear increase in the technical ROM because there is a leveling effect (Fig. 1). The same effect is also reflected in the safe-zones for the same range of prosthesis head diameters ranging from 22mm to 44mm (Fig. 2).

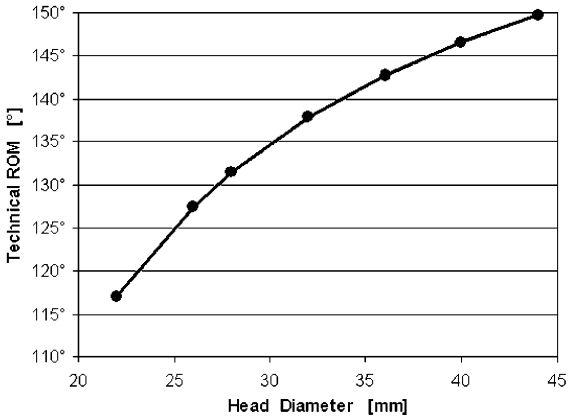

Figure 1:
The technical range of motion increases for bigger head sizes, but not linearly. The gain in ROM is smaller for larger heads although the head size increases stepwise in equal 4mm intervals.

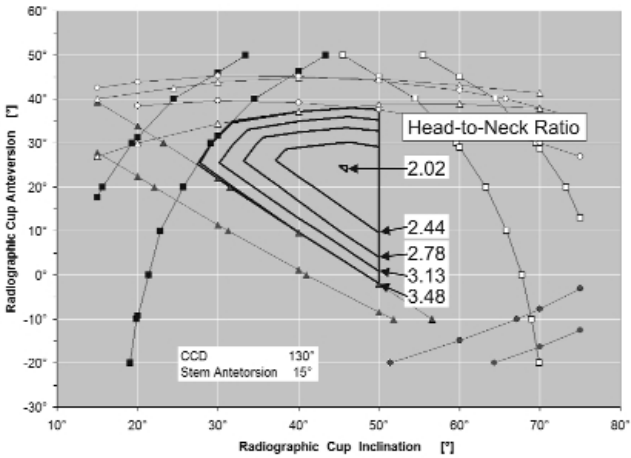

Figure 2:
The size of the safe-zone increases for bigger head sizes with higher head-to-neck ratio. Expansion of this zone is to all sides.

The position of the center of rotation relative to the opening of the cup does also have a high impact on the technical ROM [9]. Putting the center into the cup reduces the technical ROM by about 5° per mm for a 28mm head rendering the prosthesis more stable against dislocation and the opposite is true when the center is above the opening plane level of the cup. The latter makes it more vulnerable for dislocation. So, in reality the trade-off between ROM and stability against dislocation has to be resolved.

The safe-zone is not only correlated to the technical range of motion but also to the orientation of both components. It has been demonstrated that the relative orientation of both components to each other is important, not their

orientation to bony landmarks alone [7]. In particular the stem antetorsion and the radiographic cup anteversion are closely linked linearly [8]. Their sum should be held constant. This prediction has already been confirmed by clinical results [3]. The same is true for the cup anteversion and the CCD-angle but only for CCD-angles lower than 130°. Lower CCD-angle should be combined with lower cup anteversion. Therefore, an offset stem with a smaller CCD-angle requires less cup anteversion. Stems with CCD-angles higher than 135° have only a small or even no safe-zone for the intended ROM and therefore have a higher risk for dislocation [8].

Unfortenately, there is no universe recommendation on how to position the cup in order to maximizing the safe-zone. The size of the safe-zone is dependent on design and component orientation in a complex way. In fact, each prosthesis system has its own optimal safe-zone that can be computed. For a standard prosthesis having a head-to-neck ratio of 2.3 (28mm head on a 12mm neck) and a CCD-angle of 130° it is ideal to put the stem into 15 degrees of antetorsion and combining it with a cup in 25° of anteversion and 43° of abduction (center of rotation in the opening plane).

So, one has to state that yes there is a safe-zone for each prosthesis system but there is no such zone that is universally valid for all prostheses. Furthermore, the specific safe-zone can be optimized, i.e. maximized, for each prosthesis system in order to create room for errors in component orientation if ever needed. One should also be aware of the fact that by optimally positioning both components one can decrease the risk for impingement to nearly the zero level. But since component orientation is only one factor in the multifactorial dislocation event it is not sufficient to stick to the safe-zone alone but it has to be considered as a feature that is required among others. It does not guarantee a non-dislocating total hip arthroplasty.

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7.7 Tips of the trade: avoiding problems with ceramic components in THR

J. P. Garino

The large forces required to fracture ceramic components and the very low incidence of fractures is very encouraging, however this makes the assumption that the ceramic components are installed properly at the time of surgery and, in the case of hip replacements, that these devices are placed in the proper orientation.

The use of modern, modular ceramic components has increased dramatically over the past few years, particularly with the FDA approval of such devices in the USA. With this increased usage, there have been refinements in the technique of constructing the devices along with engineering improvements that have resulted in enhanced installation. But since these devices do not behave like polyethylene and in some ways are less forgiving it is important that the surgeon deciding to use ceramic components in a THR for a patient should keep several guidelines in mind to reduce the risk of complications.

Conservative neck cut

Compared with their metal counterparts, ceramic ball heads only are available in a very limited size range from approximately 0-mm to 8-mm. Larger ball head sizes, such as 36mm may have a larger range. Because a smaller range is available, it is advisable to use a conservative neck cut and remove more neck as necessary after initial trial reductions to properly restore leg length. With the use of metal ball heads surgeons occasionally would use extended length ball heads combinations with skirted extensions in order to reconstruct proper leg length or stability. Skirted ball heads are not available in ceramic and a conservative neck cut assists in avoiding problems with respect to the need for ball heads providing more than 8mm of length.

The Cup in a Horizontal Position

Ceramic-on-ceramic components, although very strong, are optimized for load bearing at 45° or less on the acetabular side to evenly distribute the forces over the greatest amount of surface area between the ball head and the cup. Because the greatest amounts of load take place with the hip in extension, placement of the cup in a more horizontal angle improves this load transfer. Minimizing rim overload with horizontal placement can potentially reduce any late chipping of the ceramic rim.

Increased Anteversion

With increasing horizontal orientation more of the cup is pulled from a posterior to a superior position leaving less posterior coverage as the horizontal orientation of the cup increases. The can be compensated for by increasing the anteversion of the cup. In addition, ceramic liners are not currently available with elevated lips like they are available in the polyethylene counterparts. Therefore further anteversion may be helpful in optimizing stability, particularly when using the posterior approach. Be aware that proper testing for stability is the key to optimize

patient function while avoiding impingement and dislocation. Proper and aggressive testing for anterior instability is critical, This is accomplished by bringing the leg into extension and external rotation.

Use of Trial Liners

The tapers on the cup and stem side of the articulation are to be used only once with ceramic components. Therefore it is very important that trial instruments be used for the liners and ballheads at the time of trial reduction and that proper manipulations of these trials take place before the final implants are opened. This may seem intuitive but many surgeons at the current time, because polyethylene is so user friendly, can impact the polyethylene liner into place and then move onto the femur without the use of trial components. If the ceramic liner is impacted and cup orientation is suboptimal, then disimpaction of the ceramic components can be very difficult, requires special instrumentation (although this instrumentation is available and it can be done successfully)and may damage the taper in such a way that reimplantation or impaction of a ceramic liner or head is not advisable. Once a surgeon is satisfied with the stability and range of motion with the trials, then he or she can comfortably move on toward impaction of ceramic pieces.

Removal of Osteophytes and Acetabular wall (when necessary)

Occasionally increased cup anteversion drops the anterior edge of the cup slightly below the top of the anterior wall or anterior osteophytes. In some instances, impingement on these anterior structures leads to a suboptimal degree of stability. In an effort to enhance the stability in this situation, careful resection of the bone responsible for impingement can be effective in optimizing stability. This maneuver may avoid the use of additional length or offset to achieve stability goals.

Placement of the Liner

The ceramic acetabular liner can be slightly difficult to place. The relatively gentle taper can allow for "cocking" of the liner in a malpositioned fashion. In the author's experience, tools included with the set to assist in placement of the liner have been suboptimal. Placement of these liners by hand is usually relatively easy and placement can be confirmed with a simple running of the finger around the rim to be sure that the component has been pressed evenly into the taper and that no area of the taper is deeper into the cup relative to any other area. It also is important to note that as the cup size increases the possibility to seat the liner incorrectly increases. Impacting the liner when improperly seated can lead to either difficult extraction or fracture of the component. Care should be taken at this time to ensure that the liner is seated carefully. Currently there are new tools for inserting the liner that are just becoming available which may be a great help as this task is becoming more difficult with the growth of minimal incision techniques. (Fig 1).

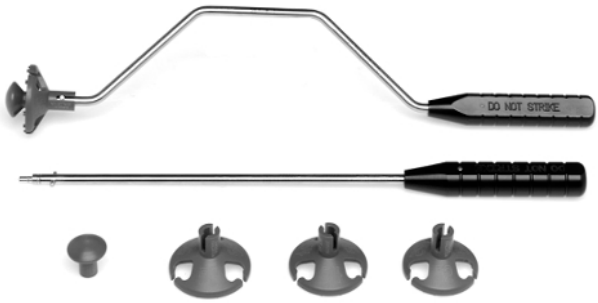

Figure 1:
Specially designed tool used to assist with ceramic liner insertion.

Ceramic Component Impaction

Currently, the tapers on the acetabular and femoral sides have been machined with numerous grooves, which on a microscopic level show a series of peaks and valleys. In order to meet the proper tolerances necessary for ceramics these grooves perform their function of maximizing the load transfer area in a very efficient fashion. When the ceramic piece is inserted and subsequently impacted there is a relative flattening of the peaks and a very even distribution of the forces throughout the entire surface area circumferentially around the taper of the ceramic piece. These pieces should not be simply twisted on or placed without impaction because they can subsequently shake loose or not undergo the full seating required to optimize their force transfer.

Summary

Ceramic on ceramic articulations in Total Hip Replacement have a long and reasonably successful history [2]. Shortcomings in these older designs primarily revolved around suboptimal cup fixation. Retrievals have shown low wear when properly implanted and when the alumina quality is high [3]. Revisions were relatively easy because osteolysis rarely was encountered. Ceramic-on-ceramic bearings in hip replacement at this early stage in the United States seem to be very promising. Although component fractures will always remain a concern and, as they have been in the past, the mechanisms of these fractures have been for the most part fully identified, and with modern technology and meticulous intraoperative technique these devices can be used with great confidence. With the reduction in wear of over 200 times that of metal-on-polyethylene a significant durable hip replacement with the potential for a service life spanning several decades now may be possible.

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SESSION 8

Future Applications

8.1 Direct to bone – possible ceramic solutions for monolithic hip implants

R. Burgkart, E. Steinhauser, M. Grässel and M. Kuntz

Introduction

In respect to minimal wear and optimal bioinertness ceramic-on-ceramic combinations for hip replacement are most favourable [2,3,9,11]. For insertion of such a system for a cementless acetabular cup nowadays a press fit metal back component will be implanted. In this shell the ceramic inlay will be inserted and seized by the conical geometry of both components. Because of the limited anatomical space in the acetabular region these implant constructs are restricted to ball diameters of 28 to maximal 36 mm. These technological limitations confine the range of motion (ROM) of the patient for maximal positions and can cause impingement, which can be followed by subluxation or even luxation. With metal-metal combinations smaller component thicknesses are already possible and thereby larger ball diameters realized. On the other hand the metal-metal combinations have the disadvantage of biological adversive effects of the metal wear as allergic reactions [1,7,8].

Aim of the study is the conception, basic development and evaluation of a new thin walled, monolithic ceramic cup for large ball diameters (>40mm) with an innovative, osteoinductive coatable macroporous surface to allow direct bony ingrowth. To realize this goal further development of a biological attractive surface structure and their technological production as well as an optimized cup design with highest product quality standards and safety features for the patient are necessary.

Methods

First a detailed analysis of the biological, technical and production engineering demands of the implant system will be realized. According to that profile the cup must provide a biocompatible macro structured surface to achieve by press fit a sufficient primary and finally secondary stability (optimal size of pores, stability within the porous structure and in the interface between porous surface structure and solid core, absence of toxic residues of the production process).

Furthermore research and development of techniques are necessary for a reproducible production process of the structured porous surface and handling of the implants with this structured surface. For this part of the study different technical approaches will be tested and biomechanically and biologically evaluated.

With specific biomechanical tests the overall stability as well as the stability of elements as the structured surface will be analysed. The tests will also include precise geometric measurements of possible biomechanical effect caused by the insertion process (deformation of the cup, effects of the operation tools on

the implant etc.) performed in anatomical specimen. If necessary according to the findings it is planned to develop new operation tools to avoid adversive effects and to optimize the insertion process for the surgeon.

The central biological question is to find the optimal structured ceramic surface features to ensure a quick sufficient bony ingrowth. For that as a first step systematic cell tests will be performed to exclude toxic effects of the new implant system. As a second step detailed biological evaluation of different implant versions will be analysed in respect of cell proliferation, differentiation, matrix production etc. Additionally different bioactive substances will be added on the ceramic surface to test the optimal cellular effects of these new combinations. Finally these extensive in vitro tests have to be validated by in vivo examinations using a sheep model for biomechanical stability testing as well as standardized histological evaluation.

To optimize the geometrical design of the cup implant for the greatest possible ROM and optimal stability to avoid luxations [6] detailed virtual 3D analysis including simulation of implant-implant as well as implant-bone impingement for common insertion position will be performed.

Preliminary Results

The developed ceramic Biolox® delta can already successfully tested in respect to its high structural mechanical strength and is therefore optimal to use for the construction of the proposed thin walled cup system. Also the biocompatibility and the outstanding tribological behaviour with minimal wear is proven for this ceramic substance [5,12].

First technological realizations of a prototype-like porous surface structure on the basis of Biolox® delta were achieved. This porous structure could be sintered – and therefore tightly integrated -to a solid thin walled ceramic core also made of Biolox® delta. The so far realized pore size ranges from appr. 150 to 400 µm.
Finally first preliminary biological in vivo tests in a sheep model have shown positive effects for bony integration without side effects [13].

Discussion

To provide the major advantages of ceramic-ceramic combinations also for large ball diameters in hip replacement the planned realization of a new thin walled, monolithic ceramic cup for direct bony ingrowth would be of high clinical importance. Technically such systems so far only exist as metal-metal combination with the known inherent disadvantages of possible allergic reaction in respect to the metal wear. All these problems could be avoided by the planned new ceramic implant system and the first technological as well as the biological results are very encouraging.

Nevertheless the known biological problems of former monolithic implants [4, 10] according to their reduced potential to provide sufficient bony ingrowth have to be extensive addressed by the planned study. To overcome these problems the proposed implant system is not only build out of a solid component but for the first time is covered by a porous surface. Beside that the bony ingrowth can be

enhanced by additional coating of bioactive substances as hydroxyapatit or bmp. If this strategy is technological feasible and biological successful the planned study have to give answers in this respect.

Another important area of intensive research in the proposed study has to cover the technical risks as reproducibility of the manufacturing, the biomechanical stability of the thin walled implant system under extreme and long term loading and – clinically very important - the degree of potential deformation of the cup and loosening of ceramic particles of the porous surface during the implant insertion. But according to the ongoing results during the planned study additional development of specific insertion tools can probably avoid these risks and can be thereby an important precondition for the success of such a new approach.

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8.2 Surface Activation of Implants

H. Mannel, D. Zukowski, A. Sewing and V. Alt

Introduction

The main problem in the clinical application of endoprostheses is the fixation of the implants in bone. Accordingly, J. Charnley introduced a secure, initial ('primary') fixation of the implant by cementation with polymethylmethacrylate [6]. Under certain conditions, however, bony integration of uncemented metal prostheses is possible and the majority patients with such endoprostheses are not restricted in any way in their daily lives. The anchoring process of cementless prostheses is a two-staged procedure. The so-called 'primary' anchorage describes the immediate, firm fixation of the prosthesis during implantation by press-fit or form-fit placement, respectively. By subsequent formation of new bone tissue at the bone-implant interface full load bearing capacity is achieved gradually, a process called 'secondary' fixation [9]. Nowadays ten-year survivorship of uncemented hip prostheses is about 87% with aseptic loosening (75%) and prosthesis-related infections (about 8%) being the main reasons for implant failure [43].

The cause of septic prosthesis loosening is bacterial colonization of the implant. A major infiltration of bacteria during surgery can lead to an acute postoperative periimplantitis within three months whereas a minor intraoperative infiltration often results in a late chronic infection within 24 months of implantation [7]. The chemotherapeutical eradication of such infections is severely aggravated by the formation of a protective slime matrix, the so called bacterial biofilm [17].

The exact causes of aseptic loosening of uncemented hip endoprostheses are unknown to date. Presumably, aseptic loosening is due to general foreign body reactions and bone resorption processes with the subsequent formation of a capsular fibrous tissue membrane. This poorly perfused 'scar tissue' elastically supports the prosthesis and, due to the lack of proper secondary fixation, might lead to implant failure [5]. Indicative of mid- or long-term aseptic loosening of total hip prostheses is the rate of implant subsidence within two years of implantation. Especially an ongoing steady-state migration or a sudden onset of subsidence after initial fixation are reliable indicators of beginning implant loosening [45].

Bioactive Coatings

In terms of excellent secondary fixation and maximum survivorship with minimum thigh pain best clinical results are reported for uncemented femoral endoprostheses with a wedge-shaped, tapered design [44]. In order to further improve bone ongrowth and bone ingrowth various surface modifications have been introduced. These modifications comprise a roughening of the surface (e.g. titanium plasma spray porous coating, sintered beads or porous mesh structures [67]) that results in a tighter interlock between the implant and the bone, the application of bioactive coatings or a combination thereof.

Relevant bioactive coatings for metal implants have been developed on the basis of bioactive glass/glass ceramics, calcium phosphate and bioactive molecules.

Bioglass and glass ceramic

Tissue bonding bioactive glasses are made of the components SiO_2, Na_2O, CaO and P_2O_5. Bioactive glass ceramics show in vivo almost no degradation and consequently are mainly used for load-bearing indications in reconstructive surgery [22]. Resorbable bioactive bioglass, however, is completely substituted by bone within 24 months at the latest. It is used as bone void filler and bone substitute under non-weight bearing conditions mostly in maxillofacial surgery [61]. Several attempts were made to coat metal implant with bioactive glass or glass ceramic. Results using plasma-spray techniques were rather disappointing with regard to the stability of the metal bond and osseous integration [30,40]. The use of enameling procedures might be a solution to overcome the problem of delamination but is still in a developmental stage [51].

Calcium phosphate coatings

Hydroxyapatite $Ca_{10}(PO_4)_6(OH)_2$ (HA) is the major mineral phase in bone. Consequently, numerous HA implant coating techniques have been developed only one of which, however, is of major clinical importance in orthopedics: HA plasma spray coating using a high temperature technique similar to porous coating of titanium (Fig. 1 left side). The biological activity of plasma spray HA coating is exemplary manifested by its capability to induce the bridging of even 2 mm gaps between an implant and bone and the conversion of fibrous tissue to bone around loaded implants [14,57]. Correspondingly, numerous authors report about the excellent clinical performance of HA coated endoprostheses in terms of minimum subsidence [14,56,62].

Major drawbacks of HA plasma spray coating are its thickness of 100-200 µm bearing the risk of delamination, the difficulty to coat complex shapes, the large size of the formed crystallites, the high content of amorphous calcium phosphate and the possible release of pieces HA that might cause excessive wear of the polyethylene components at the articulating surface of the artificial joint [8,49]. To overcome these problems several different HA coating procedures have been developed as for instance pulsed-laser deposition, sputtering, dip or spin coatings using a sol-gel technique and electrodeposition [21]. A very elegant method to obtain a HA coating on various surfaces has been developed by Kokubo et al. Many materials including for instance alkaline treated titanium that bear functional hydroxyl groups effective for apatite nucleation are coated with hydroxyapatite spontaneously when immersed in simulated body fluid (SBF), a solution highly supersaturated with calcium and phosphate A similar process of apatite nucleation is thought to happen in vivo when the respective materials come into contact with the body environment [32].

HA plasma spay coatings are, if at all, resorbed only very slowly. Resorbable calcium phosphate coatings can be obtained for example by coating with tricalcium phosphate (TCP) or brushite (BONIT® coating). In terms of bone-implant contact, biomechanical tests and clinical outcome, however, TCP coatings of titanium alloy in animal experiments or clinical application appeared to be not better or even inferior as compared to standard plasma spray HA coating [27,38].

A novel electrochemical process to obtain a high quality hydroxyapatite coating has been developed by Biomet Deutschland GmbH. The so called biomimetic BoneMaster® process is based on an electrochemical assisted deposition of calcium phosphate from a supersaturated solution under cathodic polarization of the sample. As the result of a nucleation and transformation process from an intermediate amorphous phase a thin hydroxyapatite layer is formed. The features of this layer are its thickness of only of 3-5 µm thickness and the needle-like crystallites of 300 µm in length and 60 µm in width that resemble the mineral phase of natural bone as closely as no other available HA coating (Fig. 1 right side).

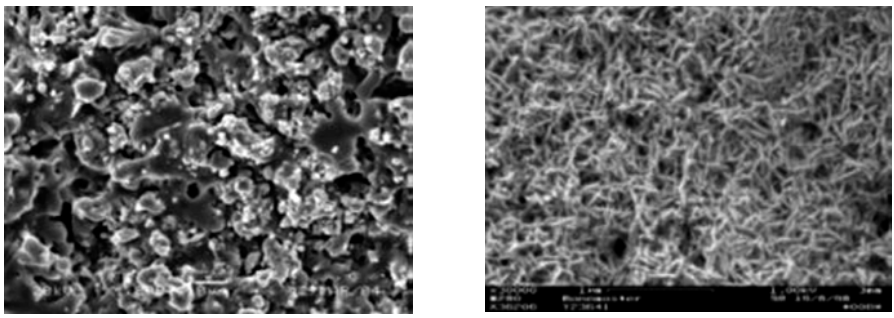

Figure 1:
Left side: Plasma spray hydroxyapatite coating (left). Right side: Surface of biomimetic BoneMaster® HA coating (Biomet Deutschland GmbH), please notice different length standard.

The coating procedure is carried out in an oversaturated Ca^{2+} / $H_xPO4^{(3-x)}$ - containing electrolyte, the driving force of calcium phosphate precipitation being a pH rise at the cathodic polarized surface of the implant. In this area, the pH-dependent solubility product is exceeded, resulting in precipitation at the implant surface. Thus, as the procedure progresses, a layer is formed over an amorphous transient phase to a porous hydroxyapatite layer of the above characteristics [50]. The hydrogen developed during the electrochemical process causes no hydrogen embrittlement of the titanium substrate, as could be shown in fatigue tests under cyclic load in comparison to uncoated samples.

The coating procedure is performed under near physiological conditions which allows the incorporation of biomolecules into the coating. At the implantation site the coating is in equilibrium with the body environment, thus reducing solubility and precipitation processes to a minimum. Due to the size of the crystallites in the layer, which are bigger only by one order from the size of hydroxyapatite crystallites in bone, the coating is subject to the normal transformation processes taking place in the body and can, therefore, be converted to natural bone tissue in the long-term.

Grit-blasted or porous titanium coated standard implants have a surface topography that is significantly rougher than the HA coating. The BoneMaster layer, therefore, does not need to fulfill load-bearing properties, giving another advantage over the relatively thick HA plasma-sprayed layer which as a comparatively fragile material, must transmit load between the elastic bone material and the rigid implant. Consequently, the mechanical integration of a coated implant therefore is still given by the surface topography of the implant and not by the coating as a brittle intermediate layer.

In-vitro cell adhesion measured by a colorimetric enzyme assay [35] showed significantly higher adhesion rates for the BoneMaster coating as compared to uncoated control samples for MC3T3-E1 mouse osteoblasts (Fig. 2). Cell morphology of MC3T3-E1 cells after one hour of adhesion was observed in SEM. The cells started spreading on the surface form its initial sphere like shape and exhibits already strong interaction with the hydroxyapatite layer by small filaments penetrating the porous structure (Fig. 3).

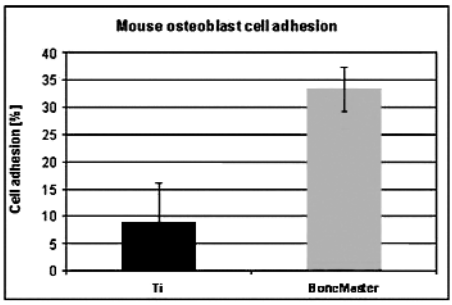

Figure 2:
Cell adhesion of MC3T3-E1 mouse osteoblasts on BoneMaster HA coating.

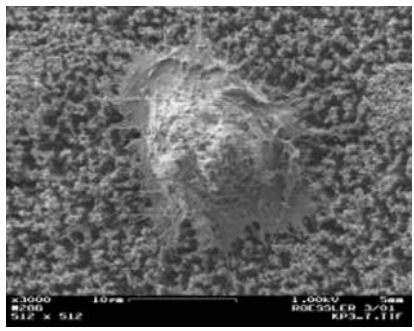

Figure 3:
SEM micrographs of a MC3E3-E1 mouse osteoblast on a BoneMaster Surface after one hour of adhesion.

In the follow-up to cell experiments, histological and biomechanical characterizations in a canine and rat model revealed significantly more peri-implant bone formation and bone/implant contact as well as significantly better biomechanical parameters for the BoneMaster coated samples as compared to uncoated ones. Additionally, the formation of a fibrous capsule around the implants was prevented completely [54,55]. To date the BoneMaster coating is in clinical evaluation with excellent results (unpublished).

Antibiotic coating

Due to infection susceptibility combined with tremendous complications of periprosthetic joint infections including amputation and joint resection end stages [68] high efforts are undertaken to prevent the development of periprosthetic joint infections. Beside unspecific general surgical efforts to reduce the risk of infection the use of local antibiotics is of special importance.

The principle of local antibiotics is to achieve a high local and bactericidal antibiotic concentration at the region of interest combined with low systemic concentrations and, therefore, with a low risk of systemic side effects. This concept has already been realized in the case of cemented joint replacements [64]. Gentamicin (trade name Refobacin™) penetrates bone tissue well, and is a swift, effective bactericide against gram negative bacteria. As extensive studies have shown, the application of PMMA bone cement with addition of gentamicin, results in significantly lower septic loosening rates and prolonged durability of the prostheses. In accordance with theses findings, the use of antibiotics in PMMA bone cement has been accepted as the general standard application in joint replacement and in about 90% of the cemented implantations in Europe, bone cements containing gentamicin are applied [11,12].

In cementless total joint arthroplasty the principle of local antibiotics could not be established in all day clinical use yet despite the fact that HA-coated implants bear a higher infection risk compared to uncoated implants [63]. Lucke et al. reported in two studies about gentamicin-coated titanium implants in a rat infection model which significantly improved infection prophylaxis compared to uncoated titanium K-wires [41,42]. Stigter et al. were the first to report on incorporation of tobramycin into HA coatings of titanium implants using a "biomimetic" coating technology at 37°C with deposition of amorphous calcium phosphate on titanium followed by immersion of the implants in a supersaturated calcium phosphate solution containing tobramycin [60]. They reported more favorable in vitro release kinetics of tobramycin of this biomimetic coating technology compared to simple soaking of tobramycin onto plasma sprayed HA. The latter has been reported to result in an unfavorable fast release of the antibiotic, e.g. for vancomycin [47]. The successful incorporation of different antibiotics into biomimetic HA coating in vitro is documented [59]. However, no animal study challenging these antibiotic coatings at in vivo conditions has ever been published and the concentrations are quite low in comparison to PMMA bone cement.

An effective antibiotic protection should last for at least six hours after prosthesis implantation [16]. However, the salt gentamicin sulfate, which is used as the standard pharmaceutical form of gentamicin, is a very water soluble substance, making it difficult to obtain release kinetics at the implantation site above sub-inhibitory levels for six hours. Therefore, gentamicin crofebate is additionally used; a yellow, poorly soluble salt that is already clinically well-established in other local antibiotic carriers on a collagen basis [23]. For the BIOMET antibiotic coating the concentration of gentamicin to be applied per square centimeter of implant surface is calculated to 250 µg based on the experience with gentamicin loaded PMMA cements depends. The two gentamicin salts are each applied in their pre-defined amounts onto the prosthesis surface, so that the respective surface concentrations can be guaranteed.

Sample specimens were tested in animal studies for the efficacy of the BIOMET antibiotic coating. The uncoated and coated samples were implanted together with a large inoculum of Staphylococcus aureus in the tibia of rabbits. None of the animals that had been implanted gentamicin coated specimens acquired a bone infection. In contrast, 88% of the animals that had been implanted uncoated specimens showed a manifest bone infection (Fig. 4).

The clinical benefit of an antibiotic coating prophylaxis for endoprostheses is obvious. For the affected patient each prosthesis-related infection is a catastrophic development that may lead to extensive health impairments and consequential damages. But also from the perspective of the health economy, every effort must be made to avoid expensive septic revision surgery as far as possible. We, therefore, presume that in the mid to long-term the usage of antibiotic-coated prostheses will advance to become an equal standard application as the antibiotic-containing PMMA bone cements.

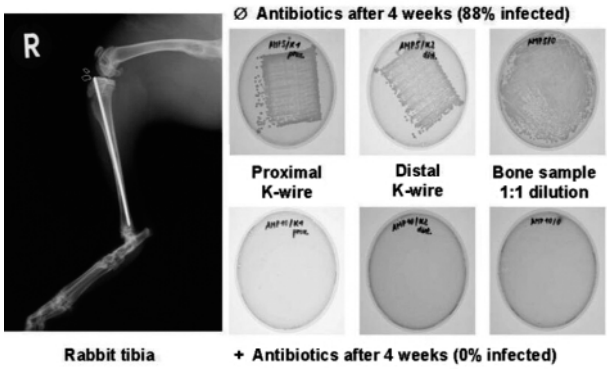

Figure 4:
Detection of bacteria in the bone of infected rabbit tibia after implantation of specimens without (top) and with (bottom) gentamicin coating. The occurrence of bacteria in the bone material is shown in the development of a dense bacterial population.

Bioactive molecules

Several attempts to bind bioactive molecules to implant surfaces have been described. The incorporation of growth factors such as insulin like growth factor, transforming growth factor or bone morphogenetic proteins (BMPs) into a biodegradable coating of poly-(D,L-lactide) has already been tested in vivo for biocompatibility, efficacy and retained biological activity [66]. Hyaluronic acid was also used as a carrier system [1]. Any carrier coating on a prostheses, however, raises concerns with regard to possible foreign body reactions and impaired osseous integration. Consequently, coating techniques that bind bioactive molecules directly onto the implant surface are of special interest. Calcium phosphate precipitation techniques run under nearly physiological conditions allow to co-precipitate proteins into the coating [65]. Such coatings have been shown to maintain the biological activity of incorporated BMP-2 [39]. To bind recombinant human BMP-2 (rhBMP-2) directly to commercially pure titanium a method has been established that first modifies the titanium by treatment with chromosulfuric acid [26]. Such immobilized rhBMP-2 was effective in promoting osseous integration and gap-bridging of titanium implants in both rabbit and sheep and was even superior to soluble rhBMP-2 in terms of fibrous capsule formation [37].

BMPs, however, always bear the risk to promote bone growth in areas that are free of bone tissue cells and where bone formation is not supposed to occur, a phenomenon that is described as ectopic bone growth. This is because BMPs are able to induce the differentiation of stem cells to bone tissue cells and moreover, cause the proliferation of present and newly-formed bone tissue cells. Systemically distributed BMP can cause new bone formation in other organs, particularly in the kidneys, which may lead to severe health damages [19,48].

RGD coating

The RGD motif (arginine-glycin-aspartate) is known to be present in a multitude of proteins of the extracellular matrix and serves as a ligand for cellular integrin receptors. The specificity with which an integrin receptor recognizes its corresponding RGD ligand in the extracellular matrix, e.g. in the vitronectin molecule, depends on the amino acids flanking the RGD group and/or the steric conformation of the RGD group [24]. The synthetic conformationally stabilized

cyclical peptides c(RGDf-N(Me)V)[1] and c(RGDfK)for instance are integrin ligands specific for the $\alpha_v\beta_5$ and $\alpha_v\beta_3$ integrins of endothelial and osteoblast cells, respectively [52].

To enable the binding of the osteoblast specific peptide c(RGDfK) to different surfaces, the molecule is attached via a chemical spacer to an anchor group specifically synthesized on the respective implant material. The so-called acrylate anchor e.g. principally is for binding to PMMA [53], while the thiol anchor and the so-called phosphonate anchor are particularly well-suited for binding to titanium [2,3]. The peptide c(RGDfK) with a phosphonate anchor produces a coating of only 7 nm thickness with a coating density of about 250 pM/cm^2 on Ti6Al4V. It is bound by adsorptive mechanisms to the implant surface, but nevertheless, the bond is so strong that the c(RGDfK) coating cannot be removed by ultrasound or treatment with nitric acid [2].

Bound via the anchoring group to the implant, the active c(RGDfK) group is present in a steric conformation that is recognizable by the integrin receptors of the osteoblasts (Fig. 5).

The improvement of cell adhesion of a mouse osteoblast to Ti6Al4V after coating with c(RGDfK) is illustrated in Figure 6. A cell on an uncoated surface cannot spread out completely it seems, but rather resembles an egg with a round elevated 'yolk' in the centre. In contrast, with a c(RGDfK) coating, the cell has accepted the surface and, as indicated by the image below, stretches out flatly on the surface like a cow-hide.

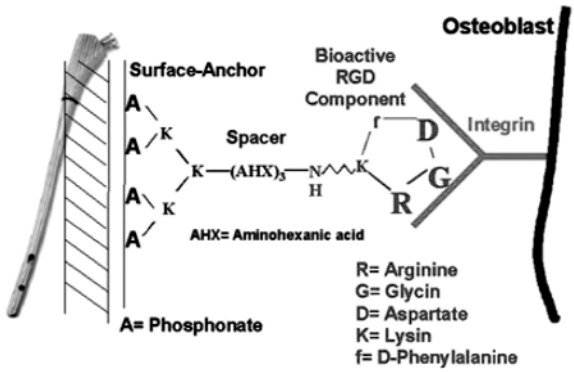

Figure 5:
The peptide c(RGDfK) bound via an phosphonate anchoring group to the implant, is recognized by the integrin receptor of an osteoblast.

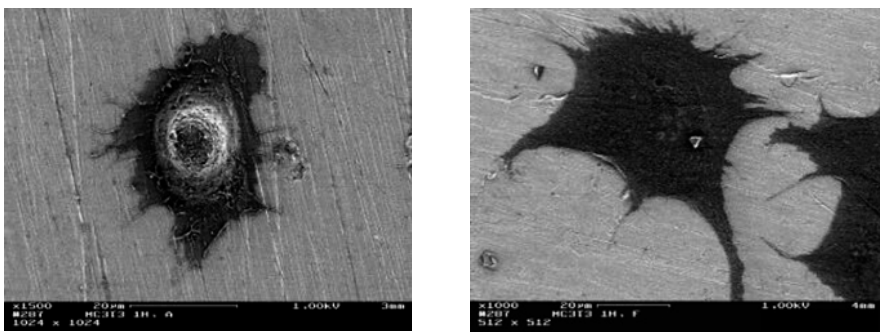

Figure 6:
Cell adhesion of a mouse osteoblast to titanium without (left) and with a c(RGDfK) coating (right).

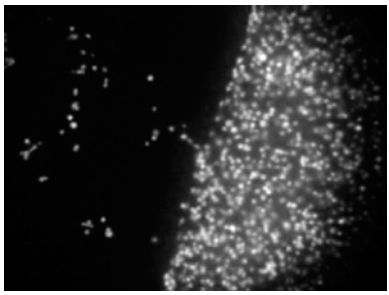

Figure 7:
Cell adhesion of mouse osteoblasts to a Ti6Al4V surface that was coated on the right part with c(RGDfK). Separated as it seems by a marked line, the cells on the left part bind to uncoated titanium only insignificantly.

However, not only the binding property of the individual osteoblast cell is changed, the number of osteoblasts that adhere to a c(RGDfK)-coated surface increases as well (Fig. 7).

Further results have verified that a c(RGDfK)-coated surface can significantly increase the adhesion of osteoblasts as compared to fibroblasts [2].

In animal studies it was investigated whether the enhanced binding of osteoblasts compared to fibroblasts actually leads to better histological and biomechanical results in vivo. An example of the results from an implantation experiment are given in Figure 8. Around the uncoated implants, there is a connective tissue lining, stained red, while the c(RGDfK)-coated implants show bone ongrowth stained green. Similar histological results are seen in different experiments with rabbits and dogs that additionally prove the higher mechanical stability of the c(RGDfK)-coated specimens and the absence of local and systemic adverse reactions [3,10,53,58].

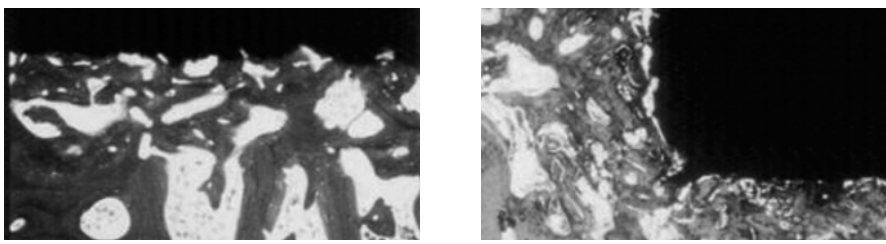

Figure 8:
Implantation of grit-blasted Ti6Al4V specimens (left) with and (right) without c(RGDfK) coating in the tibia of sheep. The histological preparations were double-stained with dyes for bone tissue and connective tissue.

The formation of new bone tissue that is promoted by the coating is restricted to the bone-implant interface and the adjacent environment. Since there is no release of the surface-bound peptide, its effects are not observed other than in the immediate vicinity of the coated implant. There is no occurrence of undesirable bone formation such as excessive growth of new bone tissue or transformations in bone structure in any of the studies. This is a marked distinction between the c(RGDfK) coatings and the BMPs. Surplus, the production of the much smaller c(RGDfK)-phosphonate peptides is completely synthetic and much more cost-effective than the synthesis of the complex and big BMPs.

Given the higher initial mechanical stability that was achieved, along with the reduced formation of fibrous connective tissue around the implant, it is justified to assume that RGD-coating of orthopedic implants will result in even less failure rates of joint replacements than can be observed to date.

Bioactive coatings for ceramics

There is considerable effort to improve osseous integration of classical ceramics made of Al_2O_3 ZrO_2 and zirconia-alumina composites which in itself are bioinert. One attempt is to generate porous surfaces [28,46]. Most of the work to obtain bioactive coatings is done with bioactive glass [18,20,34] and glass ceramics [4, 25]. The major problem of such coatings is to obtain a tight bond between the base material and the bioactive coating. In terms of shear strength glass ceramic coatings seem to be superior coatings with bioactive glass [13]. Some of these coatings have been tested in animal models and is was shown that load-bearing implantation resulted in improved osseous integration whereas coated implants under low loading revealed no improved biomechanics and tended to be encapsulated within a fibrous membrane [15,18,25]. Another approach is to obtain bioactive ceramics by addition or coating with calcium phosphate and in particular HA. Porous zirconia or zirconia-aluminum composites doped or coated with calcium phosphate showed in-vitro bioactivity in terms of enhanced alkaline phosphatase activity of osteoblast-like cells [29,33]. The above described method of using SBF in order to spontaneously precipitate HA on implant surfaces has also been applied to gels made of alkaline treated ZrO_2 and Al_2O_3. Whereas the obtained Zr-OH groups were effective to induce nucleation of apatite in SBF the Al-HO groups were not. The latter might explain the observation that in vivo alumina implants are separated from bone by an intermediate layer of fibrous tissue [31,36].

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8.3 Application of Bone Morphogenetic Proteins on Solid Implants

J. A. Mollenhauer, K. D. Jandt and P. Hortschansky

Abstract

Bone Morphogenetic Proteins (BMP) induce and propagate skeletal wound healing. They enable osteoinductive mechanisms. Applied in combination with osteoconductive solid implant materials, BMP might accelerate and enhance bone regeneration even in individuals with compromised bone metabolism, such as osteoporotic or elderly patients. Presently, soluble BMP released from rapidly degrading carriers such as collagen is favored. Here we present structural and functional aspects of bioactivity from small quantities of implant surface-fixed BMP, potentially resulting in a more controlled topical action. Solid implants such improved may prevent untoward effects from overdosing and may exhibit better storage properties than present preparations of BMP.

Introduction

Skeletal healing in trauma and implant surgery is chiefly attained through endogenous spontaneous regenerative processes in the patient. This is also true if various resorptive or stable implant materials are applied such as collagen sponges or metal implants. Secondary modifications of implanted materials such as the introduction of hydroxyapatite or chitosan [9] may improve healing by exhibiting so-called osteoconductive properties. The expression is merely descriptive and stands for the observation that bone grows towards such materials, to finally generate a bone structure oriented towards the implant. In the absence of competent cells, as may occur in patients with advanced age, osteoporosis, or otherwise impaired physiological healing even an osteoconductive implant will not initiate proper skeletal healing. In such cases, supportive metabolically active implants (such as demineralized bone powder) or medication (for example with anti-osteoporotic drugs) may overcome a number of problems. With the advent of recombinant technology, an extented perspective has been opened to include pure recombinant proteins into the small list of available stimuli for bone healing, among them proteins from the TGF-ß family such as the bone morphogenetic proteins, BMP.

BMP belong to a small group of tissue hormones which have been successfully introduced into medical applications. They are in particular applied in orthopedic and trauma surgery as a means to improve fracture healing or to initiate spinal fusion. While the interest in BMP originates from the properties of demineralized bone powder to support bone growth, modern BMP preparations are advanced biotechnological products carrying molecular features that are not present in the natural BMP as they are stored in the tissues. Secondary modifications such as the omittence of glycosylation to alter hydrophobicity or the exchange of amino acids to enhance folding or chemical stability generate sophisticated products that are then converted into galenic preparations with quite diverging properties.

In the following, a particular focus will be put on the philosophy to apply BMP as carrier-surface located bioactive compounds rather than single molecules released from a storage carrier.

Natural structural surfaces presenting BMP

Demineralized bone powder is a widely amorphous mass of collagens, proteoglycans, and glycoproteins of the bone minus the calcium phosphate minerals originally providing for the texture and topical organization of the tissue. As a consequence, embedded tissue hormones also are present as unstructured elements, being released only through random degradative processes. Since the carrier molecules (collagens and other extracellular matrix (ECM) proteins) are in part or completely denatured, degradation is uncontrolled, untoward and fast. The dimension of BMP concentration in storage tissues is somewhere in the range of 1 to 100 ng per gram tissue. Therefore the entire human body does not contain much beyond a few microgram of BMP, all of them included. The native tissues, however, contain BMP in a topically organized fashion, concentrated on the surface or in the core of collagenous fibers of the ECM (Fig. 1) or on the interface between cells and ECM (Fig. 2).

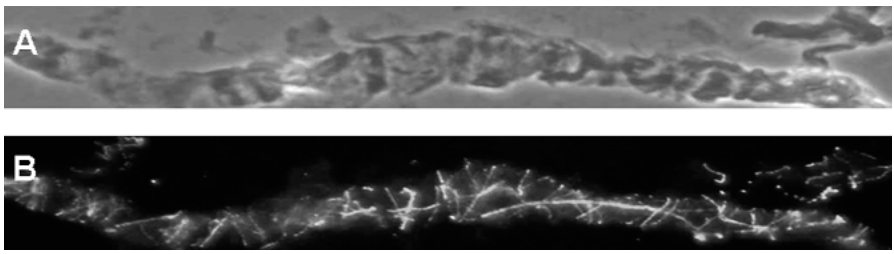

Figure 1:
Localization of BMP-2/4 on connective tissue fibers of a rat growth plate. A: phase contrast image; B: indirect immunofluorescence with a monoclonal antibody against BMP-2/4. Note the segmental arrangement of BMP-2 related fluorescence to discrete sites of the fiber.
Objective magnification: 100-fold.

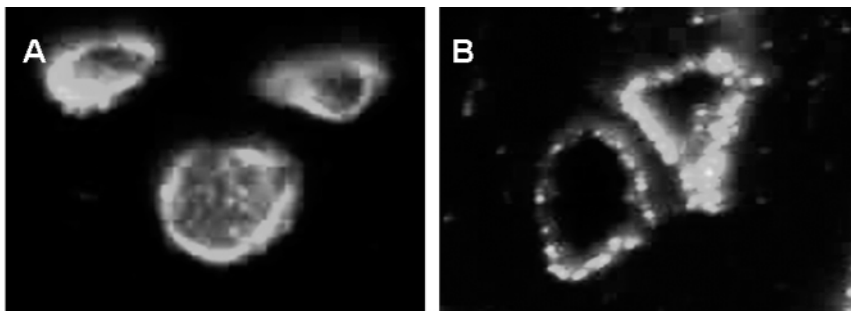

Figure 2:
Localization of BMP-2/4 in cartilage by indirect immuno-fluorescence (antibody as in figure 1). Objective magnification 63-fold. A, B: different focus levels. Note that the BMP is located almost exclusively in the immediate vicinity of the chondrocytes.

The tissue distribution as described in the two figures can also be found elsewhere in tissues storing BMP. In other words, the hormones are highly concentrated. In the example of cartilage, it can be estimated to be at least 100 times more concentrated than the mid-nanogram range suggested by the content of biochemical tissue extracts [1], being in the microgram range, at least. Cells being in the vicinity of such storage sites will therefore be able to saturate the BMP receptors on the cell surface by contacting those sites. As a consequence, a maximum stimulus will be signaled into the cell, irrespectively of the average BMP concentration of the ECM. Presentation of the receptor binding BMP domains may be facilitated during wound healing by selective (partial) degradation of ECM components harboring the hormones but direct contact may occur, as well, as detailed in the text below.

Recognition of surface-bound BMP-2 by soluble BMP receptors

Several technical options exist to probe receptor-ligand pairing on solid surfaces. From those, we applied two: surface plasmon resonance technology (BIAcore®) or enzyme-linked assays (ELISA) with one reaction partner being biotinylated. The first approach will give direct data on affinity constants, the latter allows to quantify BMP, in this case alternatively on solid surfaces by direct binding of the biotinylated receptor, or by inhibition approaches using reference BMP as competing ligand. In order to facilitate working with BMP receptors, we generated a truncated and therefore water-soluble version carrying only the extracellular domain responsible for BMP binding [12]. Corresponding to the recombinant human (rhu-) BMP-2 explored here, the receptor was ALK-3, the high affinity type I receptor for BMP-2.

The apparent dissociation constant obtained through the BIAcore® experiments was about 1 nM, as expected [7]. Important in this context is the fact that the experiment could be done by either coupling the receptor to the sensor surface and offering soluble rhu-BMP-2 which represents the configuration tested by most experiments that offer soluble BMP to cells and tissue [2,3,4] or by inversing the procedure by binding the rhu-BMP-2 to the chip surface and offering the receptor in solution, what leads to a reduction of the affinity (K_D of approx. 45 nM [11]) due to the lacking avidity effect from the homodimeric BMP. Nevertheless, the biotinylated ALK-3 was capable to detect rhu-BMP-2 on the surface of a disk of hydroxyapatite (HA)-coated Ti6Al4V alloy (Fig. 3), as measured in the ELISA procedure. In other words, the experiments prove the concept for receptor recognition towards bound ligand.

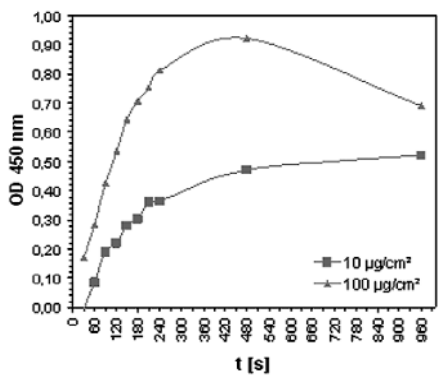

Figure 3:
Biotinylated ALK-3 binding assay with rhu-BMP (10 resp. 100 µg/ cm^2) coated on hydroxyapatite(HA)-Ti6Al4V alloy. The rhu-BMP-2 has been dried down onto the implant model out of a salt-free solution in acidic 50% acetonitril. The detection was performed with avidin-horse radish peroxidase.

The biologic consequence of BMP recognition on solid surfaces by its receptor can be dramatically demonstrated in a quite simple experiment. The mesenchymal precursor cell line differentiates into bone when exposed to BMP-2 [5]. Alkaline phosphatase neo-expression can be utilized as a marker for this event. We applied a small quantity (0.5 µg) to the surface of a 6 cm- tissue culture dish in the shape of a cross by drying a salt-free BMP solution onto the dish (Fig. 4). The area covered by the lines of the cross is about 40 mm^2 leading to a rhu-BMP-2 density of approximately 12.5 ng per mm^2. If one assumes an approximate area covered by one cell of about 100 μm^2 and a perfectly flat surface, then one cell was exposed to about 1 pg of rhu-BMP. The total amount of BMP-2 administered in this experiment was too low to induce significant differentiation if dissolved in the culture medium which amounted to a total of 15 ml over the course of 6 days.

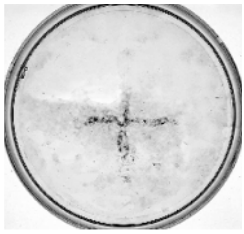

Figure 4:
Differentiation pattern of a confluent monolayer of undifferentiated C2C12 precursor cells on a 6 cm diameter tissue culture dish coated with 0.5 µg rhu-BMP-2 in the shape of the visible cross. Differentiated osteoblastic C2C12 cells were detected by an insoluble blue reaction product of alkaline phosphatase made by the differentiated cells. The original coating was in the cross-shape highlighted by the differentiation process. Note that the intensity of differentiation outside this area is almost neglectable.

BMP-2 release from solid surfaces

The methods for application of BMP to solid surfaces are quite unsophisticated and range from dipping implants into solutions containing BMP [14] via mixing the hormone with crosslinked collagen followed by freeze-drying [9] to air-drying a defined amount of solution onto a solid surface [12]. The first procedure does not allow to pre-define the amounts of BMP actually present whereas the latter ones do. As shown above, drying does not negatively affect bioactivity. Release is influenced by at least three main parameters: degradative resorption of the carrier (as for collagen), and solubility and affinity of BMP to a given carrier. The next experiment demonstrates the role of affinity to a carrier. We coated the HA (Camceram®) with our non-glycosylated rhu-BMP-2 and with a glycosylated commercial preparation (InductOS®, Wyeth). The release was measured with an ELISA based on monoclonal antibodies to BMP-2. As seen in Figure 5, the glycosylated variant displays a rapid release kinetic whereas the nonglycosylated variant remains almost completely on the implant material. This suggest that non-glycosylated BMP-2 acts as a topical agent whereas the glycosylated variant may also function as a paracrine hormone. There is another interesting aspect: when correcting for actual surface area, the macroscopic surface area of an implant is significantly enlarged by the roughness contributed by HA. In our hands, the surface corrected for HA was 30 times larger in the 1-micrometer scale than in the macroscopic scale of the milled titanium alloy, giving rise to actual molecular BMP distributions after drying of the coating solution resembling those installed in the in vitro experiment with the C2C12 cells. Also, only 1 percent of the amount of BMP was needed to achieve a significant effect on implant healing [12]. In combination, this results in significant reduction of the risk for overdosing

and the costs for doting an implant with BMP, compared to the quantities needed in approaches with resorbable BMP or with wet coating procedures.

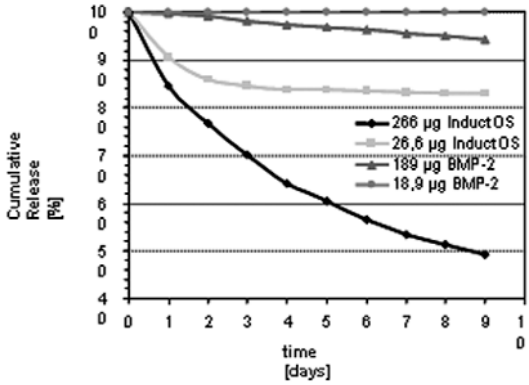

Figure 5:
Release kinetics of glycosylated (InductOS) versus non-glycosylated rhu-BMP-2 from HA. The graph presents the accumulation of soluble BMP in the buffer (1.2 ml) supernatant. The amounts of BMP coated to 50 mg Ha powder are equimolar, therefore the glycosylated BMP is present in higher quantities. The larger of the two quantities causes a build-up of several layers of BMP molecules on top of each other whereas the smaller quantity is mainly associated directly with the HA mineral.

Topical versus paracrine BMP activity

Deduced from the examples given before BMP may act as a paracrine hormone to regionally recruit competent cells and induce osteogenesis, or as a strictly topical agent giving rise to pattern formation, or as a combination of both biological processes, depending on the galenic presentation. In addition, different release kinetics may additionally shift inductive pathways via influencing the timeline of cellular differentiation.

As a commonly reported feature, solid implant conjugated BMP intensifies osteoconductive properties [6,12,8,14]. In other words, one may assume steep gradients of BMP towards the implant surface or even signal cascades reaching from individual cells being in direct physical contact with the immobilized BMP to cells in the vicinity without direct contact to BMP.

In contrast, solubilized BMP may reach a larger number of recruitable cells across the implantation site [10,11,13] but at the same time may increase the risk of overdosing or even attracting BMP-dependent tumor cells [2].

Conclusions

Solid surface bound BMP represents an economic and pharmacologically controlled way of local stimulation of bone growth and skeletal regeneration. It therefore may reduce the risk of untoward side effects and bring the costs of application to an affordable level, thus critically reducing the threshold for application in clinical standard procedures.

Acknowledgements

This work was supported in part by grants from the German Federal Ministery for Education and Research (BMBF), and by structural support from the Jena Organisation for Biomaterials (JOB).

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8.4 Future applications in ceramics

P. Merkert and M. Kuntz

Introduction

High performance ceramics have been successfully applied in hip arthroplasty for more than 30 years. It is thus the material which refers to the longest experience of bio-compatibility and wear resistance. Remarkably, it has been shown that explanted ceramic components of more than 25 years implantation duration do not show any indication of degradation, ageing or noteworthy wear.

BIOLOX® *forte* is the most widely used material for hip arthroplasty in the world. It is produced of synthetic, fine grained high purity alumina with minor amounts of sintering aids. For standard applications like ceramic ball heads and inserts the material provides a competitive solution of high reliability and excellent wear resistance. It has been the challenge for ceramic engineers to develop an improved material which maintains all advantageous properties of BIOLOX® *forte* but allows new applications which require high mechanical loading bearing capability. The result is a composite material on the basis of an alumina matrix (82 vol %) and a selection of ingredients which increase toughness and hardness [1]. As a first step of introducing the new material BIOLOX® *delta* into the market a variety of standard hip components (ball heads and inserts) were launched. Meanwhile, it is proven that the superior properties of the alumina matrix composite are successfully put into practice [2,3]. Thus, the door is open for new challenging applications which will in general be based on BIOLOX® *delta*.

In this paper an overview is given about future applications with high performance ceramics. New products or improved design solutions will be launched wherever the advantageous properties of ceramics provide better performance of the artificial joint. In particular, focus is given to integrated solutions, i.e. optimised interaction of the ceramic components to the respective environment – including biological or artificial interfaces and surgical instruments.

Large Ceramic Hip Joints

For a long time a ball head diameter of 28mm has been the most widely applied standard in hip replacement. The large difference in size to the natural joint allows the use of a modular system with comparatively thick walled components. On the other hand, the prospects of success of an artificial joint are increased when biomechanical requirements are respected. Even for everyday requirements of patients with a normal level of mobility the performance of the artificial joint is significantly improved with a higher range of motion (ROM). The most effective approach for increasing the ROM is the use of larger diameters.

Improvements in the design of the modular hip system today for most patients (in particular in the western world) allows the use of 32 or 36mm. Further substantial expansion requires new solutions for the interface of the insert to the

bone in order to maintain the outer diameter of the system. There are 3 different approaches towards this goal currently being developed at CeramTec:

1. Thin walled modular system with taper fit fixation
2. Hybrid ceramic-metal monoblock
3. Full-ceramic acetabular component with direct-to-bone interface

Figure 1 visualizes the intended solutions where the interface to the bone is provided by a metal component based on titanium.

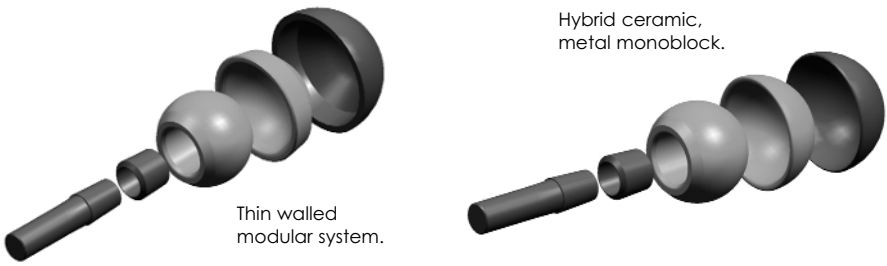


Figure 1:
New solutions for larger hip systems with metal interface to the bone.

The thin walled modular system is adapted from current conventional systems with taper fit fixation of the ceramic insert inside the metal shell. The aperture angle of the insert taper will be adapted to the individual geometry of the system. With the material BIOLOX® *delta* a wall thickness of 2,5 – 3 mm is applicable. It is also anticipated that an appropriate wall thickness of the metal shell is in a comparable range. The high strength of the alumina matrix composite provides high load bearing capability and reliability of the artificial joint. According to current concepts a ball head diameter of 40 – 44 mm can be accomplished based on such systems. Taking into account the geometric boundary conditions the outer diameter of the metal shell can be limited to 52 – 60 mm. It is thus expected that this system is applicable to an appreciable amount of patients with adequate anatomic precondition.

Further increase of functional will be possible with a hybrid ceramic – metal monoblock. A permanent assemblage of metal shell and ceramic insert will be directly provided to the surgeon. The insertion takes place analogous to the well known handling of a conventional metal shell albeit special tool for positioning and manipulating the monoblock will be used in combination with this new system. The assemblage of metal shell and ceramic insert in this case is not based on a taper fit but rather on a sophisticated physical shape fit. The accumulated wall thickness of the hybrid solution can thus be further reduced in comparison to the taper fit system. A functional diameter up to 48 mm will be realized with the hybrid monoblock hip joint.

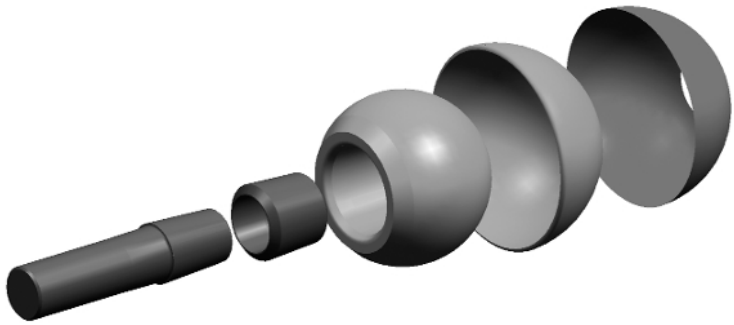


Figure 2:
Ceramic Acetabulum shell with "Direct-to-Bone" interface.

The "high-end-solution" of this concept will be achieved when the ceramic can be directly integrated to the bone. It is well known that a successful osseo-integration requires chemical and mechanical compatibility of the implanted component to the bone tissue. Mechanical compatibility is provided by a tailored "interphase" with an interconnecting pore structure of adequate pore size distribution and a transient reduction of stiffness. Chemical compatibility is realized by an functional activating treatment of the accessible ceramic surface inside the porous structure. First animal tests with full ceramic load bearing components have been successfully accomplished.

Ceramic Knee Prosthesis

In artificial knee replacement the load situation to the prosthesis material is substantially different in comparison to the hip. In particular, from the engineering point of view the condyles have to be considered as curved cantilevers under bending load. Obviously, this load situation requires advanced material properties as provided by the alumina matrix composite material BIOLOX® *delta*.

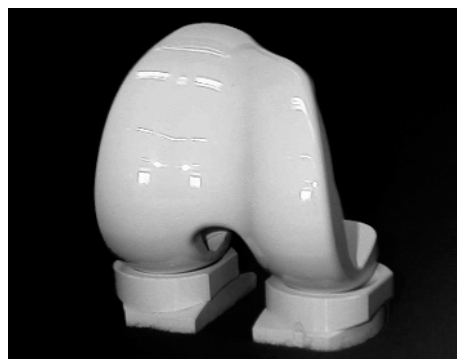


Figure 3:
Full ceramic knee prosthesis.

It is anticipated that the greatest wear reduction will be achieved using a full ceramic system, i.e. femur, tibia and tibia liner are produced by ceramic. A prototype is shown in Figure 3. However, it is intended to launch the new products in 3 steps.

1. Replacing the metal femoral component by a full ceramic component in a conventional knee joint.
2. Ceramic femoral and tibia component with a PE liner.
3. Knee joint with ceramic femur, tibia and liner.

Within the first step, the femoral knee component is now already available for clinical observation. It has been developed with selected partners adapting the design from an established mobile bearing knee prosthesis. Only marginal design fine tuning was necessary dedicated to the unique manufacturing process of the ceramic. For convenience, the interface to the bone is equivalent to the metal component – this concept allows the use of the established surgical instrument without relevant changes or additional equipment.

The benefit of this concept is mainly accomplished by reduced friction and wear of the polyethylene liner at the articulating interface to the ceramic femoral component. The inherent advantage in wear resistance of the ceramic-PE interface in comparison to the a metal-PE combination is particularly exposed due to the characteristic kinematics of an artificial knee joint. Furthermore, as the ceramic is not susceptible against third body wear, improved reliability of the system is expected in the case of adverse conditions.

Noteworthy, the first step of the knee launch results in the combination of a metal, a polyethylene and a ceramic component. As articulation in the knee joint is predominantly located to the interface of femur and liner, the release of metal ions into the blood circuit is significantly reduced. There is only one source of metal ions - the metal tibia component - which is exposed to minor wear depending on the concept and design of the knee prosthesis.

The second step will be the analogous replacement of the tibia. By introducing this component the artificial joint is assembled with non-metallic materials. Thus, additionally to the improved wear performance any release of metal ions is totally avoided. This aspect is in particular relevant if there is any indication of metal hypersensitivity of the patient.

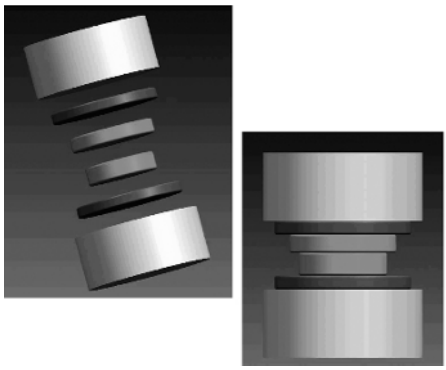
The final step of the development is then the replacement of the PE liner by a ceramic component. It is expected that the dramatic decrease of wear as it is shown for ceramic on ceramic hip joint can be reproduced in the TKA. As the ceramic does not show any water adsorption or ageing, the highest long term reliability is expected from the full ceramic solution.

Ceramic Spine Components

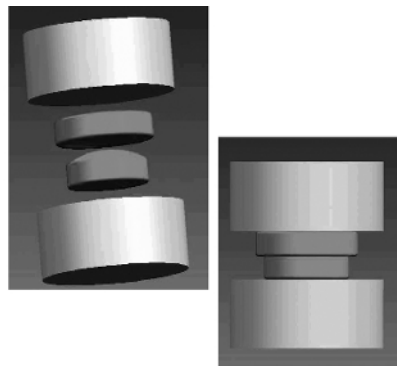
Restoring the mobility of a damaged intervertebral disk promises great benefit to the patient. The functional requirement on an artificial spinal joint is a matter of ongoing scientific discussion. In particular, it is an open question how any wear debris which is expected from all materials in artificial joint arthroplasty is tolerable in direct vicinity of the central nervous system. The application of high performance ceramic components will lead to a substantial reduce of wear particles which gives a strong impetus to the current activity.

The development of ceramic spine components is challenged by a variety of demands. The components will be much smaller as for conventional applications in arthroplasty. The wall thickness may reach dimensions of less than 1 mm. Therefore, new concepts for shape forming and handling have to be developed. The requirements on dimensional accuracy and surface properties are, in some details, even higher than other joints. Moreover, specific test concepts are required in order to provide an artificial joint of highest reliability and system stability.

Figure 4:
Anchorage of spinal components:



Hybrid solution, interface to the spinal body is provided by non-ceramic component (interphase).



Pure ceramic, direct integration of the ceramic components to the bone.

A special feature of this development is the interface of the ceramic spinal joint components to the vertebral body. This subject is schematically discussed in Figure 4. The system must provide primary anchorage as well as long term stability. Current activity is focused on a hybrid solution with a durable combination of the ceramic articulating bodies to non-ceramic components. Osseointegration as well as axial and lateral load transfer is provided by the interphase.

A further advantage of the ceramic spine prosthesis which is in particular appreciated by the surgeons is the excellent behavior of the material at diagnostic imaging. It provides excellent contrast but does not produce any artificial effects.

Summary

Obviously the development of future applications inevitably depends on the well-engineered total system with 3 key factors

1. The high performance ceramic articulating bodies.
2. The tailored functional interface to the biological environment.
3. Compliance of the surgical technique and instrumentation.

High-performance ceramics steadily expand into new fields of arthroplastic surgery. This development is only possible with steadily growing mutual comprehension of ceramic technology and biomechanical engineering. Alumina matrix composite ceramics are distinguished to other materials by a unique combination of physical and chemical properties which provide that basis to the excellent suitability in arthroplasty. It is the challenge of the developing engineers to integrate this material into customized systems The growing experience in this field announces further future applications – e.g. for shoulder, finger or ankle joints – which is already discussed in the surgeon community.

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Poster

1. The use of a ceramic "sandwich cup" in 140 hip arthroplasty with a 5 years follow-up or more

M. P. Philippe, J. Hummer, T. Musset, P. Poilbout and C. Schwartz

Introduction

Wear leads to loosening of hip prostheses. It is now well-known that the couple ceramic-ceramic limits wear. The rigidity of the massive ceramic cups and their great volume limit their use. The "sandwich insert" (alumina insert in an ultra-high density polyethylen cup) seems to be an interesting compromise.

Material and Method

Between the 17/03/1999 and the 20/06/2001we operated 140 patients. There were as many men as women, of an average age of 60 years and with an average BMI of 23.5. In 83% of the cases arthritis was concerned. The Merle d'Aubigné score was preoperative of 11.1 points. We used a non-cemented titanium alloy acetabular cup, elastic thanks to a slot, with a low thickness and hydroxyl-apatite coated; it contains a polyethylene cup in which is enchased an alumina insert. (Atlas, FH Orthopedics.) The femoral stem in all the cases was posed without cement too.

Results

All the patients could be re-examined after 5 years or more. Clinically the Merle d' Aubigné score grew at 17.2. One patient presented dislocations which need surgical treatment. Another presented an infection requiring a new operation too. There was no rupture of the alumina implant in this series. Radiography showed an excellent osseous integration except one. No wear could be measured.

Conclusion

With still a short follow-up for orthopedic surgery of the hip it can be noted that the results are completely satisfactory on the clinical and radiological level; the survival of the sandwich "alumina in polyethylene" implants is similar to the best of the other implants on the market and without complications with regard to his originality.

2. THR Charnley type with Zr/Pe Bearing results at more than 5 years FU

J. H. Caton

Introduction

The long term results of Charnley type total hip replacements (at over 25 years follow-up) have shown that the longevity of the prostheses was inversely proportional to the wear of the polyethylene (PE) and to the penetration into the cup. In order to reduce this wear, we used, as from 1997, a Charnley type prosthesis with a Zirconia head with a diameter of 22.225 mm (Prozyr type Saint Gobain Desmarquet), hoping to reduces the wear and thereby ensure an enhanced longevity of the implants.

Material and Method

We reviewed 145 patients who had undergone a THR (152 arthroplasties) with a conventional Zr/PE bearing and at a follow-up of at least 5 years. These patients had been operated on between 1997 and 1999, the PEHD cup being obtained from CENTERPULSE ZIMMER Society. The measurement method of wear correlated the technique of LIVERMORE with determination of the head according to the technique of CHEVROT and KERBOULL, associated with our inter-observer radiologial digitized measurement on digitized X rays after these had bee enlarged.

At mean follow-up of 70 months (60 to 86 months), the POSTEL-MERLE d'AUBIGNE score was 17.72 and the mean overall frontal wear at the longest follow-up was 0.81 mm (wear with an Acoplot type PEHD cup was 0.71 mm and wear with an isofit cup on a hybrid prosthesis was 0.83 mm). The mean wear per year was therefore, for this series of implants, 0.13 mm. We observed no fracture of the ceramic head. The rate of osteolysis that we noted was 9.12% with extremely minor osteolytic lesions most often located at the level of the Calcar. It must be noted that for a preceding series of patients operated on in 1997 with the same implant, we had observed at 3 years follow-up a mean wear of 0.40 mm, in also 0.12 mm per year with a ZrPe bearing and 0.2 mm/year with a metal/Pe bearing.

Discussion

We did not come across any greater wear of the couple Zr/PE as compared to the usual wear of the couple metal/PE 22.225. This is in contradiction with the observations of J. ALLAIN and D. GOUTALLIER in 1999 and with those of Ph. PIRIOU et al at the SOFCOT in 2003. Neither did we observe, like HAMADOUCHE et al (SOFCOT 2001) any major osteolytic lesions. On the other hand, we did not as

shown by BM WROBLEWSKI, note a decrease in the rate of penetration of the head in the PE, BM WROBLEWSKI having show, in 2004, that a prosthesis with an identical bearing Prozyr Zr 22.225 with a conventional PE in the cemented cup at a mean follow-up of 4.3 years (range 0 to 8 years) had a mean penetration of 0.03 mm per year.

Conclusion

At the present time, at more than 5 years follow-up, we report less wear on a Charnley type prosthesis with a Zr/PE couple versus metal/PE couple of 50%.

3. Wear Performance of Carbon Fibre Reinforced Implantable PEEK against BIOLOX® Forte and BIOLOX® Delta

J. Devine, A. Unsworth and S.C. Scholes

Introduction

Whilst there have been great advances in the wear performance of materials selected for total joint replacement, engineers continue to search for new materials to prolong the lives of implantable devices by reducing wear and the potential for osteolysis. PEEK has been successfully used in a number of implant applications due to its combination of mechanical strength and biocompatibility. In response to the growing interest in the wear performance of these materials, multi-directional pin-on plate testing has been carried out on a number of PEEK based materials against various polymeric, ceramic and metal counterfaces to identify successful wear couples.

Material and Method

Two four station pin on plate machines (Fig. 1) were used in this study applying reciprocation and rotational motion. The polymeric materials were machined from injection moulded plaques. Pitch and PAN based fibres were used for carbon fibre reinforced materials. BIOLOX Forte and BIOLOX Delta samples were provided by CeramTec.

Control pins were included to account for any weight change due to lubricant uptake. A load of 40N was employed and reciprocating and rotating speeds of 1Hz were chosen.

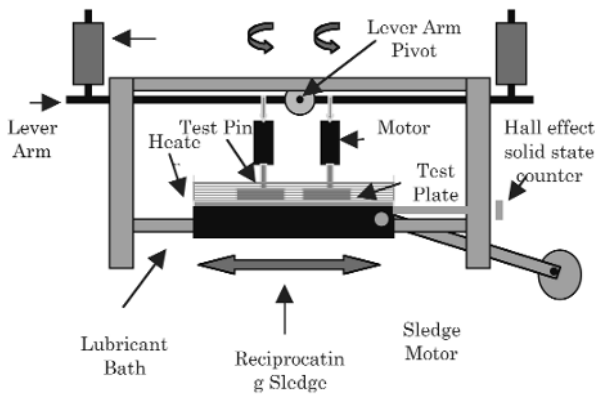

Figure 1:
Pin on Plate Machine.

It is essential that wear screening tests correctly estimate the wear performance of materials. Prior to these tests, the mean wear factors for PTFE, acetal and UHMWPE bearing against metal have been calculated and compared with clinical wear factors [1]. This demonstrated that clinically relevant values of wear could be achieved by this screening method and would provide a useful comparison for the implantable PEEK study.

Results

A number of wear combinations demonstrated excellent wear performance after 2 million cycles. For example the combination of PAN based carbon Fibre reinforced PEEK pins against BIOLOX Delta produced consistently low wear of the polymer pins (Fig. 2).

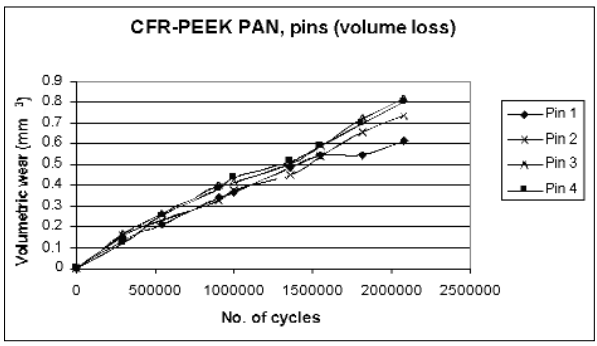

Figure 2:
Volumetric Wear Rate for CFR-PEEK pins against Biolox Delta plates.

The combined wear factor for this wear couple was 0.18 x 10^{-6}mm^{3}N^{-1}m^{-1}.

Discussion

It was shown that CFR-PEEK materials can offer wear factors which are significantly lower than those for UHMWPE against cobalt chrome (1.1 x 10^{-6} mm^{3}N^{-1} m^{-1}) [1]. Furthermore the CFR-PEEK materials have been found to demonstrate excellent mechanical properties with a strong interface between the PEEK polymer and carbon fibres.

Conclusion

The combination of mechanical strength, biocompatibility and proven wear performance may offer alternative materials and design options in bearing applications.

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4. Big diameter ball heads on Corail Stem: Rational indication and advantages

S. Ghera

The corail stem has now been in use for 25 years with very good results.
The surgeon may apply a big head diameter to it, with the advantages of the high stability and low wear offered by this kind of implant.
The Charnley concept using a 22mm diameter head produced a low frictional torque.

Nowadays the metal on metal interface allows very low wear due to a completely different tribology The diameter used in this implant may range from 36 up to 55 mm.

Why use a big diameter head ? To get the following advantages:

- Wider range of motion: the sliding distance grows with the diameter.
- More prosthetic stability: wider Rom and bigger head produce a more stable joint; also an attractive effect of metal on metal is produced, as sutdied by Villar.
  Any patientes with a high risk of dislocation (those with epilepsy, parkinsonism, constitutional laxity, fracture) could be helped by this type of implants.
- Less wear: MOM surface and big diameter generate a lubrication system in the joint that is impossible with polyethylene or with small diameter heads. Much less debris will be produced.
- Using the Corail stem allows a widening of the indication for resurfacing total hip repalcement: as in porotic patients, in dismorphyc head-neck, cysts of the head, wide osteonecrosis (III and IV Ficat stage).

This surgical technique is significantly easier than resurfacing and no neck fracture is obviously observed.
However the difficulty of complete sitting of the cup must be checked, on account of the lack of holes in the cup.

On the femoral side the corail broach must be tested for torque stability. The smallest stable broach must be selected and used to choose the definitive implant. No excavation of greater trochanter need be done, because the design of prosthesis does not interfere with it. The thigh pain effect has disappeared. From 2003, in all the fracture patients (33 cases) no dislocations were observed.

5.A The Role of Pre-Irradiation Crystallinity on the Oxidation Resistance of UHMWPE

F. D'Angelo, A. Ferretti, T.S. Thornhill and A. Bellare

Introduction

- Oxidative degradation of gamma sterilized ultra-high molecular weight polyethylene (PE) in total joint replacement prostheses has been well documented [1,2].
- It has been recently shown that the degree of crosslinking and wear resistance decreases with increase in pre-irradiation crystallinity [3].
- In this study, we hypothesized that pre-irradiation crystallinity affects oxidation resistance since high crystallinity PE can trap more free radicals in the lamellae, which could be released over time, leading to higher long-term oxidation than low crystallinity PE.

Material and Method

UHMWPE (PE): Starting material was a GUR 1050 (Hoechst-Ticona, Bayport, TX) ram-extruded rod stock (PolyHi Solidur, Ft. Wayne, IN), crystallinity 53.8%.

The rod stock was machined into cylinders of 25mm length and 12.5mmm diameter to snugly fit into a custom-built high-pressure cell and stored in water to minimize further exposure to ambient air.

A Carver hydraulic press was used to apply a pressure of 500 MPa to PE specimens preheated to 160°C, 180°C, 200°C, 220°C, 240°C and 260°C, slow cooled to room temperature followed by pressure release.

Crosslinked (XPE): The rod stock was subjected to a dose of 50 kGy gamma-irradiation (Isomedix, Northborough, MA).

Oxidation: A Parr bomb reactor filled with oxygen gas at 5atm pressure and 70°C temperature for 2 weeks (ASTM standard F2003-02).

Sledge Microtome: Thin sections of 100-200mm thickness of all PE samples were prepared using a Leitz Wetzlar (Leica, Nussloch, Germany).

Oxidation Index Fourier Transform Infrared (FTIR) Spectroscopy was performed using a Nicolet Magna 860 spectrometer. The oxidation index, OI, was defined to be the ratio of the area under 1740cm-1 carbonyl and 1370 cm-1 methylene stretching absorbances.

Results

- FTIR experiments showed that the bomb aged PE had a substantially higher OI compared to air aged PE at all subsurface depths, with the maximum OI just below the surface (Fig. 1).
- There was a substantial increase in crystallinity to approximately 70% for crystallization temperatures in the range of 180-220°C and an applied pressure of 500 MPa with no statistically significant differences in crystallinity among the various PE samples ($p>0.05$, ANOVA with Fisher's PLSD post-hoc test, Fig. 2).
- FTIR revealed that the maximum OI (present at the surface) generally increased with increase in crystallization temperature and the differences in maximum OI (Fig 3).

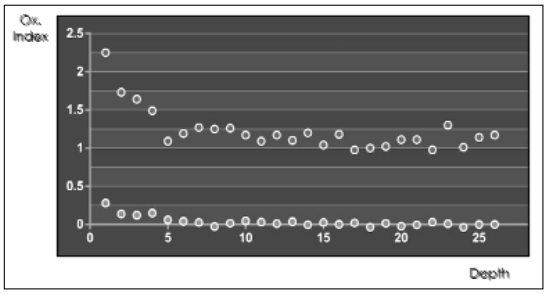

Figure 1:
Oxidation index versus subsurface depth of 50kGy irradiated PE aged in air (circles) and accelerated aged in oxygen bomb (diamond). The bomb aged 50 kGy PE had a maximum OI of 1.68 ± 0.13 compared to 0.29 ± 0.09 for the air aged PE. The maximum OI of the air aged PE was subtracted from all bomb aged PE to reflect oxidation solely associated with the bomb aging.

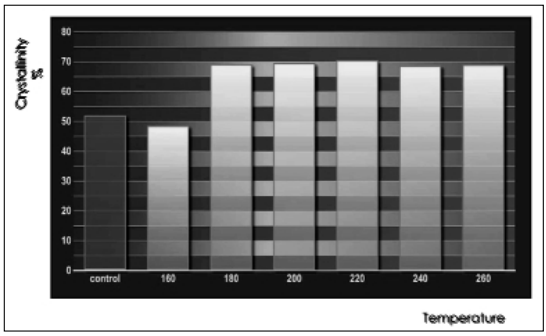

Figure 2:
Histogram of percentage crystallinity at various crystallization temperatures at 500MPa applied pressure.

Discussion

- This study showed that both the pre-irradiation crystallinity and temperature of crystallization at 500MPa pressure, affect the oxidation resistance of irradiated PE.
- The maximum OI, present at the surface of accelerated aged PE, increased with increase in crystallization temperature.
- A comparison of the maximum OI of control PE, 160°C/500MPa PE and 180-260°C/500MPa PEs showed that the maximum OI increases with crystallinity.
- In agreement with a recent study [3], which demonstrated that higher pre-irradiation crystallinity was associated with lower crosslinking and higher wear.
- In conclusion, this study showed that high pre-irradiation crystallinity does lead to higher oxidation.

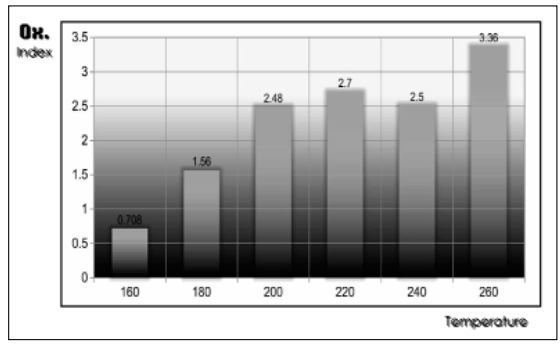

Figure 3:
Plot of Maximum oxidation index versus temperature of crystallization at 500MPa applied pressure.

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5.B The Effect of Pressure-Annealing on the Oxidation Resistance of Irradiated UHMWPE

F. D'Angelo, F. Conteduca, T. S. Thornhill and A. Bellare

Introduction

UHMWPE wear debris and related osteolysis are of a great concern for long-lasting joint replacements [1,2].
Radiation crosslinked ultra-high molecular weight polyethylene have a very high resistance to wear [3,4].

In this study, we hypothesized that annealing below the melting temperature at high pressure would be effective in decreasing free radical concentrations, thereby reducing long term oxidation.

Material and Method

UHMWPE (PE): Starting material was a GUR 1050 (Hoechst-Ticona, Bayport, TX) ram-extruded rod stock (PolyHi Solidur, Ft. Wayne, IN), crystallinity 53.8%.

Crosslinked (XPE): The rod stock was subjected to a dose of 50 kGy gamma-irradiation (Isomedix, Northborough, MA).

3 groups of pins of 25mm length and 9mm diameter, stored in water to minimize further exposure to ambient air. A Carver hydraulic press was used to apply the pressure.

- 100, 200, 300, 400 and 500 MPa to irradiated PE specimens at room temperature for 20min followed by pressure release.
- 100, 300 and 500MPa, to irradiated PE specimens at 130ºC for 20min, followed by slow cooled to room temperature and pressure release.
- PE specimens were heated to 130ºC, pressurized to 500MPa, then further heated to 160ºC, 180ºC, 200ºC and 220ºC for 20min, slow cooled to room temperature followed by pressure release.

Oxidation: A Parr bomb reactor filled with oxygen gas at 5atm pressure and 70ºC temperature for 2 weeks (ASTM standard F2003-02).

Sledge Microtome: Thin sections of 100-200mm thickness of all PE samples were prepared using a Leitz Wetzlar (Leica, Nussloch, Germany).

Oxidation Index Fourier Transform Infrared (FTIR) Spectroscopy was performed using a Nicolet Magna 860 spectrometer. The oxidation index, OI, was defined to be the ratio of the area under 1740cm-1 carbonyl and 1370 cm-1 methylene stretching absorbances.

Results

- FTIR experiments showed the bomb aged 50 kGy PE had a maximum oxidation index (OI) of 1.68 ± 0.13 compared to 0.29 ± 0.09 for the air aged PE (Fig. 1.)
- Group (a): There was no general trend in the maximum oxidation index (OI). Application of high pressure does not affect resistance to oxidation.
- Group (b): There was a clear increase in the OI. High pressure annealing increases oxidation with increase in pressure at 130°C.
- Group (c): The maximum OI decreased substantially but there was no trend in the OI as a function of annealing temperatures.

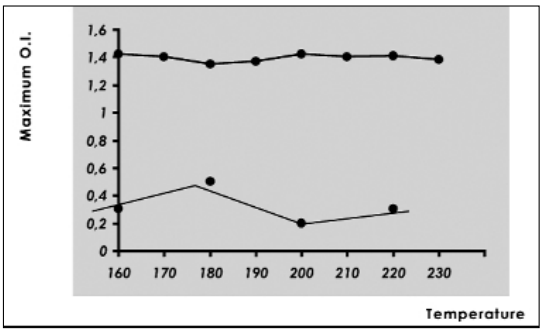

Figure 1:
Maximum OI of accelerated-aged irradiated PE versus annealing temperature at 500MPa pressure. The maximum OI of the air aged PE was subtracted from all bomb aged PE to reflect oxidation solely associated with the bomb aging.

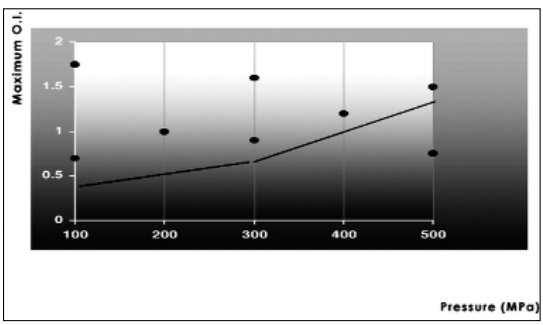

Figure 2:
Plot of Maximum OI of accelerated –aged irradiated PE versus pressure for annealing at room temperature (triangles)and 130°C (dots connected with dashed lines).

Discussion

- These results can be explained in terms of the phase diagram of PE (Fig. 3), which shows that the melting temperature increases at approximately 20°C/100MPa of applied pressure from an initial value of 133°C at atmospheric pressure [5].
- In protocol (a), there was no thermal energy at high pressures to decrease free radical concentrations.
- In protocol (b) the annealing temperature of 130°C was much lower than Tm at 500MPa, consequently the OI increased with increase in pressure at isothermal annealing conditions.

- For protocol (c) the annealing temperature range of 160-220°C is below the estimated Tm of 233°C at 500MPa yet there was a substantial decrease in free radical concentrations.
- In conclusions, this study showed that pressure-annealing can be effective in decreasing oxidation in irradiated PE but only at high temperature

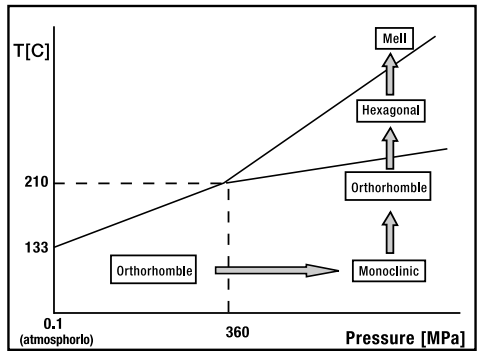

Figure 3:
Schematic of the phase diagram of PE showing temperature and pressures when PE is in the melt state, and as orthorhombic, monoclinic and hexagonal crystals.

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8. Wear Simulator Study of the Tripolar All Ceramic Hip Prosthesis

L. M. Jennings, J. Fisher, T. D. Stewart, B. Masson and J.-Y. Lazennec

There is increasing interest in the use of ceramic on ceramic bearings for hip prosthesis world wide, due to recognition of their extremely low wear and biocompatibility of the wear debris. Recent developments in ceramic matrix composites and the introduction Biolox Delta with improved fracture toughness, further reduces the risk of fracture and also extends the design flexibility of the material. The bipolar polyethylene hip prosthesis has been extensively used in France, as this provides improved function and stability.
However there remain concerns about polyethylene wear and osteolysis.

Figure 1:
Leeds II Physiological Anatomical hip joint simulator.

Figure 2:
Pendulum friction simulator.

A novel tripolar all ceramic bearing for hip prosthesis, Ceram Concept USA has been designed and developed, which combines the functional advantages of the bipolar hip with the tribological advantages of ceramic bearings.

The tripolar has a 22mm head, a 22/ 32 mm mobile ceramic head, and a 32mm internal diameter ceramic acetabular insert (Fig. 3). All components are manufactured from Biolox Delta ceramic matrix composite, CeramTec, Germany.

The wear of the tripolar bearing was compared to a 28 mm ceramic on ceramic, Biolox Delta, bearing couple in a hip joint simulator over of 5 million cycles, using 25% bovine serum as a lubricant. Simulator studies (Fig. 1) were carried out under standard ISO conditions, but also under novel microseperation conditions which replicate head/cup rim contact at heal strike and simulate stripe wear on a standard ceramic femoral head as found on standard ceramic on ceramic retrievals.

Minimum of three specimens was studied for each case. Friction was also compared in a pendulum friction simulator (Fig. 2).

Figure 3:
Tripolar device.

The tripolar hip showed reduced frictional torque due to articulation at the smaller diameter 22mm inner femoral head (Table 1).

Under standard conditions the wear of the tripolar and the conventional ceramic on ceramic bearing were very low. The wear of the tripolar all ceramic hip was less than 0.01 mm^3/ million cycles the detection limit for wear measurement, while the conventional ceramic on ceramic bearing produced a wear rate of 0.04 mm^3/ million cycles. The difference between these very small wear rates is not clinically significant.

Wear Rates (mm^3/million cycles) ± Standard Error for Tri-polar and Conventional Biolox Delta Ceramic on Ceramic Bearings

	Standard ISO	Micro-Separation
3Δ™ Tri-polar	<0.01	<0.01
Conventional	0.07 ± 0.03	0.16 ± 0.05

Coefficient of Friction and Frictional Torque for Tri-polar and Conventional Biolox Delta Ceramic on Ceramic Bearings

	Coefficient	Torque
3Δ™ Tri-polar	0.02	0.7 Nm
Conventional	0.04	1.8 Nm

Table 1

Under microseperation conditions there was a significant difference in the wear performance. For the conventional Biolox Delta ceramic on ceramic bearing, stripe wear was found on the head and a bedding in wear of 0.32mm^3/million cycles and a steady state wear of 0.12mm^3/million cycles. The all ceramic tripolar bearing did not reveal stripe wear on either articulating component and the overall wear could not be detected, less than 0.01mm^3/million cycles. The design of the tripolar bearing with the mobile ceramic head prevented edge loading of the head on the edge of the cup, so significantly reducing wear under these severe, but clinically relevant microseperation conditions.

9. Metallic but not ceramic wear particles increase prostaglandin E_2 release and interleukin-1β (IL-1β) gene expression in human blood monocytes in vitro

G. Falcone, M. Galli, C. Toriani Terenzi, A. Pozzetto, G. Tringali, V. De Santis, M. Vairano, P. Navarra and G. Pozzoli

Introduction

Polyethylene debris-induced inflammation consists in granulomatous reaction within the synovial tissue surrounding sliding surfaces. Beside the attempts to improve the mechanical characteristics of polyethylene, an increasing interest in clinical use of alternative bearing surfaces, such as metal-on-metal and ceramic-on-ceramic has been raised in order to overcome the problem.

A large body of evidence suggests that the foreign-body inflammatory response around ceramic joints may be less intense than that around metal-polyethylene or metal-metal arthroplasties. For example, osteolysis around the loosened ceramic components is very limited, and pseudomembranes generated from the tissue surrounding retrieved alumina-on-alumina implants present mainly a fibrocitic reaction with less macrophages or giant cells; furthermore, the determination of prostaglandin E_2 (PGE_2) in tissue retrieved from loosened prosthesis showed lower prostanoid levels in the alumina/alumina group compared to the metal/polyethylene group.

Since monocytes and lymphocytes play a key role in inflammatory and immune responses, in this study we used primary cultures of human monocytes and lymphocytes to compare the effects of metallic and ceramic particles on the production and release of PGE_2, as well as mRNA expression of various pro-inflammatory cytokines.

Material and Method

Powders

Alumina and metal powders were supplied by Smith & Nephew (Memphis, TN, USA). The average diameter of alumina particles was 1 µm. A mixture of different metals was employed. Metals were present in the following percentages: Chromium 30%, Cobalt 50%; Molibdenum 10%; Alluminium 10%. Particle size was: Chromium < 10 µm; Cobalt 1.6 µm; Molibdenum 2-4 µm; Aluminium 3-4.5 µm. Powders were sterilized by gamma irradiation at a dose of 2.5 Mrad. Endotoxin inactivation was evaluated by E-toxate assay (Sigma Chemicals Co, St Louis, MO, USA).

Isolation of peripheral blood mononuclear cell subsets

Human peripheral blood mononuclear cells (PBMC) were obtained from EDTA peripheral blood of 8 healthy Donors. Cell viability was determined by vital dye exclusion with a solution of 0.3 % Trypan blue; cells showing less than 80% of viability were not considered for experiments. The purity of T lymphocytes and monocytes was assessed by cytofluorimetric analysis and resulted 89 ± 4%.

Co-culture of cells and alumina or metal particles

To study the effects of alumina and metal powders, 4 x 10^4 monocytes/well and 4 x 10^5 T lymphocytes/well, were co-cultured.

At the end of experiments, incubation media were collected and stored at –35 °C until assay for PGE_2 immunoreactivity. To measure cytokine mRNA, monocytes were gently scraped and lymphocytes were collected by centrifugation and kept at -80 °C until RNA extraction.

PGE_2 radioimmunoassay (RIA)

PGE_2 was measured by RIA.

RNA extraction

Total RNA was extracted using the RNeasy® Micro kit (Qiagen, Hliden, Germany).

RNase protection assay

To measure mRNA expression of a number of inflammation-related genes, the RiboQuant™ multi-probe template set hCK-2 (PharMingen, La Jolla, CA, USA) containing cDNA templates for human IL-12p35, IL-12p40, IL-10, IL-1α, IL-1β, IL-1Ra, IL-6 and IFNγ, was used.

Statistical analysis

Data were analyzed by one-way ANOVA, followed by post-hoc Newman-Keul test for multiple comparisons among group means, using a Prism™ computer program (GraphPad, San Diego, CA, USA), and differences were considered statistically significant if $P < 0.05$.

Results

Effects of alumina and metals on PGE_2 release from monocytes and lymphocytes

Alumina and metals were tested at concentrations ranging from 0.01 mg/ml to 0.1 mg/ml. Bacterial endotoxin (LPS, 100 ng/ml) was used as positive control. LPS dramatically increased PGE_2 levels in the incubation medium of monocyte cultures after 24 h. Alumina had no effect on PGE_2 release, whereas metals induced a concentration-dependent increase in PGE_2 release, that was statistically significant at the dose of 0.1 mg/ml. In lymphocytes, LPS elicited a weak but significant increase in PGE_2 release, whereas both alumina and metals did not modify PGE_2 release at any of the concentrations tested. Trypan blue exclusion test showed no changes in viability associated to experimental treatments in both monocytes and lymphocytes.

Effects of alumina and metals on IL-1 b mRNA levels

In monocytes, LPS caused a 2-fold increase in IL-1β mRNA levels after 24 h ($P < 0.01$ vs control). The other genes assessed showed changes lower than 5%, that were considered not significant. The exposure of monocytes to metals resulted in a selective increase in IL-1β mRNA accumulation (+ 48% compared to control, $P < 0.05$), thus confirming the pro-inflammatory effect of this mixture. By contrast,

alumina did not modify IL-1β mRNA levels. None of the test substances elicited any response on purified lymphocyte population.

Discussion

In this study we compared the potential of clinically relevant alumina ceramic and metal wear particles to induce an in vitro inflammatory response in vitro. We report that metal, but not ceramic, particles exert a profound stimulatory action on the release and gene expression of inflammatory mediators in human mononuclear phagocytes. In contrast, none of the tested substances had effect whatsoever on lymphocytes. Since lymphocytes are preferentially involved in delayed responses, it is possible that no response is observed in a 24 h paradigm. We found that, at the higher dose tested, metals increased the release of PGE_2 and produced a selective increase in IL-1β mRNA levels in monocytes. An overproduction of PGE_2 is thought to play a crucial role in the pathogenesis of aseptic loosening on membranes around the implant. Our results indicate that another pro-inflammatory cytokine, IL-1β, may play an important role in the pathogenesis of inflammatory responses to metal particles.

In conclusion, here we have shown that PGE_2 levels production and IL-1β mRNA expression may be a reliable marker to study the pro-inflammatory effects of wear debris in vitro. The lower biological activity of alumina compared to metal suggests that the former should be preferred in implants not only for its mechanical properties, but also for its favorable biological behavior.

10. BMP-2 modified ingrowth characteristics of coated hydroxyapatite-titanium implants in aged sheep

A. Sachse

Introduction

Ingrowth of metal implants into aged organisms can be severely compromised due to reduced healing capacity of bone, lack of precursor cells for new bone formation, or osteoporosis. The purpose of the current study is to explore potential benefits for implant ingrowth from bone morphogenetic proteins-2 in age-compromised individuals.

For this were animal species used for testing bone morphogenetic protein (BMP)-fostered bone healing. In the overwhelming majority of the animal studies, skeletally mature animals were chosen as targets. Occasionally, adolescent animals were selected. In general, the data obtained in those studies indicate above-average bone formation, irrespectively of the specific BMP subtype. However, at least to our knowledge, none of the studies focused on significantly aged animals as an experimental model. We therefore decided to test implant ingrowth on ewes with typical features of aged postmenopausal higher mammals such as depleted bone marrow and osteopenia or osteoporosis.

Material and Method

BMP-2 has been produced as a bacterial recombinant maltose binding protein fusion protein and in vitro generation of mature BMP-2 by renaturation and proteolytic cleavage. Ewes of 10 to 12 years out of reproductive using with significant radiologic and histologic signs of osteoporosis and diminished and adipocytic bone marrow received a subtibial cylindrical grooved hydroxyapatite-titanium implant of 12x10 mm. The implant was placed laterally below both tibial plateaus, with the left side being carrying BMP-2 and the right side without BMP-2, serving as its internal control. Samples were analyzed by histology, radiology, and mechanical testing.

Results

- We have seen the ingrowth of the cylinders with and without of BMP-2, but the quantitative and the qualitative healing with BMP-2 on surface was much better.
- BMP-2 induced bone growth in the fat marrow as well as in the osteoporotic bone.
- Implants without BMP-2 did not induce bone growth in the marrow cavities.
- Healing in the absence of BMP-2 succeeded in the vicinity of pre-existing bone (mostly in the cortex) but very frequently only under formation of a non-

ossified bridging connective tissue, obviously utilizing the osteoconductive property of the HA coating.
- BMP-2 induced both osteoinductive and osteoconductive healing and included the formation of a spongiosa with reorientation of the bone tissue towards the geometry of the cylinders and secondary compaction into corticalis-like bone.
- This process included within the first 7-9 weeks the transition of original cortical bone into spongiosa that was reverted later.
- After 20 weeks, the formation of new compact bone resulted in an enhancement of mechanical resistance in the BMP-2 treated bone, to cause a high longitudinal stability of the cylinders (pull out breaking force 2700 N compared to 1400 N in the absence of BMP-2).

Discussion

The presented animal model provided first evidence that the application of BMP-2 may foster bone healing and regeneration even in aged-compromised individuals by recruiting competent precursor cells from deficient bone marrow. Several studies indicate stimulation of bone marrow cells by BMPs, even though to various degrees and on various cell types of the marrow.

Most surprising, in this context, is the fact that we did not observe even traces of enchondral ossification with the formation of a cartilagenous callus but seemingly direct ossification of mesenchymal tissue as known for desmal ossification. That finding is in contrast to other reports who clearly identified enchondral ossification around BMP-2 treated implants. The healing pattern found in the controls followed the known pattern of osteoconductive healing with appositonal bone growth as described for hydroxyapaptite coatings whereas the BMP-treated implants induced embryogenetic pattern formation –like response prior to osteoconductive ingrowth. The results indicate that in sheep BMP-2 mediated implant ingrowth by the activation of embryogenetic processes and activation of bone regeneration that include recruitment of seemingly lost precursor cell populations from the residual fat marrow and, in the end, produce an adaptively growing bone.

Conclusion

Taken together, the present study allows to predict a therapeutic value of BMP-2 for metal implant osseointegration in aged or otherwise compromised bone tissue with reduced spontaneous healing.

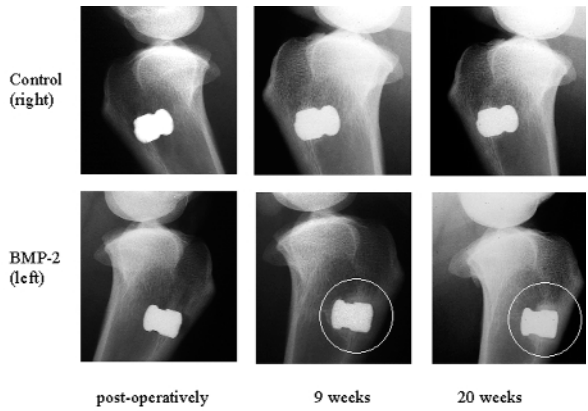


Figure 1:
In vivo radiological survey of typical implant ingrowth. Radiographs have been taken from the lateral view of the knee, with the right leg carrying the control implants without BMP-2 and the left implant those with BMP-2 added. The circles across the left implants indicate areas of increased x-ray density not seen in case of the right controls.

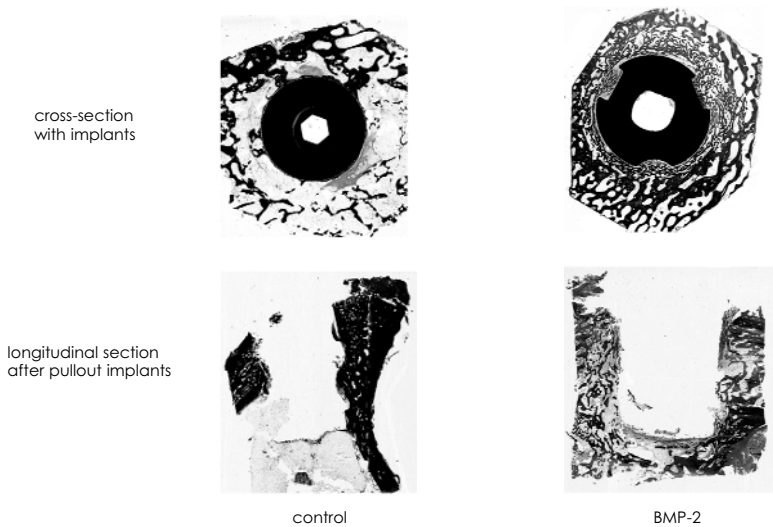


Figure 2:
Histology survey from specimens. The microphotographies display cross sections from the cylinders with the implants still in place (top row) or after removal during histological preparation (bottom row) in Masson-Goldner staining. Note the significant formation of bone in the BMP-2 treated sample even within the grooves designed to restrict osteointegration.

11. Ultimate Compression Strength Testing of Alumina Ceramic Femoral Heads in Revision

N. G. Dong, P. F. Sharkey, M. A. Kester and A. Wang

Introduction

Ceramic bearings have been shown to significantly reduce the wear in hip joint. However there are the needs to use ceramic femoral heads in revision. To date, despite the warnings by manufacturers of not using on used stem taper, there is no quantitative data available. The purpose of this study was to investigate the strength of ceramic femoral head when used in replacing metal femoral head or failed ceramic head during revision surgery.

Material and Method

Tests were performed to investigate the strength of C Taper alumina 28mm+0 ceramic heads used in simulated situations of revising a ceramic or metal femoral heads: Ultimate Compression Strength (UCS) testing of new alumina ceramic femoral heads on

1. New titanium alloy trunnions, N=5
2. The trunnions used in series 1, N=5
3. Titanium alloy trunnions that had been previously tested in axial fatigue using CoCr alloy femoral heads, N=5.

The titanium alloy trunnions were manufactured in same specs of commercially available hip femoral components. UCS testing was performed at a rate of 1.27mm/min. Axial fatigue testing was performed with 0.498 to 4.89KN for $10x10^6$ cycles at 10Hz in a saline environment according to ISO 7206-10.

Results

The average UCS of new ceramic heads on new trunnions was 69.6 ± 2.2 KN. The average UCS of new ceramic heads on damaged trunnions by fractured ceramic heads was 47.3 ± 14.0 KN or 32% reduction in ceramic strength (p= .0399). The average UCS of new ceramic heads on trunnions used with CoCr heads was 58.3 ± 6.8 KN or 16% ceramic strength reduction (p= .0034). Both results showed a significant reduction in the ceramic UCS (t-test, 95% confidence level).

Conclusion

There were significant reductions in the UCS of alumina ceramic femoral heads on trunnions used with CoCr heads or damaged by fractured ceramic heads.

12. BIOLOX® option: A new revision strategy with BIOLOX® ceramics

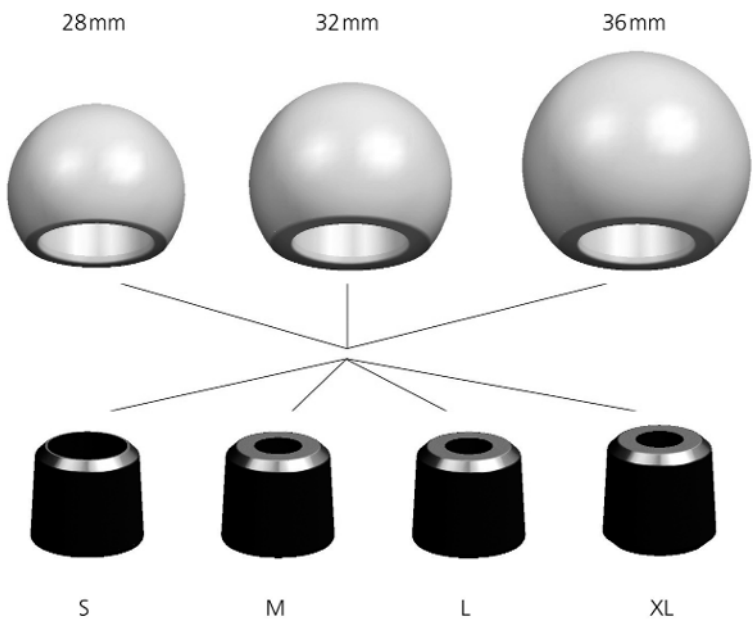
B. Masson

Introduction

Every revision operation offers the surgeon the possibility of selecting a system or solution, which represents the latest state-of-the-art in both technology and knowledge.

Properties and benefits

Typically, in revision operations it is an old prosthesis which has to be revised, can be upgraded by means of BIOLOX® Option either to a standard ceramic/polyethylene combination or to the preferred ceramic/ceramic combination. In both cases, there are possible benefits for the patient. These include a minimising of abrasion and wear, a reducing of the rate of loosening and consequently an addressing of the problem of particle induced osteolysis. In addition, with the introduction of the XL neck length, the optimisation of neck length in primary hip replacement using a ceramic ball head has become a reality.



Conclusion

With BIOLOX® Option the optimisation of neck length in primary hip replacement using a ceramic ball head has become a reality.

In case of revision the surgeon can use a new ceramic ball head without removing the stem. This system can be used with any ceramic acetabular insert of the Biolox® family and with existing polyethylene and highly-crosslinked polyethylene inserts.

13. Duolox®, a ceramic Bipolar System for Hemiarthroplasty

B. Masson

Introduction

DUOLOX®, the self-centering, bipolar system made of BIOLOX® ceramic, combines the proven design advantages of a modern bipolar prosthesis with the excellent material properties of BIOLOX® ceramic.

Properties and benefits

The DUOLOX® System is in keeping with the trend towards joint-conserving, less invasive, hip replacements. The surgical procedure avoids the loss of bone substance in the acetabulum and thus improves eventual re-operability. If a follow-up operation is required, it provides a far better starting position and as a result it lowers the long term cost of revision. In comparison with more costly total hip replacement, considerations which are of importance to the surgeon are the easier, less complication-prone, surgical procedure, the lower effort involved and the patient's generally shorter hospital stay. The DUOLOX® System provides material cost savings, since there is no metal-back. At the same time it provides a high value treatment, which makes use of the well-proven BIOLOX® ceramic, without the risks of metal and polyethylene wear. The increasing wish from patients for earlier mobilisation, shorter rehabilitation and quicker return to life, at home and at work, are additional factors which are assuming a social, industrial and economic relevance.

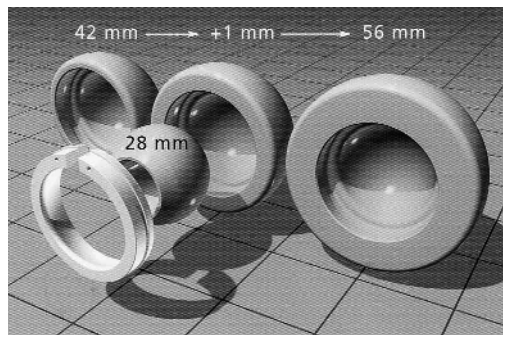


Figure 1:
Ceramic bipolar system Duolox® : Biolox® forte bipolar shell with outer diameter from 42mm to 56 mm, in 1 mm steps.
Duolox® can be used in combination with all 28mm Biolox® ball heads.

Conclusion

The DUOLOX® System is the treatment of choice for specific indications, namely where the acetabulum is intact and worth-conserving, and this is especially so for younger patients and patients with metal sensitivity.