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Instructional lecture

Ceramic/ceramic total hip arthroplasty

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Abstract Alumina-on-alumina total hip arthroplasty has been used for 30 years, mainly in Europe. The theoretical advantages of this combination are represented by its remarkable sliding characteristics, its very low wear debris generation, and its sufficient fracture toughness. These advantages are achieved if the material is properly controlled with high density, high purity, and small grains. The authors summarize the results obtained with ceramic/ceramic total hip arthroplasty. Information is provided about in vivo behavior regarding wear debris characterization and quantification, and histological tissue examinations for inflammatory reactions, which were not encountered except when alumina debris was mixed with metal or cement. Modification of socket fixation resulted in improved clinical outcomes. With a press-fit metal shell and an alumina liner utilized for 10 years, the results are excellent especially in a young and active population. Alumina-on-alumina seems at the moment to be one of the best choices when a total hip arthroplasty has to be performed in young and active patients.

Key words Almina ceramic · Total hip arthroplasty · Orthopaedic surgery

Introduction

An alumina/alumina couple was first used as an acetabular implant in total hip arthroplasty in 1972 by Boutin[2,3] in France, followed, in 1974, by Mittelmeier in Germany;[24] Furuya in Japan, Pizziferato in Italy, and Salzer in Austria were part of this pioneering period.

The initial aim was to suppress the osteolysis related to polyethylene wear debris, already described by Willert et al.,[39] and to replace this plastic material that could deteriorate over time.[30] The goal was to enhance long-term results in young and/or active people and to provide them with a safe, non-wearing material that could last for a very long time without any activity limitation. Since this pioneering period, more than 150000 alumina-on-alumina implants have been performed, mostly in Europe. Few were used in the United States. Many reports emphasized fracture risk, early clinical failure, and osteolysis.[15,19,26,40] But other large experiences were more optimistic.[1,11,17,18,29,34,35] It is the evolution of this material over time and all the expertise arising from retrieved material and patient analysis that we wish to present here. Alumina ceramic, being highly oxidized, initially demonstrated high biocompatibility, in bulk or particulate forms.[6,12,14,16,26,27]

Hard-on-hard materials had the theoretical advantage of very low wear debris generation and low friction. But only alumina-on-alumina showed very long-term stability, because of the lack of third body wear which is observed with metal-on-metal; as well as great stability which is not the case for zircon-on-zircon.

For the alumina-on-alumina sliding couple, many details have to be addressed in order to make this couple effective and of great value. These details concern the material, its geometry, its fixation system, and also its surgical implantation.

Material qualities

Toughness to prevent fracture and wear is directly related to the material quality, i.e., what is required is high purity, high density, low porosity, and low grain size (2 μm ± 1).[7,25,41] This was obtained by improving the manufacturing processes and, moreover, by using a high isostatic pressure system. There were, in fact, many different alumina materials used in the past.

Alumina quality improved over time.[38] During the first period of use, from 1970 to 1979, alumina ceramics

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a,b

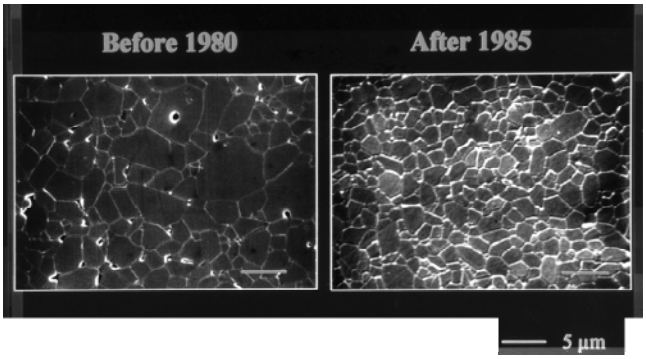

Fig. 1a,b. Different qualities of alumina. **a** Before 1980; large grain size, high porosity. **b** After 1985; small grain size, low porosity

exhibited low density, high porosity, and a relatively large grain size (up to some tenths of microns).[38] Up-to-date alumina exhibits a mean grain size of 2.2 ± 1 μm (Fig. 1).

Material geometry

Material geometry concerns microgeometry (roughness, which has decreased) and macrogeometry (represented by circularity and sphericity, which is now less than 1 μm). Clearance between the two components also appears to be a very significant issue.

Clearance in the order of 50 μm appears to be the optimum. This was obtained by ground pairs of components, which were then sold as a unit, from 1977 to 1993. Since that time, improvements in manufacturing processes have allowed us to benefit from low clearance pairs with exchangeable components.

Design and bone fixation

Many different designs and fixation systems have been explored in the past and are still being explored. These fixation systems may play a major role in the clinical outcome, and the surgeon must be aware of the advantages and disadvantages of each design/fixation system. Boutin, in the first design, used a cementless plain alumina socket with one peg, and changed to two pegs, and then three pegs, in 1974. The stem was cemented, and since 1972 it has been made of titanium alloy: this was the first to be made of this material; the 32-mm head-on-cone fixation was initially of concern. Initially it was glued, and subsequently, brazed. These two systems gave rise to many early failures and fractures. In 1977 we introduced the Morse taper, which had been in use in Germany since 1974. Cemented collared titanium, which was smooth and covered with titanium

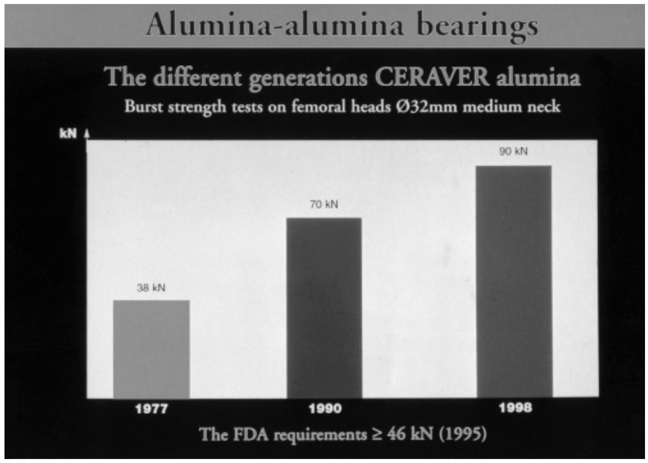

Fig. 2. Burst strength test of head/cone fixation over the years. United States Food and Drug Administration (*FDA*) requirements are ≥46 kN *Ceraver*

oxide, was introduced at the same time. The Mittelmeier design included a bulky cementless screw-in-ring alumina socket, a smooth cobalt chromium cementless stem with grooves, and a large head with a Morse taper. It resulted in many early failures not directly related to the alumina materials, but to poor design and difficult surgery.[21,24,42] Since the seventies, a higher security levels has been reached. These incremental improvements are related to material quality, design, geometry roughness, and alumina material fixation. Conical sleeving has been enhanced by improving cone technology. The manufacturing processes were concerned not only with the accuracy and tolerance of the cone angle but also with the roughness of the material, which allows a better resistance to fracture. Thus, for the Ceraver (35) 32-mm head, the burst strength, which is the test recommended by the United States Food and Drug Administration (FDA), improved from 38 kN in 1977 to 90 kN in 1998 (FDA recommendation is ≥46 kN) for a cone of 12–14 (Fig. 2).

Major issues

Major issues concerning this material were related to ceramic material fracture, wear in clinical use, and clinical outcome regarding loosening. We will address these items.

Some alumina head fractures have been related to poor material technology or poor cone manufacturing. Regarding this issue, it is recommended that the same manufacturer be responsible for both the cone and the ceramic head. If fracture risk is still of some concern, at worst, its calculated risk could be in the order of 1 per 2000 for a 10-year period. It was in the order of 1% in the initial phase.[7,10] We have observed many examples of heavy trauma to the hip with fracture of the acetabulum or of the femur without any disorder in the alumina material.[23]

Regarding tribological properties, the alumina-on-alumina couple exhibited a very low friction coefficient (0.01) after a short running-in period.[3,7,32] Sphericity and circularity reached values of 1 μm. Roughness, represented by the Roughmoss (Ra) reached 0.1 μm. Some manufacturers insisted on the necessity of obtaining a low initial clearance, in the 30-μm range.[3,32] This was obtained by matching the two components. Since 1993, improvements in machining processes allow us to obtain unmatched components with a low clearance.

Wear debris

Wear debris was very difficult to create with hip simulators; thus, it was only recently that biological studies compared ceramic debris with that of other tribological materials.[4] Clinical studies, as well as analysis of retrieved alumina components and biological tissues surrounding failed implants, were the only way to understand the wear mechanism and the in-vivo behavior of the material.

In-vivo wear

In-vivo wear was measured on retrieved implants by Dorlot[8] and Dorlot et al.[9] Walter,[38] and Plitz and Griss.[27] Their conclusions could be summarized as follows: in a normal situation, when the socket did not tilt before retrieval, the wear was always very low. Linear wear was in the order of 5 to 9 μm per year.[8,9] In a more recent study, Prudhommeaux et al.[28] looked at the in-vivo wear in relation to alumina quality. They found a direct relation between these two parameters. Bad alumina quality resulted in heavy wear, and good alumina in low wear. They also investigated the role of additional factors, represented by tilting of the socket and impingement before revision. The overall wear calculated by the weight of debris generated was in the order of 1000 times less than that of metal-on-polyethylene, and 40 times less than that of metal-on-metal articulation. Regular wear for good alumina is in the order of 3 μm per year.

Biological reactions to wear debris

Biological reactions to wear debris were investigated by Boehler et al.[1] and Lerouge et al.[19,20] The usual reaction is of fibrocytic type, with very few macrophages and no giant cells. In some special situations, when the prosthesis was loosened for a long time or when there was an impingement between the socket and the stem, alumina debris was found in conjunction with metallic debris. In such instances, massive macrophagic reaction led to foreign body granuloma.[3,4,32,35,40,42] We also found that zirconia particles used as cement opacifier were partly involved in the macrophagic response.[19,20] The conclusion was also that, in the normal situation, debris generation was limited and mainly gave rise to a fibrocytic reaction. In some patients, mechanical loosening was encountered.

Alumina ceramic loosening

Mechanical factors and alumina rigidity are usually suspected to be responsible for alumina ceramic loosening.[23,25] In our experience, we suspected poor cement fixation to be the reason for these failures. Another concern is related to bone weakness that cannot sustain this hard material. This could be an explanation for our observation of clinically better results in a young population. In such a population, the bone is able to adapt to this rigid material (in regar to Wolf's law), while osteoporotic bone is not. Regarding the Mittelmeier prosthesis, poor design, including threaded cups, has to be blamed.

Osteolysis

Some studies[42] have described severe osteolysis related to the use of the alumina-on-alumina couple, while others have described virtually no osteolysis. Because of implant/bone relative mobility, radiolucent lines were described around the Mittelmeier prosthesis. However, we suspect these radiolucent lines not to be related to true osteolysis and foreign body reaction, although some authors have stated a contrary opinion.[41,42] True foreign body reactions were occasionally described by Boutin et al.,[3] Boehler et al.,[1] ourselves,[35] and, more recently, by Yoon et al [42] They were always related to a very large amount of alumina ceramic debris generated by abnormal contact (mushroom-shaped head, vertical socket) and after a long period of component loosening. To conclude this section, on biological reaction to alumina debris, the only common conclusion of all clinical studies concerning this sliding couple was the very low rate of osteolysis in all long-term series.[11,13,17,18,30,33,34,37] One study[31] described a sarcoma that developed 1 year after the implantation of a ceramic-on-ceramic prosthesis. This is the only case described, and one must note that the patient had already had a cobalt chromium screw for hip fixation for 15 years.

Clinical outcome

We started our trial in 1977 with a cemented plain alumina socket and a cemented titanium alloy collared

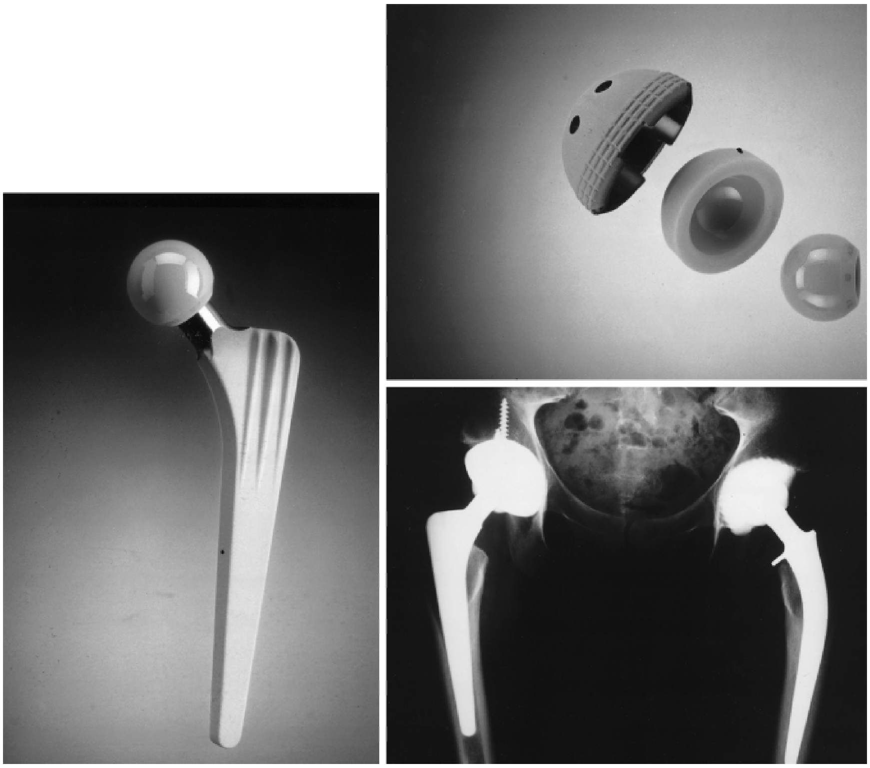

Fig. 3a,b. Up to date design. **a** Cementless stem, fully hydroxyapatite (HA) coated; **b** cementless titanium shell, fully coated with HA, with an alumina liner. **c** One-year follow-up in a 22-year-old girl operated for severe AVN following bone marrow transplantation. Cementless Cerafit and multicone cementless stem on the *right*, cementless bulky alumina and cemented stem on the *left*. Fully active, 18 points on both sides on the Merle D'aubigné Postel scale

stem, smooth and anodized.[25,33] Clinical results are now available for a 20-year period. Cemented acetabular fixation resulted in an overall 83% survivorship at 10 years, with 70% at 15 years. However, results were better in a young population, with 86% survivorship at 15 years in patients less than 50 years of age, and the stem showing a 97% survivorship at 15 years. Most of the revisions were related to the loosening of the cup. Osteolysis was encountered in fewer than 1% of our patients and was related to patients with early socket loosening who postponed the revision. These patients demonstrated an impingement problem after the ceramic cup had tilted.

The pioneering period (1977–1983) allowed us to document clinical results and to analyze alumina components and tissues retrieved at revision.[19,20,36] The results confirmed the very low wear rate in vivo: an average of less than 5 μm of linear wear per year was found in normal situations. This value was at least ten times larger if the prosthesis had tilted before revision.[8,9,28] Histological studies demonstrated the excellent biological tolerance of alumina ceramic debris. The man reason for the failures in this series was related to aseptic loosening of the cemented socket. This phenomenon was significantly more frequent in the old population, and also with larger socket sizes.[25] We speculated that this was related to weak bone quality and the reduced ability of old bone to adapt, in terms of Wolf's law. That is why we changed to other strategies. In the elderly, we changed to an all-polyethylene socket, cemented and sliding against a ceramic or a metallic head. In the younger, more active men, we retained the alumina-on-alumina bearings. We also retained the 32-mm head, in order to increase the mechanical resistance and to decrease the risk of impingement, because this head provides a range of motion of 129° for a medium neck and a 12/14 cone angle.

During the past 15 years, we have continued to use the same cemented stem, but have changed to other means of socket fixation. We limited the use of Al_2O_3 on Al_2O_3 to selected young and/or active and heavy patients, including those with strenuous activities. We tried a screw-in titanium ring with an alumina insert. Some early failures related to the screw-in ring fixation were encountered, but no problems were documented regarding the alumina liner fixation and, in 1989, a press-fit titanium shell covered with a pure titanium mesh with an alumina liner was used. Some screws could insure the fixation. The liner was held by conical sleeving with a 5° 40′ angle. In selected patients, we also used a plain cementless alumina socket.[13] Survivorship analysis and clinical results in regard to pain and range of motion showed results very similar to those obtained with more conventional implants. However, roentgenographic studies showed that osteolysis was never encountered while the patients were allowed to perform all types of activities without any limitation. The results with the press-fit bulky alumina showed a 93% survivorship at 80 months.[13] Failures were, again, related to socket mobilization and loosening. The main advantage of this socket fixation system was the absence of osteolysis and the simplicity of the revision procedure.

The Cerafit with the titanium mesh resulted, in some instances, in late failure related either to surgical difficulties or to some osteolysis due to titanium debris generated by the mesh. That is why, for the past 3 years, we have been using a press-fit titanium shell that is rough and fully coated with hydroxyapatite (HA). HA could be considered because it is softer than alumina and cannot be of concern in a third body abrasive system. In selected patients, we also changed to a cementless stem fully coated with HA (Fig. 3a,b).

Hardness

The hardness of alumina ceramic is a significant issue. Elasticity mismatch between bone and alumina ceramic or between bone and polymethylmethacrylate could be the reason for failures. In many patients it seemed that bone adaptation did succeed in anchoring and sustaining the alumina material; however, in some osteoporotic bone, or when weak muscles were unable to protect from impact loading, adaptation did not take place, resulting in some aseptic loosening, either by fracture of the cement or by slow migration of the socket.

Long-term results on alumina/alumina have now reached more than 20 years. Clinical and radiological results in patients overall allow us to expect an exceptional long-term survival in very demanding patients. Fracture risk is now about 1/2000 for a 10-year period.[10,35] As we (and other authors) rarely encountered osteolysis, any revision becomes a very easy procedure, without the need for bone reconstruction. Revision usually concerned the socket, the stem being left in place.

After more than 2500 alumina/alumina couples implanted in our department, we have reached the conclusion that this material should be dedicated to young and active people, while alumina/polyethylene or metal/polyethylene are still successful for elderly or less active patients. Providing there is good alumina quality, state-of-the-art cone technology, and precise surgery, a very long implant survival can be expected. If revision has to be performed, absence of osteolysis results in a surgical situation close to that in a primary case. Limitations for the use of alumina are: (i) a particularly small socket or (ii) the need for a small head, or (iii) osteoporotic bone. Cost is not a major issue because it is now possible to manufacture high-grade alumina at a reasonable price, and because greater longevity has to be considered. Compared with other ceramics, alumina-on-alumina is safe enough. New couples, such as alumina on zircon, diamond, and ion-implanted alloys are promising, but these materials have only very recently been put on trial. Metal-on-metal was reintroduced 10 years ago, with a new technology. These implants are still made of cobalt chromium alloy. They resulted in higher wear (10 to 40 times more) than alumina-on-alumina and produced a high blood concentration of cobalt or chromium, which could lead to some problems in the future. We know that biological tolerance of metallic debris is low, and this could lead to some adverse effects which have not yet been shown after a short time on trial.

Alumina-on-alumina has at last been recognized in the United States as one of the best answers to the problems of debris generation, and many trials are now underway way in this country, after 30 years of use in Europe.

References

1. Boehler M, Knahr K, Salzer M, et al. Long term results of uncemented alumina acetabular implants. J Bone Joint Surg Br 1994;76:53–9.
2. Boutin P. Arthroplastie totale de hanche par prothèse alumine frittée. Rev Chir Orthop 1972;58:229–46.
3. Boutin P, Blanquaert D. Le frottement Al/Al en chirurgie de la hanche: 1205 arthroplasties totales. Rev Chir Orthop 1981;67: 279–87.
4. Boutin P, Christel P, Dorlot JM, et al. The use of dense alumina-alumina ceramic combinaton in THR. J Biomat Mat Res 1988;22: 1203–32.
5. Catelas I, Huk O, Petit A, et al. Flow cytometric analysis of mouse macrophages response to ceramic and polyethylene particles: effects of size, concentration and composition. J Biomed Mater Res 1998;41:600–7.
6. Christel P. Biocompatibility of surgical-grade sense polycrystalline alumina. Clin Orthop 1992;282:10–18.
7. Clarke IC, Willmann G. Structural ceramics in orthopedics. In: Cameron H, editor. Bone implant interface. London: Mosby; 1994. p. 203–52.
8. Dorlot JM. Long-term effects of alumina components in total hip prostheses. Clin Orthop 1992;282:47–52.
9. Dorlot JM, Christel P, Meunier A. Wear analysis of retrieved alumina heads and sockets of hip prostheses. J Biomed Mater Res 1989;23:299–301.
10. Fritsch EW, Gleitz M. Ceramic femoral head fractures in total hip arthroplasty. Clin Orthop 1996;328:129–36.
11. Garcia-Cimbrelo E, Sayanes JM, Minuesa A, et al. Ceramic-ceramic prosthesis after 10 years. Arthroplasty 1996;11:773–81.
12. Griss P, von Andrian-Werburg H, Krempien B, et al. Biological activity and histocompatibility of dense Al_2O/MgO ceramic implants in rats. J Biomed Mater Res Symp 1973;4:453–62.
13. Hammadouche M, Nizard RS, Mennier A, Brot P, Sedel L. Cementless bulk aluma societ preliminary results at 6 years. J Arthroplasty 1999;6:701–7.
14. Harms J, Mäusle E. Tissue reaction to ceramic implant material. J Biomed Mater Res 1979;13:67–87.
15. Heck DA, Partridge CM, Reuben JD, et al. Prosthetic component failures in hip arthroplasty surgery. Arthroplasty 1995;10:575–80.
16. Heimke G, Griss P. Five years experience with ceramic-metal-composite hip endosthesis II. Mechanical evaluations and improvements. Arch Orthop Trauma Surg 1981;98:165–71.
17. Huo MH, Martin RP, Zatorski LE, et al. Total hip replacements using the ceramic mittlemeier prosthesis. Clin Orthop 1996;332: 143–50.
18. Ivory JP, Kershaw CJ, Choudry R, et al. Autophor, cementless total hip arthroplasty for osteoarthrosis secondary to congenital hip dysplasia. Arthroplasty 1994;9:427–33.

19. Lerouge S, Huk O, Yahia LH, et al. Characterization of in vivo wear debris from ceramic-ceramic total hip arthroplasties. J Biomed Mater Res 1996;32:627–33.
20. Lerouge S, Huk O, Yahia LH, et al. Ceramic-ceramic vs metal-polyethylene: a comparison of periprosthetic tissues from loosened total hip arthroplasties. J Bone Joint Surg Br 1997;79: 135–39.
21. Mahoney OM, Dimon JH. Unsatisfactory results with a ceramic total hip prosthesis. J Bone Joint Surg Am 1990;72:663–71.
22. Mckellop H, Clarke I, Markolf K, et al. Friction and wear properties of polymer, metal and ceramic prosthetic joint materials evaluated on a multichannel screening device. J Biomed Mater Res 1981;15:619–53.
23. Meunier A, Nizard R, Bizot P, et al. Clinical results of ceramic bearings in Europe. Symposium on alternative bearing surfaces in total joint replacement — ASTM STP 1346-Jacobs JJ, Craig TL, editors. San Digeo: American Society for Testing and Materials; 1998.
24. Mittelmeier TH, Walter A. The influence of prosthesis design on wear and loosening phenomena. Crit Rev Biocompat 1987;3:319.
25. Nizard R, Sedel L, Christel P, et al. Ten-year survivorship of cemented ceramic-ceramic total hip prosthesis. Clin Orthop 1992; 282:53–63.
26. Pizzoferrato A, Cenni E, Ciapetti G, et al. In vitro cytocompatibility and tissue reaction to ceramics. In: Raviglioli A, Krajewski A, editors. Bioceramics and the human body. Amsterdam: Elsvier; 1992. p. 288–91.
27. Plitz W, Griss P. Clinical, histomorphological and material related observations on removed alumina-alumina hip joint components. In: Weinstein, Gibbons, Brown, et al., editors. Implant retrieval: material and biological analysis. New York: NBS Special Publication 601, US Department of Commerce; 1981. p. 131–56.
28. Prudhommeaux F, Nevelos J, Doyle C, et al. Analysis of wear behavior of alumina/alumina hip prosthesis after 10 years of implantation. In: Legeros RZ, Legeros JP, editors. Biomechanics 11. International symposium on ceramics in medicine. New York: World Scientific Publishing: 1998.
29. Riska EB. Ceramic endoprosthesis in total hip arthroplasty. Clin Orthop 1993;297:87–94.
30. Rose RM, Nusbaum HJ, Shneider H, et al. On the true wear rate of ultra high-molecular-weight polyethylene in the total hip prosthesis. J Bone Joint Surg Am 1980;62:537–49.
31. Ryu RK, Edwin EG, Skinner HB, et al. Soft tissue sarcoma associated with aluminium oxide ceramic total hip arthroplasty. A case report. Clin Orthop 1987;216:207–12.
32. Sedel L. The tribology of hip replacement. In: Kenwright J, Duparc J, Fulfold P, editors. European Instructional Course Lectures 1997;3:25–33.
33. Sedel L, Kerboull L, Christel P, et al. Alumina-on-alumina hip replacement: results and survivorship in young patients. J Bone Joint Surg Br 1990;72:658–63.
34. Sedel L, Nizard R, Kerboull L, et al. Alumina-alumina hip replacement in patients younger than 50 years old. Clin Orthop 1994;298:175–83.
35. Sedel L, Bizot P, Nizard R, et al. Perspective on a 25 years experience with ceramic on ceramic articulation in total hip replacement. Semin Arthroplasty 1998;9:123–34.
36. Sedel L, Simeon J, Meunier A, et al. Prostaglandin E2 level in tissue surrounding aseptic failed total hips: effects of materials. Arch Orthop Trauma Surg 1992;111:255–8.
37. Toni A, Terzi S, Sudanese A, et al. The use of ceramic in prosthetic hip surgery. The state of art. Chir Organi Mov 1995;80:125–37.
38. Walter A. On the material and the tribology of Al/Al coupling for hip joint prostheses. Clin Orthop 1992;282:31–46.
39. Willert HG, Bertram H, Buchorn GH. Osteolysis in alloarthroplasty of the hip: the role of ultra high molecular weight polyethylene wear particles. Clin Orthop 1990;258:95–107.
40. Wirganovicz PZ, Thomas BJ. Massive osteolysis after ceramic on ceramic total hip arthroplasty. A case report. Clin Orthop 1997;338:100–4.
41. Wu C, Rice RW, Johnson D, et al. Grain size dependence of wear in ceramics. Ceram Eng Science Proc 1985;6:995–1011.
42. Yoon, Taek RY, Sung MR, et al. Osteolysis in association with a total hip arthroplasty with ceramic bearings surfaces. J Bone Joint Surg Am 1998;80:1459–68.