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

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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.

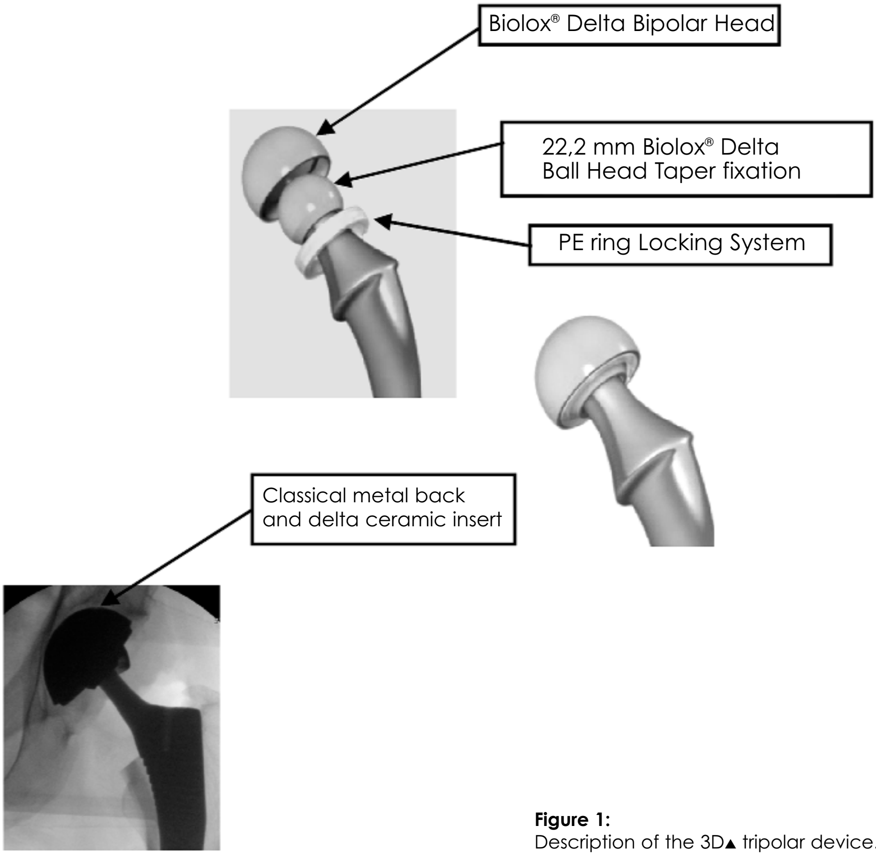

Figure 1:
Description of the 3D▲ tripolar device.

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.

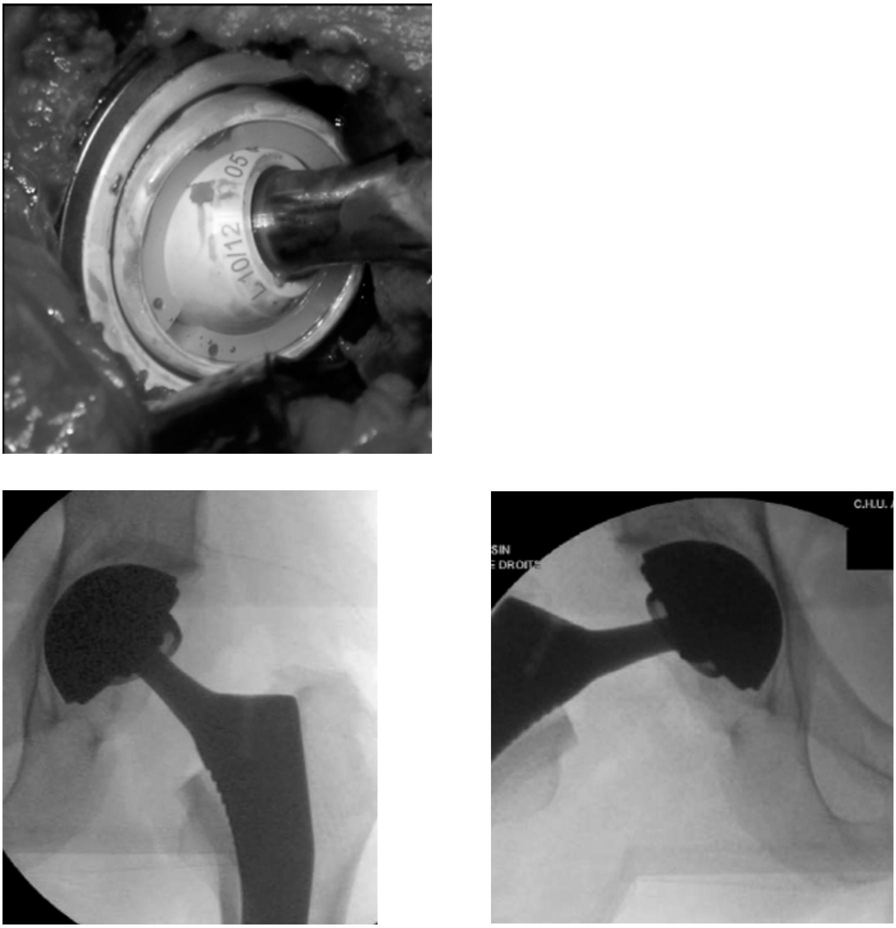

Figure 2:
Implanted 3D system and its adaptation.

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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