Chapter 6

All Ceramic Tripolar THA to Prevent Dislocations in Risky Patients

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Additional information is available at the end of the chapter

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1. Introduction

Dislocation remains one of the most common complications after total hip arthroplasty (THA), especially for ceramic-on-ceramic prostheses. Suboptimal implant positioning, muscular insufficiency, significant lower limb discrepancies, and neurological problems are standard causes for THA dislocations or subluxations [1-3]. Instability may also be linked to 2 specific mechanisms, lever-out (with impingement) and shear-out (without impingement).

Microseparation and edge loading of the femoral ball head on the insert are relevant issues for hard-on-hard bearing surfaces, either ceramic on ceramic or metal on metal [4-5]. Tripolar polyethylene (PE) THAs have been extensively used for more than 20 years in Europe [2, 6-7], and clinical data demonstrate that they provide significant improvement in hip stability. Significant concerns nonetheless remain about PE wear and osteolysis. Recent developments in ceramic matrix composites and the introduction of Biolox Delta® with improved fracture toughness have further reduced the risk of fracture and also extended the design flexibility of the material. A novel tripolar all-ceramic bearing for hip prostheses (Ceram-Concept, Newark, DE, USA) has been designed and developed to deal with the problems described above. The tripolar delta ceramic (TDC) THA combines the functional advantages of the tripolar PE THA with the tribological advantages of ceramic bearings.

2. The concept

The orientation of the cup in terms of anteversion and inclination has significant consequences on the joint's range of motion and resistance to dislocation [8]. The position of the rotation center in the cup-ball head system affects joint stability: it has been shown that an inset of the rotation center of a few millimeters increases the peak resisting moment against dislocation [9][10]. This benefit in terms of stability has a disadvantage, however: it decreases the range of motion of classical ball-insert systems. The TDC joint allows the center of rotation to be located much deeper inside the insert without significant negative impact on the range of motion [10] [11].

The first all-ceramic tripolar joint was a 22/32 combination including a 22-mm head, a 22/32-mm mobile ceramic head secured with a PE ring, and a 32-mm internal diameter ceramic acetabular insert. Another possibility is a 26/36 combination, including a 26-mm head, a 26/36-mm mobile ceramic head (or "intermediate component" or "bipolar head"), and a 36-mm ceramic acetabular insert. All components were manufactured from Biolox Delta ceramic matrix composite, Ceramtec, Germany.

Tripolar hip prostheses have two bearing surfaces: the outer bearing surface, between the acetabular cup and the intermediate component (bipolar head), and the inner bearing surface, between the intermediate component and the femoral head component (Figures 1-2). The outer surface of the intermediate component is a portion of a solid sphere, the center of which is identical to the center of the acetabular insert during joint loading. The center of the inner bearing surface of the intermediate component (bipolar cup) corresponds to the center of the femoral head and is designed to be inset from the center of the outer bearing surface of the intermediate component (i.e., the center of the acetabular component).

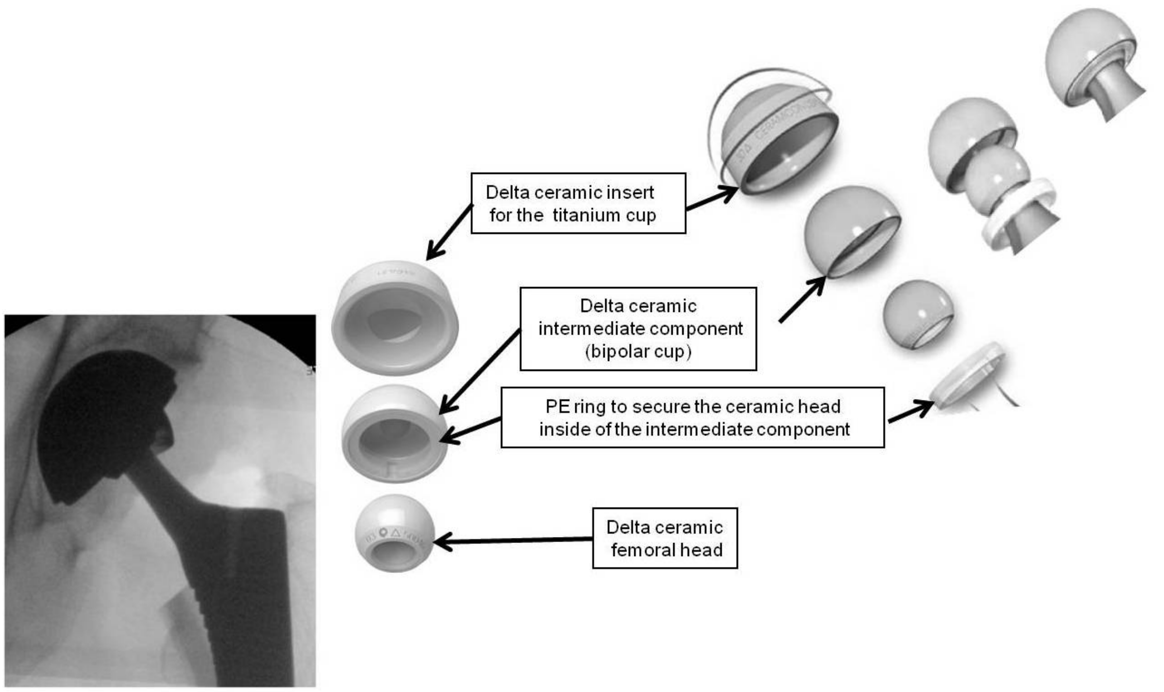

Figure 1. Tripolar hip prostheses have two bearing surfaces: the outer bearing surface, between the acetabular cup and the intermediate component (bipolar head), and the inner bearing surface, between the intermediate component and the femoral head component

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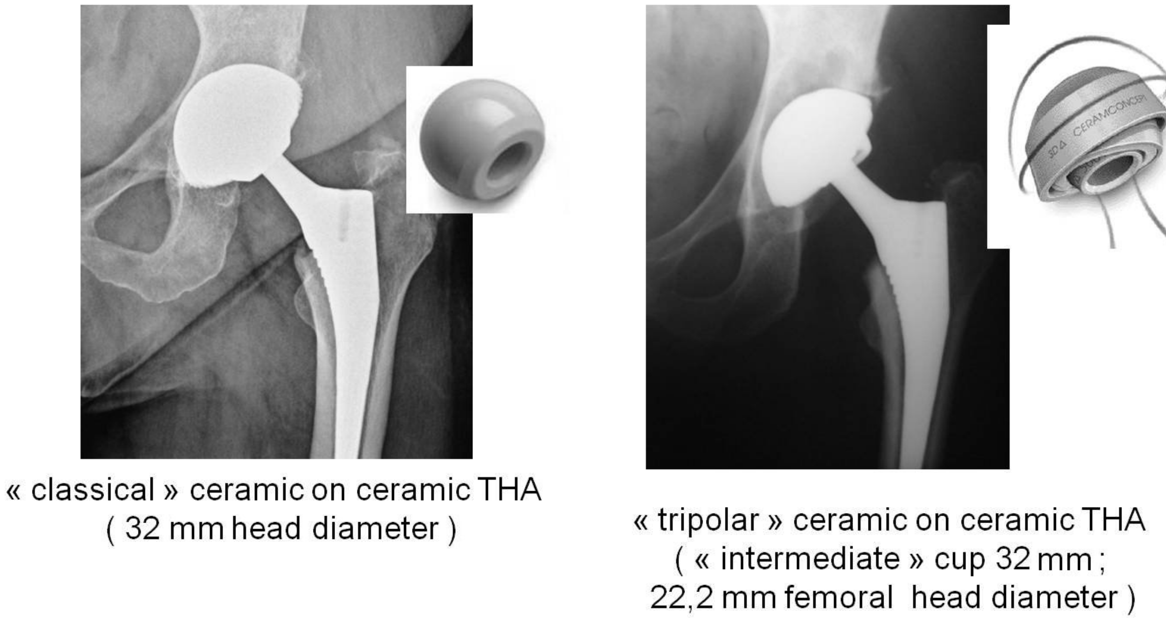

Figure 2. Comparison between a conventional ceramic –ceramic prosthesis and a tripolar delta ceramic prosthesis : Implantation procedures for metal-back or acetabular insert placements or for femoral adjustment are the same. The only originality of the tripolar system is the interposition of a "double femoral ball head" or " bipolar head" on the femoral taper.

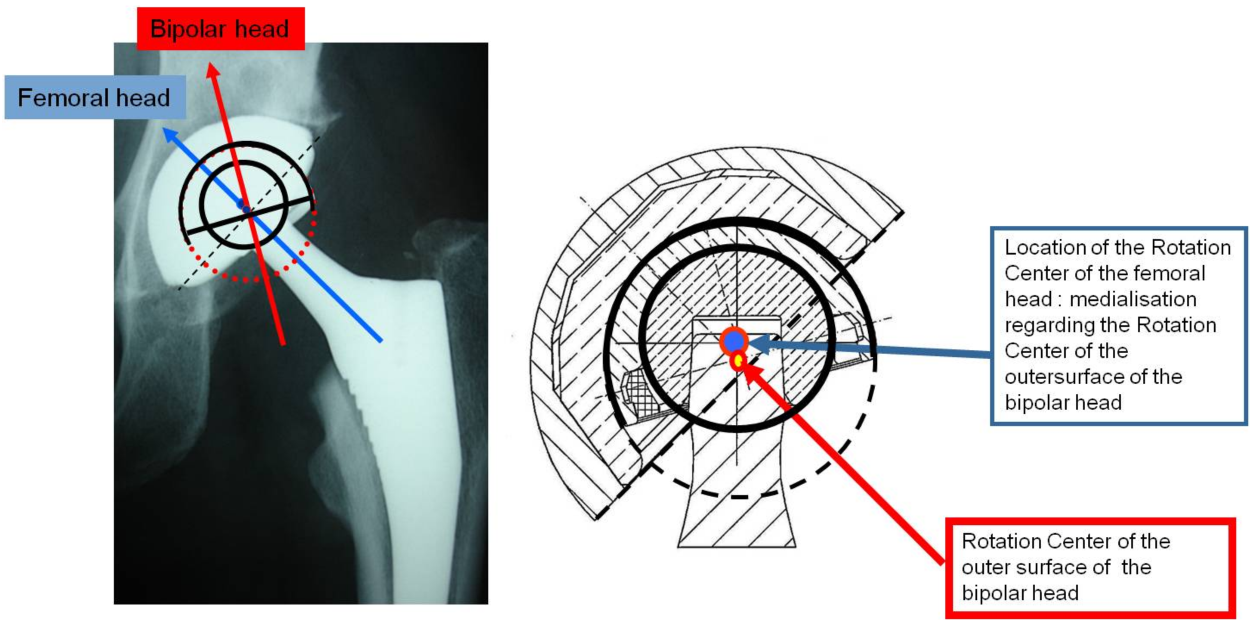

Figure 3. The outer surface of the intermediate component (bipolar head) is a portion of a solid sphere, the center of which is identical to the center of the acetabular insert during joint loading. The center of the inner bearing surface of the intermediate component corresponds to the center of the femoral head and is designed to be inset from the center of the outer bearing surface of the intermediate component (i.e., the center of the acetabular component).

This geometric arrangement thus creates a certain amount of eccentricity between the acetabular component and the femoral head component (Figure 3). If the centers of rotation of the femoral head and of the outer surface of the bipolar head are not aligned when TDC joint loading begins, the intermediate component starts to align itself: the bipolar head (i.e., the intermediate component) can, through the two bearing ceramic delta surfaces, act as a self-adjusting cup and deal with the variations of femoral head and acetabular orientation (Figure 4).

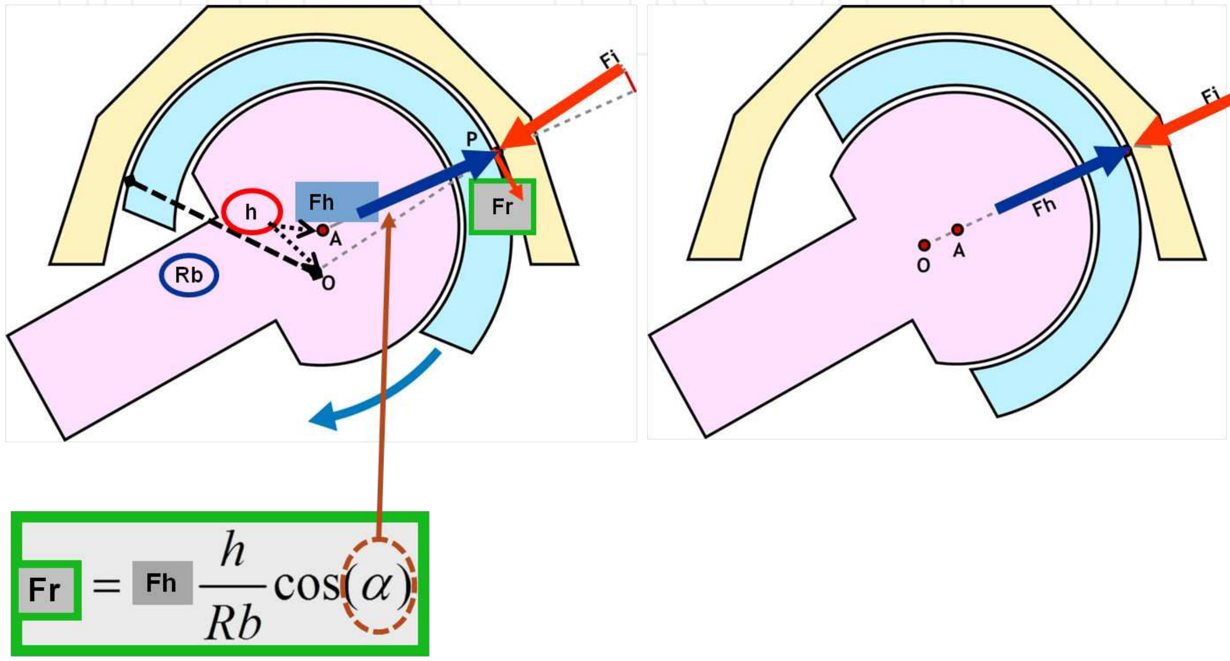

Figure 4. Mechanism of adaptation of the bipolar head in the TCD joint : the non alignment of the rotation centers for the femoral head (A) and the bipolar head (O) induces a self adaptation of the bipolar head. Fh is the contact force which acts on the head at point P. This force is applied on the femoral head through the femoral neck. If friction is neglected, it is necessarily aligned with its centre A. Fi is the reaction force of the acetabular insert upon the bipolar head. If friction is neglected, it is necessarily aligned with its centre O.If Fr and Fi are not mutually in equilibrium, they create a resulting force Fr. The resultant force Fr inducing the adjustment of the bipolar head can be calculated (h is the value of the medialisation of the femoral head center (O A distance) ; Rb is the radius of the bipolar head ; alpha is the angle between Fh et Fi).

3. Preclinical studies

3.1. Evaluation of the mechanical performance of the femoral head and the bipolar head

The mechanical reliability of this device was evaluated by a qualification program according to the criteria defined by CERAMTEC and the standards for marketing authorization. Standard qualification programs were performed on the 22.2-mm ball head and the standard XLW 32/41-mm cup insert. A new program, based on a ball head qualification program, was set up for the bipolar head (intermediate component). Specifications of the bipolar compo-

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nent (diameter, roundness, clearance, etc.) are identical to those for the 32-mm ceramic ball head (Figure 5).

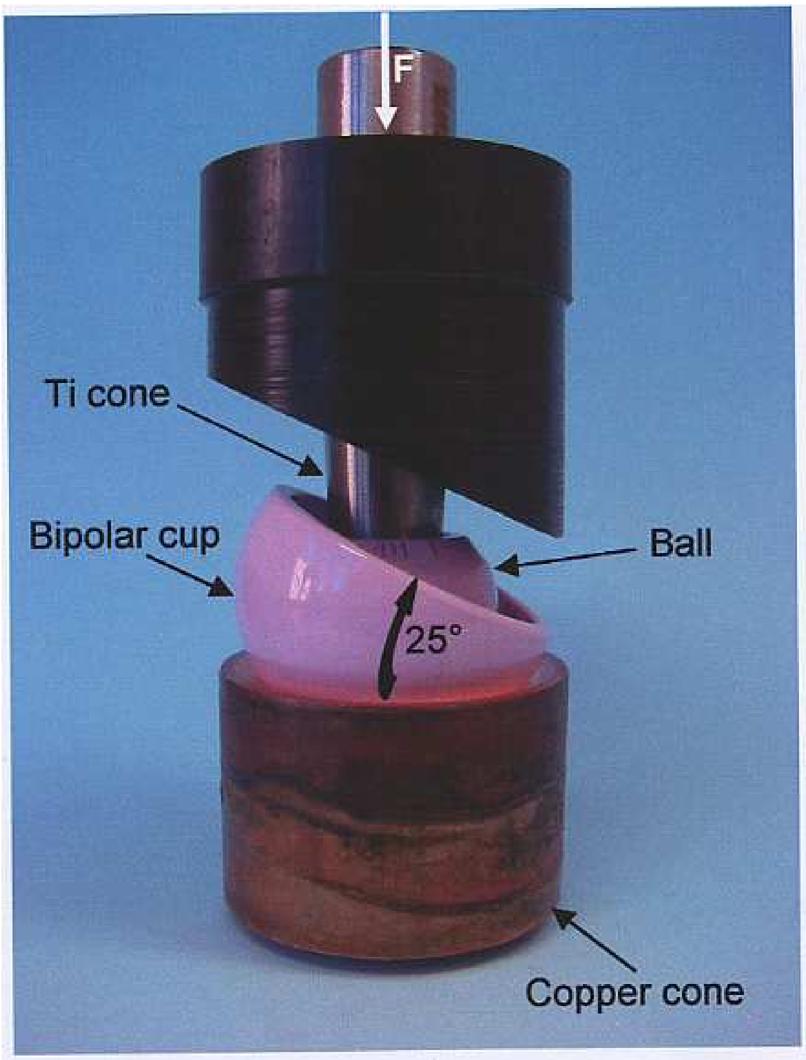

Figure 5. Experimental protocol for burst tests on tripolar delta ceramic (TDC) implants.

The bipolar component has particularly high resistance to fracture, as shown in Table 1 [9].

Static Test (kN)	Avarage value	Minimal value
Avarage value required 46 kN Minimal value required 25 kN	129	58
Post fatigue Test	**Average value**	**Minimal value**
Avarage value required 46 kN Minimal value required 20 kN	91	82

Table 1. Evaluation of the intermediate component: static and post-fatigue tests

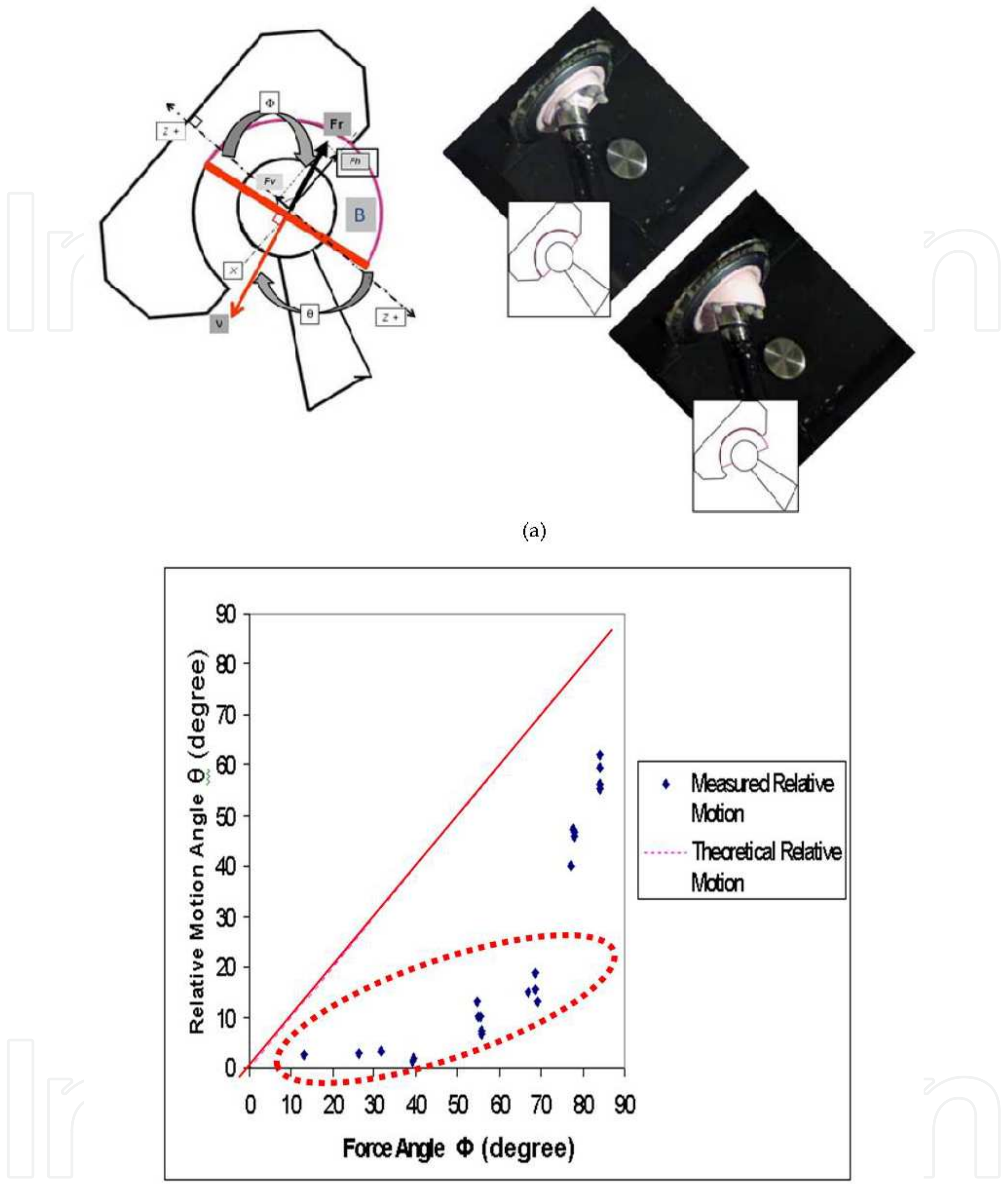

Figure 6. a) *In-vitro* investigation of the relative motion of the intermediate component for shear-out situations. In shear-out situation, dislocation is supposed to occur without impingement between the acetabular cup and the femoral component. When the direction of the total joint contact force (Fr) goes beyond the edge of the acetabular cup, dislocation occurs. The implementation of an experiment with the tripolar system is more complex than with a classical THA. A series of tests was conducted to record the position of the intermediate component with a motion analysis system. The resultant force on the intermediate component is defined as F_r. The vertical force applied to the intermediate component is defined as F_v; the horizontal force is defined as F_h. The center of the inner bearing surface of the intermediate component (i.e., the center of the femoral head component) is designed to be inset from the outer bearing surface of the intermediate component (i.e., the center of the acetabular component), thus creating a certain

amount of eccentricity between the acetabular component and the femoral head component. Theoretically, when the loading on the joint arc surface is not in line with the centers of the arc, self-alignment of the intermediate component will be initiated. Shear-out situation was simulated by applying different magnitudes of F_h while keeping F_v at a fixed value. For a given F_v, as the magnitude of F_h increased, the direction of the resultant force F_r moved toward the edge of the acetabular cup and eventually beyond the edge chamfer. The angle between the direction of Fr and the negative z-axis is defined as Φ; the angle between the direction of the normal vector (V) of the bipolar component (B) and the positive Z-axis is defined as θ. The angle Φ between the resultant force Fr and the negative z-axis was calculated experimentally from the force data recorded by load cells. Reflective markers were rigidly glued to the rim of the intermediate component representing the plane of the bipolar head whose orientation was to be measured. Positional data of the markers implanted on the bipolar component were recorded by motion analysis cameras. Since F_h and F_v were applied in x-z plane, the motion angle between the normal vector of the measured plane and the positive z-axis (θ) was plotted against the resultant force angle (Φ). (b) The dash line 1 represents the θ vs. Φ curve in an idealized theoretical situation (suction force ignored, frictionless). In the ideal situation the normal vector of the intermediate component at any time should seek alignment with the direction of the joint contact force. Dots represent the measured θ vs. Φ curve. Qualitatively, θ increases with the increase of Φ. The rotation of the intermediate component in x-z plane is correlated with the direction of the resultant contact force. At Φ below 40 ° (when the direction of the load was not much deviated from the aligned center-shaft), there was a "toe" area which meant the intermediate component remained in its original horizontal position and did not react to the change of direction of the resultant force F_r.This was due to the effects of surface adhesion and friction : the rotation moment formed by the offset contact forces must first overcome the resistance of suction and friction before it can effectively rotate the intermediate component. As Φ went beyond the toe region, the slope of the experimental curve gradually increased ; the slope of the curve is not exactly superimposable to that of curve 1 because of the suction force and friction.

3.2. Biomechanical tests

- Two typical scenarios (lever-out and shear-out) that can lead to dislocations were investigated. The studies provided evidence that the relative motion of the intermediate component is closely related to the eccentricity between this component and the femoral head [11-12].

We compared the adaptation in impingement situations with lever-out loading between a standard ceramic joint (32-mm ball head/ceramic insert) and the TDC, with a 32-mm self-adjusting cup.

- The variable for assessing dislocation stability was torque during subluxation (resisting moment) against levering the head out of the cup [13]. With the standard system (ceramic ball and socket), dislocation appears as soon as there is contact between the femoral neck and the acetabular insert because of the moment applied. This dislocation by impingement is directly related to range of motion.

The mechanism with the TDC system is different, as are the steps involved. First, the ball head alone rotates. In a second stage, contract forces cause rotation of the bipolar head. Finally, the ball head and the bipolar head rotate together [14]. The moment that must be applied to the joint to obtain luxation is higher than for the conventional system: the increase of this peak resisting moment has been measured at 18.71%

Shear-out loading has also been investigated: the direction of the normal vector (V) of the intermediate component (bipolar head) expresses its relative motion. Adaptation was explored by evaluating the orientation of V in various directions and at various magnitudes of the force to the TDC joint. The orientation of the resultant force (Fr) on the bipolar head is expressed by the angle Φ (Figure 6). Until that angle reaches 40°, the intermediate component remains in its original position, not reacting to the change of direction of this Fr force.

At that point, the intermediate piece adapts and the curve expressing the orientation of vector V changes abruptly.

3.3. Tribological tests

- Simulator studies were carried out under ISO standard conditions, but also under microseparation conditions that replicated head/cup rim contact at heel strike.
- Microseparation is most appropriate for the evaluation of ceramic bearings, as the experimental conditions are optimal for reproducing clinical wear rates and wear mechanisms, including stripe wear, as found on standard ceramic-on-ceramic retrievals. The aim of the tribological tests was to assess the wear characteristics under standard and swing phase microseparation between 200 and 500 μm for a total of 5 million cycles with the Leeds II Physiological Anatomical hip joint simulator [15].
- Under standard conditions, wear was very low on both the tripolar and the conventional ceramic-on-ceramic bearings. The wear of the tripolar all-ceramic hip was less than 0.01 mm^3/million cycles, which is the detection limit for wear measurement, and the conventional ceramic-on-ceramic bearing produced a wear rate of 0.04 mm^3/million cycles. The difference between these very low wear rates is not clinically significant.
- Under microseparation conditions, wear performance differed significantly. In a previous study, conventional Biolox Delta components were tested under microseparation conditions in the same simulator with reported wear rates of 0.32 mm^3/million cycles during bedding-in (0-1 million cycles) that then fell to a steady state wear rate of 0.12 mm^3/million cycles (1-5 million cycles) [8, 12]. Furthermore, stripe wear appeared on the standard Biolox Delta heads and increased the surface roughness Ra from <0.005 μm to between 0.02 μm and 0.13 μm.
- Testing of the TDC joint showed no macroscopic visual evidence of wear. Wear was less than 0.01 mm^3/million cycles (i.e., below the detection limit for wear measurement). No stripe wear was observed; the surface roughness of the ball heads and the outer and inner surfaces of the bipolar head were smoother at the end of the test, indicating that they had undergone a polishing effect.
- The design of the TDC joint with its mobile ceramic head prevented edge loading of the head on the edge of the cup, so significantly reduced wear under these severe, but clinically relevant microseparation conditions [15].

Dislocation tests have been performed to evaluate the resistance of the PE ring in securing the ball head inside the intermediate component. Results were similar to those for similar PE rings that have been used for more than 18 years in standard double-mobility hip joints. The average maximum load for clipping the PE ring was 151.1 N before the tests; it rose to 175.5 N after 5 million cycles of microseparation. The increase in clipping resistance is due to the water load of the ring that occurs in the course of 5 million cycles. 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 back side of the PE rings showed no damage, with only a light polishing effect observed in places [9].

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4. Clinical data

Clinical results come from the first 2000 consecutive cases in a multicenter study. No specific learning curve was necessary: the surgeons did not change their implantation procedures for metal-back or acetabular insert placements or for femoral adjustment. The only originality of the system is the interposition of a "double femoral ball head" on the femoral taper. Positioning the femoral head on the taper is simple, as the intermediate cup is easily secured in a second step with the PE ring (Figure 7,8,9) [10].

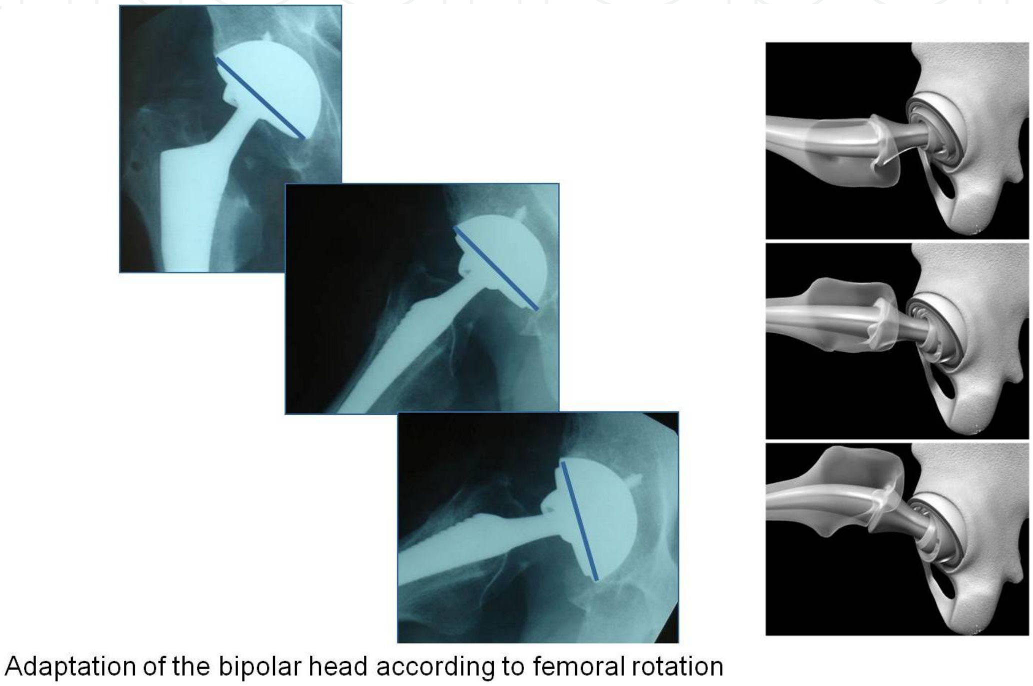

Figure 7. Adapted of the bipolar head according to femoral rotation

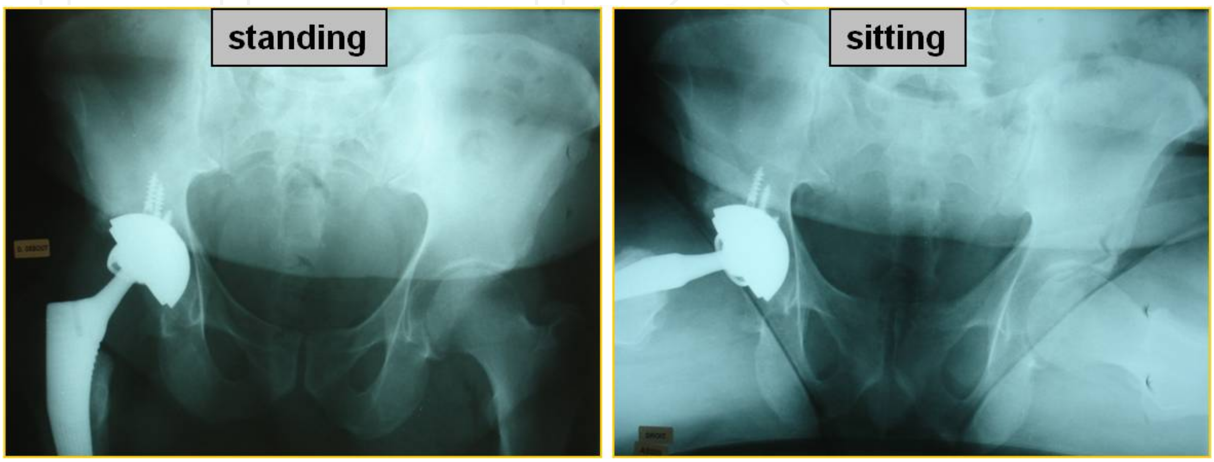

Figure 8. Adaptation of the bipolar head according to standing and sitting position

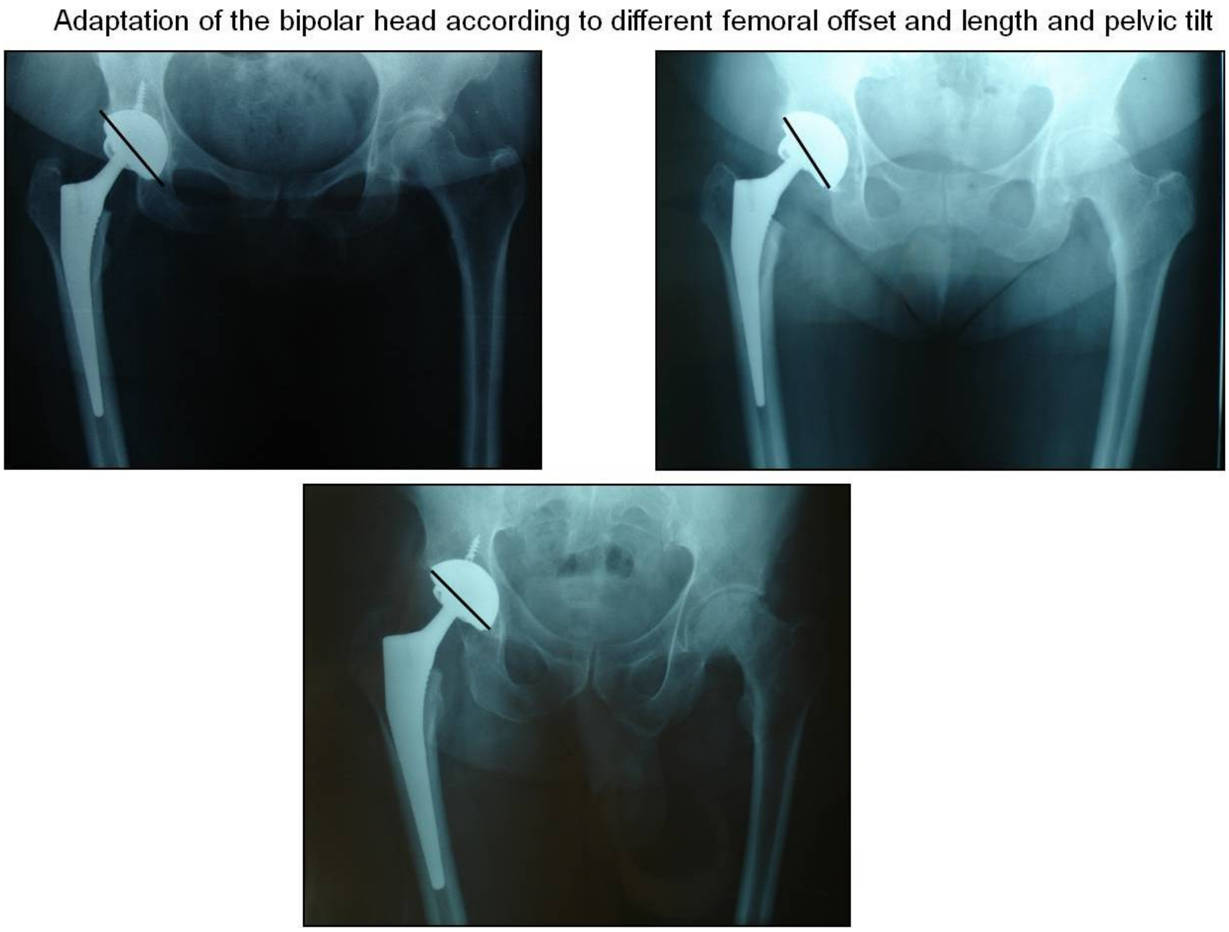

Figure 9. Adaptation of the bipolar head according to different femoral offset and length and pelvic tilt

In our experience, indications for this device are risk of instability, stiff coxarthrosis, osteonecrosis, revisions, oblique pelvis or significant rotational problems, neurological disorders, and some patient problems (alcoholism and psychiatric disorders). The Harris hip score indicates that clinical changes are similar to those with standard THA. The dislocation rate was 0.6%, despite a posterior approach in 87% of the cases. The main explanations were inadequate reconstitution of femoral neck length and/or offset. In a few cases (1.2%), patients described some occasional and irreproducible loud noise from the hip area, similar to that described for standard PE double-mobility systems. Experience with the double mobility PE joints has related this noise to sudden relocation of the intermediate component. The phenomenon is completely different from squeaking in terms of sound characteristics and mechanical aspects. A specific radiologic protocol allowed us to use the EOS® low dose imaging system to observe the adaptation of the intermediate component in standing and sitting positions. The mobility of the intermediate component is consistent with earlier studies and with experimental data. In some patients with significant lower-limb anatomic abnormalities, the tripolar system has been a successfully used as a salvage procedure to resolve cases with complex instability (Figure 10).

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		Bipolar cup	Acetabular cup
standing	Frontal inclination	18°	32°
	anteversion	- 46°	45°
sitting	Frontal inclination	41°	36°
	anteversion	43°	42°

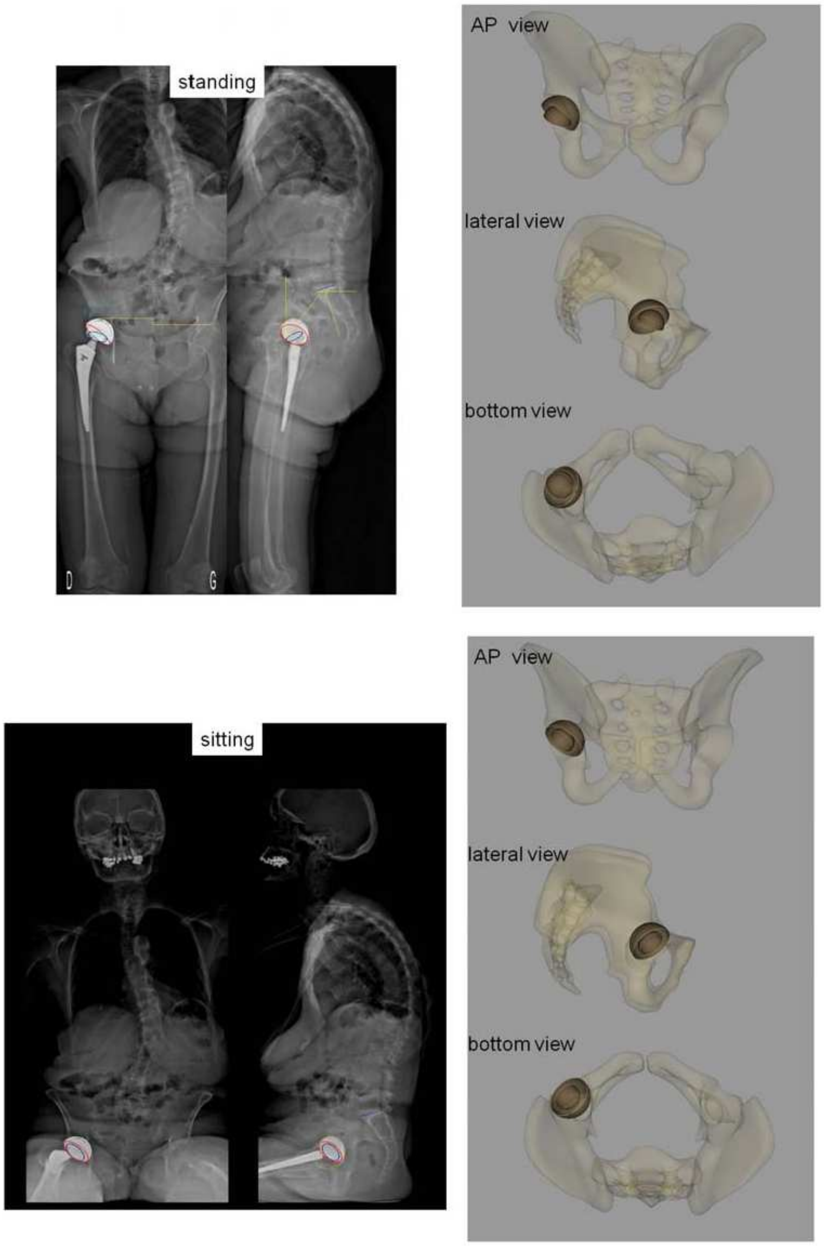

Figure 10. EOS imaging in standing and sitting position. In this case, the scoliosis including a significant pelvic rotation induces a specific adaptation of the intermediate component (bipolar head). One can observe the adaptation of the bipolar head with retroversion in standing position to compensate the hyperanteversion of the femoral neck. The orientation of the bipolar head is significantly different from the acetabular cup anteversion. In sitting position, the adjustment is different and the 2 cups anteversions are equivalent.

5. Conclusions

The use of the tripolar all-delta-ceramic joint appears to be an interesting alternative for optimizing THA function where, 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. Its effectiveness against dislocation and microseparation can be explained and documented experimentally. The tripolar ceramic joint provides significant resistance to wear and stripe wear. Nevertheless, it cannot compensate for suboptimal THA implantation resulting in excessive shear-out laxity due to shortening of the head-neck length or lack of femoral offset [3, 16].

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