

## 2.3 Two Bearing Ceramic Surfaces with a Self Adjusting Cup: A New Solution to avoid Dislocation and Subluxation in Total Hip Prosthesis

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### Introduction

Dislocation remains one of the most common complications after total hip arthroplasty.

The ceramic on ceramic bearing surface hasn't yet solved this problem. Its prevalence ranges from 0.6% to 7% according to different publications series. [1-2-3-4-5-6-7-8-9]. These wide variations are related to the type of hip surgery, the type of prosthesis used, the patient's characteristics, surgical techniques, and the surgeon's experience.

Ceramic on ceramic requires a more exacting technique and component position. Intra operative assessment is more critical [10]. Dislocation is a major cause of failure of Ce-Ce prosthesis compared to a classical Metal PE bearing couple (0,51% versus 0,14%). [11].

Precise cup position appears to be a main factor influencing the risk of dislocation.

Clinical studies show that the dislocation risk is 6,9 times higher if total anteversion is not between 40° and 60° after THA [12]. This accentuates the interest in alternatives with 3D $\Delta$  Ceramic Self Adjusting Cup joint as anteversion variations also occurs according to sitting or standing positions. [13-14].

### Anatomical and geometrical study

Three dimensional analysis of dislocation and micro separation demonstrates that some factors are related to prosthesis design and surgical implantation. But one of the main problems remains the lack of accuracy in pre and per-operative planification, mainly for the acetabular cup: different morphological and functional parameters depending on the patient are more or less controlled during surgical implantation:

1. The range of motion of a normal spine induces variation of sagittal acetabular tilt between standing and sitting position. The modifications of sagittal orientation are associated with less cup anteversion in standing position and more cup anteversion in sitting position.
2. Diseases affecting lumbosacral junction and/or prior surgical procedures (ageing spine, lumbosacral fusion) reduce the adaptation of T.H.P. to sitting or standing position.

In patients with limited spinal motion and/or permanent backward rotation of the pelvis, changes in anteversion between the sitting and standing position may be very small. This explains the possible catastrophic consequences of selecting an inappropriate position during hip replacement.

3. Regarding those morphological and functional parameters, acetabular implantation is an arbitrary compromise. Standardising the position of the patient and the operative technique does not eliminate the risk of sub optimal acetabular cup positioning in patients with unusual anatomical characteristics.

Furthermore hip prosthesis articulations currently used are non anatomical, and therefore don't have the mechanical characteristics and tolerance of the natural hip.

### 3D $\Delta$ Ceramic Self Adjusting Cup solution.

The use of 3D $\Delta$  ceramic self adjusting cup joint seems an interesting alternative to face those difficult situations for adjustment and hip stability as, in some cases, no ideal solution can be found for acetabular implantation.

One manner of increasing the stability of an artificial joint is to modify the position of the rotation centre. Some publications explain that an inset of few millimetres increases the peak resisting moment. [15-16]. The moment necessary applied to get dislocation must be higher. This benefit in term of stability has a big disadvantage in loss of range of motion.

The 3D $\Delta$  system has allowed to move the rotation centre much deeper inside the insert without any impact on the ROM, in other terms the 3D Delta could give more stability with a comparable ROM as a standard system.

A study in collaboration with the CEA (Atomic Research Centre) explains in detail the behaviour of these 3 ceramics components. The "Self adaptation" of the intermediate cup can be demonstrated: the additional outer-bearing surface motion creates a second "adjustable acetabulum"

After defining different parameters (Inclination of the insert 45°, Forces and Moment applied on rotation centre) a comparison of the mechanism of dislocation between a standard system (composed of a Ball head against an Insert) and the 3D $\Delta$  system (composed of two ceramic on ceramic bearing surfaces with a self adjusting cup) has been performed.

With the Standard system, the dislocation appears if a contact occurs between the neck and the insert because of the moment applied. This dislocation by impingement is in direct relation with the range of motion.

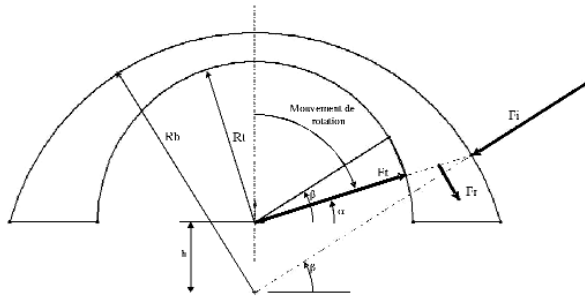
With the 3D $\Delta$  system, the mechanism is different and shows different steps:

- Rotation of the Ball head alone.
- Rotation of the Bipolar head in the opposite direction because of contact forces, until contact between the Bipolar head and the stem.
- Finally rotation of the Ball head and the Bipolar head will appear together.

This Self adjusting cup phenomena is now well described and due to the eccentrication of the Bipolar head from the Ball head; the phenomena is different to the workings of a classical tripolar prosthesis.

With "h" the offset between the rotation centre of the ball head and the rotation centre of the bipolar head, applied forces are not on the same application point. This offset creates a resultant force  $F_r$  that rotates the bipolar head until its adjustment .

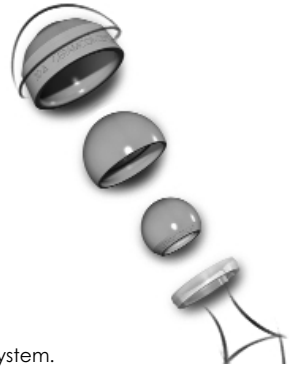
Two Biomechanical studies in the USA and in Europe are ongoing and will confirm the resistance to dislocation of the 3D $\Delta$  system, compared to other systems available on the market.



**Figure 1:**  
Self Adjusting Cup Mechanism.

## Mechanical performance

In collaboration with CeramTec AG a qualification program has been established to evaluate the mechanical reliability of this device. The system is made by 3 ceramic components:



**Figure 2:**  
3D ceramic Self Adjusting Cup System.

A standard ball head of 22,2 mm, a Bipolar head (intermediate piece) and a standard XLW fix insert 32/41 mm.

A standard qualification program for the Ball Head and the fix insert has been performed. Concerning the Bipolar head, a new program has been set up based on a ball head qualification program. Specifications of the Bipolar head, diameter, roundness, clearance, etc... are strictly the same as a 32mm ceramic ball head.

All 3 components have successfully passed the qualification. Mechanical characteristics of BioloX® Delta enable the manufacturing of this special device and especially of the intermediate cup with excellent strength properties.

Finally, tests have been performed to evaluate the resistance of the PE ring to secure the ball head inside the intermediate piece. Results are comparable to similar PE rings used for more than 18 years with double mobility Metal Polyethylene.

Previous tribological tests with BioloX® Delta bearing couples show very low wear rate.

Currently a study is on going in the Bio-mechanical Laboratory in Leeds (UK) over 20 Mc on standard hip simulator and on Hip simulator with microseparation.

## Conclusion

3D $\Delta$  self adjusting cup joint offers new solutions to reduce the risk of dislocation and sub luxation. The device also reduces the wear by using the new ceramic Biolox<sup>®</sup> delta.

The decision to use the 3D $\Delta$  device could be made preoperatively. The surgeon could decide during the operation if the patient needs a classical Ceramic on Ceramic bearing couple or the 3D $\Delta$  system in case of concerns about stability. The device could also be used against a PE insert to have a benefit in stability only.

Reducing the risk of dislocation and reducing drastically wear are two advantages that could place the 3D $\Delta$  system as the best choice in primary Total Hip Arthroplasty. Obviously this choice applies to recurrent dislocation also.

The use of the 3D $\Delta$  device could have a positive impact in terms of cost by reducing significantly the number of revisions.

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