Review article

Does Biolox® Delta ceramic reduce the rate of component fractures in total hip replacement?

P. Massin a,*, R. Lopes b, B. Masson c, D. Mainard d, the French Hip & Knee Society (SFHG) e

a EA REMES, université Paris-Diderot, Sorbonne-Paris-Cité, hôpital Bichat, 46, rue Henri-Huchard, 75010 Paris, France
b Hôtel-Dieu, université de Nantes, 1, place Alexis-Ricordeau, 44009 Nantes cedex 1, France
c 18, rue des Potiers, 31320 Vieille-Toulouse, France
d Université de Lorraine, hôpital Central, 29, avenue de Lattre-de-Tassigny, 54035 Nancy, France
e 56, rue Boissonade, 75014 Paris, France

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A B S T R A C T

Biolox® Delta ceramic has been optimized with nano-sized, yttria-stabilized tetragonal zirconium and strontium oxide to help limit cracking propagation. Although its mechanical properties are better than those of earlier generation ceramics, existing data on this material are limited, thus the goals of this study were to determine: 1) the remaining rate of implant fracture; 2) the ideal combination of head diameter and component position. Hypothesis. We hypothesized that the use of the ceramic composite Biolox® Delta had reduced the risk of implant fracture. Materials and methods. The bibliographic search (in Pubmed database with the key words «ceramic fracture» and «total hip prosthesis») identified 46 articles on fractures in third or fourth generation ceramic components, including 5 involving Biolox® Delta. Manufacturer’s data and ANSM (Agence nationale de sécurité du médicament et des produits de santé) (National Agency for Safety of Drugs and Medical Products) reports were compared with the few clinical cases published in the literature. Results. According to the manufacturer (CeramTec GmbH, Plochingen, Germany), the use of Biolox® Delta ceramic has reduced the rate of femoral head fractures to 0.003% compared to 0.021% with alumina ceramic. The fracture rate of liners has remained stable, at approximately 0.03%. The number of ANSM reports confirmed these tendencies. The rate of head component fractures decreases as the head diameter increases. The quality of impaction on the more taper (cleanliness of the taper, insertion along the axis) plays an important role. Although it is generally only available for cup sizes above 50 mm, a 36-mm head diameter seems to be optimal because it prevents impingement between the cup rim and the neck of the stem, without increasing micro-separation with larger diameters. Conclusion. Although Biolox® Delta ceramic is more resistant to fractures than alumina ceramic, it can be fractured under suboptimal implantation conditions including edge loading. Its use requires the same precautions as other hard-on-hard bearings and requires special attention to cup position, insertion on or in more tapers and adjustment of leg length.

Level of evidence: V expert’s opinion.

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1. Introduction

The ceramic Biolox® Delta was commercialized as of 2000, and was developed to reduce the frequency of head component and liner fractures during total hip arthroplasty, which was already very low [1]. Biolox® Delta is an alumina ceramic composite that is mainly optimized with nano-sized, yttria-stabilized tetragonal zirconia and strontium oxide [2]. The transformation of the zirconia phase into the alumina ceramic matrix limits the development of potential cracks [3]. Improvement of the mechanical properties of the ceramic composite increases its reliability and provides more freedom of design. In particular, the use of large diameter femoral head components should theoretically reduce the risk of dislocation without changing the diameter of the neck, as well as improving stem mobility and reducing the risk of impingement between the rim of the liner and/or cup and the neck of the stem.

Fracture of a ceramic bearing component can be favored by various factors that are not due to the intrinsic properties of the material; in particular component design, technical aspects and factors associated with implantation. We hypothesized that the use of the ceramic composite Biolox® Delta has reduced the risk of implant fracture, providing potential new uses for this material.

* Corresponding author. Tel.: +33 1 40 25 75 03; fax: +33 1 40 25 71 84. E-mail address: philippe.massin@bch.aphhs.fr (P. Massin).

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which is one of the most resistant to long-term wear available today. There are very few clinical results published in the literature, and several questions remain including:

- what is the remaining risk of fracture of the liner and head component with the ceramic composite Biolox® Delta?
- what is the ideal head diameter and component position for an optimally functioning ceramic-on-ceramic bearing?

2. Materials and methods

2.1. Materials

A search in the literature for ceramic fractures based on the key words “ceramic fracture” and “total hip prosthesis” identified 132 articles in the Pubmed database. An additional search for the ceramic composite Biolox® Delta identified 14 additional publications. Eighty-six of these studies were excluded because they did not directly concern ceramic fracture, which left 58 studies, including 53 which involved third generation ceramics (Biolox®Forte) and five fourth generation ceramics (Biolox® Delta) [4–8]. Eleven articles concerned the very specific aluminia “sandwich”, design which resulted in very high levels of liner fracture, and which is no longer used in France. After excluding these 11 articles, 42 articles remained on 3rd generation ceramics in their most conventional form, that is, pure ceramic liners. Sixteen of these papers were single case reports. There were also two case reports [6,8] out of the five studies on Biolox® Delta. We added two recent oral communications that could be consulted in the referenced collection of abstracts of the medical societies [9,10].

2.2. Methods

The ceramic fracture rate was identified and compared to the manufacturer’s data (CeramTec) and to the medical device vigilance reports filed at the ANSM by surgeons (Agence nationale de sécurité du médicament et des produits de santé) (National Agency for Safety of Drugs and Medical Products). They were compared to the entire population of patients who received implants with at least one ceramic bearing. For the liner, the total estimated number of patients with a ceramic-on-ceramic bearing implant was used. For the head, the total estimated number of patients with a ceramic head component was used, whatever the type of liner. Head fractures were evaluated in relation to the quality of the morse taper and head size. Liner fractures were evaluated in relation to certain parameters: cup size, interior design of the cup, quality of insertion in the metal cup and cup position.

2.3. Results

According to the manufacturer’s (CeramTec GmbH, Plochingen, Germany), the use of Biolox® Delta ceramic has significantly reduced the rate of femoral head fractures. The rate of fracture for the 2,050,000 Biolox® Forte ceramic femoral heads and the 250,000 Biolox® Delta ceramic femoral heads delivered between January 2000 and March 2008 decreased from 0.021% (20/100,000) to 0.003% (3/100,000) with the use of Biolox® Delta ceramic. The manufacturer later re-calculated this rate for the 1 500 000 Biolox® Delta ceramic heads sold in 2012 to 0.002%, claiming that the rate of head fracture with the use of the ceramic Biolox® Delta had been reduced 10 fold.

According to the ANSM, there have been 428 reports of head component fractures with third generation ceramic since 2001 and three since 2008 with the fourth generation ceramic composite. These figures must be compared to the number of THA performed during the same period, which increased from 107,803 in 2001 to 150,000 in 2011 according to the Technical Agency for Information on Hospitalizations (Agence technique de l’information sur l’hospitalisation (ATIH)). Considering that 50% of THA have ceramic heads alone (whatever the type of liner) and the progression of the ratio 4th generation ceramic/3rd generation ceramic (which was reversed in 2008), the rate of head fractures was 0.18% with 3rd generation ceramic and 0.0013% with 4th generation ceramic which represents a 100 fold decrease in fracture rate of ceramic heads, although the manufacturer only reported a 10 fold decrease. However, it should be noted that the number of reported 3rd generation ceramic head fractures was twice as high as that reported by the manufacturer, while there was less disagreement for fracture rates with the fourth generation ceramic composite.

Our review of the literature showed a head fracture rate between 0 and 10% with Biolox® Forte ceramic, with a median near 0 [1]. There were only 2 series published on Biolox® Delta. Lombardi et al. [7] reported one head fracture/44 THA after 2 years follow-up, while Cai et al. [4] did not report any ceramic fractures in 50 patients (50 hips) after a mean 3 years of follow-up.

The use of Biolox® Delta ceramic does not seem to have reduced the rate of liner fractures. According to the manufacturer, the fracture rate of the 980,000 Biolox® Forte liners and the 740,000 Biolox® Delta ceramic liners has remained stable going from 0.032 to 0.028% (Table 1).

The number of liner fractures reported to the ANSM since 2001 was 449 for 3rd generation ceramic and 28 since 2008 for the 4th generation ceramic composite. Considering that an estimated 25% of all THA implanted in France used ceramic-on-ceramic bearings and the progression of the rate of 4th generation/3rd generation ceramic, the rate of liner fracture was 0.086% with the 3rd generation ceramic and 0.025% with the 4th generation ceramic (Table 1). The rate of liner fracture has not significantly changed with the composite ceramic. The rate of reported liner fractures was similar to that reported by the manufacturer, whatever the generation of ceramic.

This very low rate was not supported by certain results in the literature that reported higher rates of fracture with «Biolox® Delta» ceramic liners. Hamilton et al. [5] reported a perioperative liner fracture rate of 1.1% and a postoperative rate of 1%. Massin et Vogt [9] reported four liner fractures in a series of 106 hips implanted with the same cup from the same manufacturer (Fig. 1). That series also reported an insertion error identified on the postoperative X-ray which required immediate revision before fracture occurred. Mawdsley et McCourt [10] also recently reported six cases of liner fracture with Biolox® Delta which was explained by an insertion error of the head component in the cup. Hwang et al. [6] and Tahe-riazam et al. [8] reported one case of liner fracture.

Several factors could influence the rate of head fractures, including certain technical factors (quality of impaction, cleanliness of the morse taper during impaction) and the diameter of the femoral head:

- the quality of impaction, which should be performed along the axis of the neck of the prosthesis and on a clean morse taper, plays an essential role. Persistent tissue debris or a damaged morse

| Table 1 | Fracture rate of third and fourth generation ceramic heads and liners from the manufacturer and the ANSM. |
|----|----|----|----|----|
| Third generation | Forth generation |
| Liner | Head | Liner | Head |
| Manufacturer (%) | 0.032 | 0.021 | 0.028 | 0.002 |
| ANSM (%) | 0.086 | 0.18 | 0.025 | 0.0013 |

ANSM: Agence nationale de sécurité du médicament et des produits de santé (National Agency for Safety of Drugs and Medical Products).
taper surface (scratches) can reduce the static fracture load to 20% of its normal value (that of a clean, undamaged taper) [11];
• the fracture rate also depends upon the diameter of the femoral head: the manufacturer reported that the rate of fractures in 3rd generation ceramic heads (Biolox® Forte) was 0.005%, for a diameter of 36 mm, 0.008% with 32 mm diameter heads and 0.03% with 28 mm. But the problem of using large diameter femoral heads is complex. Indeed, several parameters are involved in optimal bearing function;
• increasing head diameter reduces the risk of impingement between the neck and the rim of the ceramic liner or the metal cup, and increases the range of motion (Fig. 2) [4]. This risk seems to be rare for a diameter of 32 mm except for extreme cup positions, and there seems to be no risk at all in a diameter of more than 36 mm with the most commonly used necks/stems on the market (neck diameter of approximately 12 mm). When the head diameter increases, the risk of dislocation decreases by the same mechanism. This possibility of improving taper articulation circumduction, as well as reducing the risk of fracture support the use of the largest head diameters possible;
• however, the use of large diameter head components has its limits because it changes the functioning of the bearings [12].

Positive offset develops in head diameters of more than 36 mm, that is the head center is outside the cup center, thus reducing the angle of head coverage. Sariali et al. [12] showed that this resulted in a phenomenon called “edge loading” during phases of micro-separation, which are inevitable during walking (Fig. 3). The larger the head diameter is, the greater the frequency of this phenomenon. Whatever their origin, (micro-separation or subluxation caused by intraprosthetic impingement), these tribological limits significantly increase the friction between the two elements of the bearing couple [13] and can cause audible noise (squeaking) [14,15]. Although this can modify the ceramic surface, the possible influence on the rate of fracture of the bearing couple is unknown.

Liner fracture can be caused by several factors including certain due to implantation, cup design and other functional “limits” during edge loading:

• although a liner that is too thin may be the cause of fracture, there are no specific data on the inferior limit. Manufacturers produce liners as thin as 3.5 mm. This condition means that a 36 mm diameter head should be used with a 50 or 52 mm diameter cup and a 32 mm diameter head with 46 or 48 mm cups depending on the manufacturer. On the other hand, the head diameter should be reduced to 28 mm with cup diameters below 46 mm;
• vertical positioning of the cup has been blamed in cases of 2nd generation ceramic liner fracture. On the other hand, cup inclination does not seem to influence the risk of fracture with Biolox® Delta ceramic [16]. The design of the interior of the cup, in particular the morse taper that receives the liner, has also been blamed because insertion may be difficult and can result in misaligned impaction creating excess peripheral stress which seems to be supported by observations made of fractured explants with chipped edges. Insertion along the axis of the morse taper is all the more difficult if the angle of the morse taper is narrow (below 10° which was the case in products in which fractures of Biolox® Delta ceramic were observed) (Fig. 4). When the taper angle is reduced by the manufacturer to improve liner/cup cohesion, this complicates insertion and requires specific instruments to help guide insertion of the ceramic liner, as well as longer morse tapers, which reach 9 mm or 11 mm in some recent cups. These precautions do not solve the problems of tissue interposition and soiled tapers, which are very difficult to control during surgery, especially mini-invasive procedures, and with perforated, non-impermeable metal cups;
• cup diameter and thickness may also indirectly affect the quality of liner impaction and liner fractures are generally described in thin 50 to 54 mm diameter cups [8,9].

With the use of large diameter heads, the thickness of the metal cup is reduced to 3 mm in 50 and 46 mm cups used with 36 and 32 mm diameter heads, respectively. Cup deformities may occur

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During impaction, preventing complete liner insertion. These difficulties do not occur when polyethylene liners are used because they are flexible enough to adapt to the new form of their socket. Ceramic liners, which are extremely rigid, cannot adapt in this way so impaction and stabilization in the socket is incomplete, creating an increase in peripheral stresses. In small sized cups, there is a certain advantage to using pre-assembled cups in small components, to solve the problems of cup microdeformities during impaction, taper cleanliness and difficulties inserting the liner. Numerous circumstances can create edge loading, significantly changing the tribology of hard-on-hard bearings and perhaps increasing the risk of implant fractures [17]. The development of neck/cup impingement can cause head subluxation and edge loading, producing metal debris, which, deposited on the ceramic surface, could also change the tribiological conditions as suggested by the results of a recent meta-analysis [18], by generating third-body particle wear [19]. Although the wear in 3rd generation ceramic is significantly increased when it is functioning under “extreme” conditions, Biolox® Delta ceramic, used under the same conditions, resists better [20,21]. Finally, under all these “extreme” conditions, the abnormal increase in shear forces on the liner can create micro-displacements between the liner and its metal back [15] especially if the taper angle is wide (greater than 10°), because cohesion between the liner and the cup is weaker. With finite element analysis, Walker et al. [15] developed a model angle of 18° with cup anteversion of 40°. They reported displacements of 40 micrometers during weight-bearing at the liner–cup interface [15]. Walter et al. [22] had already observed the effect of excess cup anteversion in a clinical series of THA with “squeaking” but the influence of this effect on the fracture rate is unknown.

3. Discussion

There is no unbreakable ceramic, and this is also true for Biolox® Delta ceramic, because insertion maneuvers and component design can create conditions that are beyond its fracture load. Although improving the mechanical properties of the material certainly reduces the risk of head fracture to very low rates, these figures are probably underestimated in the manufacturer’s reports and ANSM reports from surgeons. The surgeon should be aware of the specific technical maneuvers necessary when using ceramic components, in particular for impaction of components on (head) or in (liner) the Morse taper. The optimal head diameters for ceramic bearings are between 32 and 36 mm, to reduce the risk of impingement between the neck component and the cup as well as the phenomenon of edge loading. This type of bearing does not react well to joint laxity and the accompanying micro-separation, making precise perioperative adjustment of leg length necessary. The absence of excess pistoning should be confirmed during trial reduction before surgery in a patient who has not been curarized, although this maneuver alone can loosen a liner that has not been fully impacted.

In relation to cup design, faulty insertion of the ceramic liner because of a Morse taper with a narrow angle (less than 10°) can cause liner fractures even if the prosthesis is used under normal conditions. Thus, an 18° morse taper has been adopted in 99% of prostheses implanted worldwide in prostheses with ceramic-on-ceramic bearings because it facilitates insertion of modular liners into the metal cup. In the absence of edge loading, this design does not cause any problems of secondary mobilization or micromotion of the ceramic liner.

Pre-assembly under dry conditions of the liner and the metallic cup before implantation is most certainly a future solution, however, there is a risk that the surgeon will not be able to choose the size of the head diameter because it will not be possible for the manufacturer to offer all head diameters for each cup size. With Biolox® Delta ceramic, the optimal combination seems to be a 32 mm head for 46 and 48 mm diameter cups and a 36 mm head for larger cups. For the moment, 28 mm heads seem to be the only available option for cups smaller than 46 mm. Experimental clinical evaluation of 22 mm diameter ceramic Biolox® Delta heads is ongoing with dual mobility ceramic-on-ceramic systems.

Finally, the surgeon must control relative cup orientation in relation to the neck when the hip is in positions of extreme circumduction, which may require the use of specific computer navigation in cases with head diameters below 32 mm.

4. Conclusion

Although progress has been made with fourth generation Biolox® Delta ceramic, specific precautions for the implantation of hard-on-hard bearings must still be taken. Risk of wear and of implant fracture are reduced with Biolox® Delta. It offers the best existing tribological conditions on the market for total hip prostheses. This material is extremely safe to use, in particular under boundary conditions with edge loading, which tolerates better than other bearings, such as those in earlier generation ceramics.

Disclosure of interest

Philippe Massin received royalties for patented material from the company Ceramconcepts: Bernard Masson is a scientific advisor and receives fees from the company CeramTec.

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