Ceramic Total Knee Arthroplasty – An Update

a report by
F Benazzo,1 F Macchi,2 S Rossi1 and P Dalla Pria3

1. Orthopaedic and Traumatology Clinic, University of Pavia, Fondazione IRCCS Policlinico San Matteo; 2. Ceramtec Medical Product Division; 3. Lima-Lto, San Daniele del Friuli, Udine

Ceramic Total Knee Arthroplasty (TKA) can be considered a reliable operation with good, long-lasting clinical results.1,2 However, it does have a weak point: its polyethylene liner, whose wear triggers the well-known cascade of bone resorption with debonding of the metallic components, leading to the failure of the implant.3,4 Different materials – cross-linked polyethylenes – have been introduced to total joint implants for both the hip and the knee in an attempt to resolve this problem. However, more time is needed to demonstrate the efficacy of these improved materials in terms of wear.5,6 Different sterilisation processes have decreased the oxidation of the plastic material and have shown their efficacy in reducing wear through decreased delamination, but are not able to positively influence adhesive and abrasive wear caused by the metal surface of the femoral component. Furthermore, studies on retrieved femoral components have shown their surfaces to be more abrasive and ridged, which over time can increase the wear of the liner.7 Finally, allergy to the metal ions released by the metallic component of cobalt–chromium–molybdenum (CoCrMo) implants is an emerging issue, although its clinical relevance is still uncertain. As a result, current research is focusing on new materials. Ceramic, whose resistance to abrasion and better wettability and lubrication are well-known,8 can play an important role in reducing wear – both adhesive and abrasive – and in increasing the lifetime of the component. In addition, ceramic is totally inert, and thus can avoid the potential problem of allergy to metal ions.

In this paper we will provide an update on the issue of ceramic TKAs.

Ceramic in Prosthetic Surgery

Ceramic components were introduced to total hip replacement in the 1970s in France by Dr Boutin, who used a ceramic–ceramic coupling for the first time.9 The material employed for the heads and acetabular cups was Alumina (aluminum oxide, Al2O3), whose biocompatibility and optimal tribological features were immediately evident. However, the material was brittle and the engineering of the components was insufficient (the cups were cemented directly onto the bone); the breakage of several heads and the debonding of the cups from the bone limited the spread of this initial component. Greater success was achieved in the early 1990s when the basic material was improved, with better sinterisation, to create the 99.7% pure BIOLOX®, and again in 1994 with the introduction of BIOLOX forte, which had better mechanical resistance due to the smaller dimensions of the grains, increased density and a more homogeneous structure. The main defect of Alumina is its low toughness, or withstand plastic deformations. In contrast, Zirconia (zirconium oxide, ZrO2, stabilised with yttria: Y–ZTP) is tougher; however, it is limited by its low hydrothermal stability and the fact that it cannot be coupled with itself due to its deformation characteristics.10–12 Ceramic was introduced to the field of knee arthroplasty by Langer in 1973,13 when it was used for unicompartmental implants. From then on, since the early 1980s, experience with ceramic TKA has been almost exclusively in Japan.14–18 The Japanese experience was based on the use of Alumina: prosthetic designs were either cruciate-retaining or posterior-stabilised; and the coupling was always ceramic–polyethylene. The first implants were performed by Oonishi17,19 and produced by Kyocera Corp; afterwards, other designs were presented, such as the Low Friction Anatomical (LFA; Kyocera Corp., Kyoto, Japan), now in its third edition, the Kyoto Ceramics-1 (KC-1; Company Kyoto, Japan), the Yokohama Medical Ceramic Knee (YMCK; Kyocera Corp., Kyoto, Japan) and the Bisurface (University of Kyoto). In hip replacement, the ceramic components have a very simple design and shape with an axial-symmetrical structure – spheres and cones – with optimal contact conditions – spherical hinges and conic couplings – that can tolerate high articular loads with a moderate tensioal layer. In contrast, the designs required in TKA, in particular for the femoral component, and the contact conditions – the relevant differences between the curvature of the femoral component and the polyethylene liner – need to be of an adequate size to avoid the stress forces at the edges of the femoral resections (traction stress) and at the points of contact with the polyethylene (contact stress under the surface). Alumina prostheses are therefore thicker than the equivalent metal implants and thus require a larger bone resection. This problem was only partially resolved with the introduction of Zirconia, while new designs have been made possible by the introduction of BIOLOX delta.20

The BIOLOX delta project sought to combine the resistance and toughness of Zirconia with the better wear, resistance and toughness of Alumina to create a composite material using an Alumina matrix; the desired end result was a material with good biocompatibility, chemical and hydrothermal stability, high resistance to wear and good mechanical features (toughness and strength). To obtain these characteristics, particles of tetragonal Y-ZTP were uniformly distributed in the Alumina matrix; a small percentage of chrome oxide (Cr2O3) was then added to counterbalance the reduction of hardness caused by the introduction of
Zirconia. This process allows any cracks within the material to be blocked by the conversion of the tetragonal particles of Zirconia to the monoclinic system. This phase-changing is followed by the absorption of energy by and subsequent increase in volume of the Zirconia particles; this stops the progress of the crack by closing off its potential routes. In other words, it is as if the ceramic can self-repair, with the particles of Zirconia working like an air bag to capture the energy of the cracks.

In order to improve the resistance and toughness of BIOLOX delta and increase its reliability in terms of the static distribution of resistance, the introduction of strontium oxide (SrO) was assessed. SrO generates flat crystals of strontium aluminate (SrAl$_2$O$_3$, which are uniformly distributed in the Alumina matrix during the sinterisation process. Due to their size, these flat, elongated crystals block any cracks by decreasing their energy.

**The Polyethylene Issue**

While ceramic has demonstrated its superiority over metal in total hip arthroplasty (THA) – especially in cases of ceramic–ceramic implants, which from a tribological point of view last forever – the advantages of ceramic in TKA are yet to be determined. For example, in THA the difference between the diameter of the head and that of the acetabular liner is very small and the effect of gravity prevents articular liquid coming between the two components; here, the better wettability of ceramic represents an evident advantage in terms of lubrication. In TKA, on the other hand, the difference between the curvature of the femoral component and that of the liner is very large, especially in flexion, and gravitational forces push the articular liquid into the convex polyethylene. This improves lubrication, meaning that the wettability of the material is less important.

As regards wear, less abrasion of the polyethylene surface of the tibial component can be expected if the femoral component is ceramic, but there is no difference in terms of pitting, which is caused mainly by the shear forces generated under the polyethylene surface. In clinical series, ceramic TKAs have not shown better results than metal implants, whose survival rate at 15 years is over 98%. Because the issue of implant survival seems to be related principally to the release of polyethylene debris, attention should be focused on the polyethylene and the processes it undergoes, as well as on improving the material of the femoral component.

In the majority of cases, the severe effects of wear and delamination experienced with polyethylene liners are due to oxidation phenomena, most of which are related to the sterilisation process that is commonly used. Polyethylene sterilisation with ethylene oxide (ETO), or with gamma rays in the absence of oxygen, can guarantee long-lasting implants regardless of the material used for the femoral component.

Yasuda\textsuperscript{23} and Minoda\textsuperscript{24} both demonstrated less wear of the polyethylene liner with the use of Alumina compared with CoCrMo femoral components, although the sterilisation process performed on the polyethylene in the two groups of prostheses was not indicated. Ezzet\textsuperscript{25} demonstrated the advantages of using Oxinium compared with CoCrMo components in terms of wear on the polyethylene liner. The reduction of polyethylene wear when using ceramic compared with CoCrMo implants could be explained by the reduction of abrasive and adhesive wear processes and scratches; in vitro studies this phenomenon was related to the superficial roughness of the femoral component.\textsuperscript{26} However, according to a study conducted by Lancaster in 1997,\textsuperscript{27} if the roughness of the femoral component is the same, there are no differences between ceramic and metal implants.

At the moment, some recent studies looking at these polyethylene issues, led by Ceramtec in collaboration with the Orthopaedic Institute of Rizzoli (Bologna), are under data review and will be published soon.

**Current Concepts of Ceramic in Total Knee Arthroplasty**

Despite the undeniable advantages related to its tribological characteristics, at present ceramic has very few applications in the field of TKA. However, the improvements that have been made to ceramic materials, the expanding number of indications of this kind of surgery to include younger and younger patients and the growing number of people allergic to metal ions\textsuperscript{28} mean that the opportunities for ceramic implants are increasing. In fact, the need for long-lasting implants and the necessity of not exposing patients to the risk of developing allergies to metal ions or to metallosis phenomena have led researchers to develop more reliable ceramic materials. With the introduction of BIOLOX delta, most of the problems related to the structural limits determined by the fragile nature of ceramic seem to have been solved. However, there are still some firm rules regarding the use of these implants that have been derived from the experience with Alumina prostheses: chiefly, the need always to use cement.\textsuperscript{17,18}

Finally, there is a need for large series of patients with long-term follow-up to evaluate long-term clinical and radiological results with ceramic implants. For this reason, an international study group conducting a prospective multicentre study in three European nations (Germany, Italy and Spain) has been founded to evaluate the clinical, functional and radiological outcome of TKAs using a ceramic femoral component – the MultiGen Plus (Lima-Lto). This study is discussed in more detail below.

**Future Evolution of Ceramic Total Knee Arthroplasty**

The solution to the problem of polyethylene wear in TKA is prosthetic designs that do not contain polyethylene, instead using the ceramic–ceramic coupling that is already used in many THA systems. As discussed above, ceramic–ceramic coupling is possible in THA for two reasons: the minimal dimensional difference between the head and the cup, and the absence of translational movements. Neither of these applies to TKA. The problem with TKA is that the kinematics of the knee is both rotational and translational; a hypothetical solution to this is mobile bearing at the femoral component–liner interface. However, although this solution may theoretically be reliable according to the above-cited criteria, it cannot yet be put into practice due to inadequate lubrication between the liner and the tibial baseplate, where the kinematics is translational. In a ceramic-on-ceramic joint, the radius of curvature of the coupled surfaces must be different to allow the interposition of the lubricant, which is otherwise impossible due to the very high stiffness of the ceramic. With no lubrication, the joint is dry and very high localised contact pressures can occur on the ceramic; this can cause the ceramic to fracture. In addition, a dry ceramic-ceramic contact causes an audible high-frequency noise (squeaking). In contrast, a flat-on-flat ultra-high-molecular-weight polyethylene (UHMWPE)–metal or UHMWPE–ceramic joint does not create any mechanical problem because UHMWPE is a self-lubricant material and is much softer than ceramic, so it is slightly deformed under load and the lubricant can therefore spread on the joint interface, reducing the friction between the counterparts. A theoretical solution to the problem with ceramic–ceramic joints could be the modification of the articular kinematics; this was hypothesised at the end of the 1990s in a project based on a double rotation of the mobile bearings.\textsuperscript{29} Despite
For patients who still have great plans

Thanks to the outstanding material properties of high performance ceramics, BIOLOX® makes arthroplastic wear couples last longer. Artificial joint components made of BIOLOX® ensure excellent survival rates and a high quality of life for your patients!

- High abrasion resistance
- High biocompatibility
- No third-body wear

Want to know more? We’ll be happy to send you our new brochure “BIOLOX® – Ceramics for Hip Arthroplasty” with scientific information about wear couples. Please send your order to:
Fax: +49 7153 611 950 or eMail: medical_products@ceramtec.de

CeramTec AG, Medical Products Division, www.biolox.com
promising preliminary results, the project was never completed and the debate on alternative solutions is still open.

Discussion and Conclusions

The prevalence of metal sensitivity among the general population is approximately 10–15%, with nickel sensitivity having the highest prevalence in the presence of a common cross-reactivity between nickel and cobalt.26 The prevalence of metal sensitivity among the general population is approximately 10–15%, with nickel sensitivity having the highest prevalence in the presence of a common cross-reactivity between nickel and cobalt.26

The BIOLOX ceramic has demonstrated high biocompatibility both in vitro and in vivo. Hypersensitivity tests with epicutaneous applications in vivo and lymphocyte-transforming tests (LTTs) in vitro have as yet shown no allergic reactions to BIOLOX delta, indicating that the material is totally bio-inert.8,20 This biocompatibility and bio-inertia — in association with the well-known tribological advantages of ceramics, such as hardness, lubrication and wettability — has led researchers to develop solutions that could enable the use of this material on a large scale in TKA, especially after the optimal results achieved in THA.

For this reason the aforementioned international study group founded in collaboration with Lima-Lto has created a protocol for a prospective study on 200 patients undergoing TKA with a Multigen Plus prosthesis with a ceramic BIOLOX delta femoral component — a Ti6Al4V alloy tibial plate and a UHMWPE liner sterilised with E10 in the absence of oxygen, implanted with the use of a high-quality, high-viscosity cement — to evaluate long-term results with this implant (see Figures 1 and 2). The protocol includes intra-, peri- and short- and long-term post-operative evaluations — either clinical or radiological — according to well-established, standardised and scientifically recognised and approved criteria.

The study is being conducted in Germany by Prof. W Mittelmeier (Universität Rostock, Rostock), Dr D Ganzer (Dietrich-Bonhoeffer-Klinikum, Altentreptow) and Prof. W Rüther and Prof. Ch Lohmann (Universitätsklinikum Hamburg-Eppendorf); in Italy by Prof. F Benazzo (Fondazione IRCCS, Policlinico San Matteo, Università di Pavia), Prof. A Giunti and Dr D Tigan (Istituti Ortopedici Rizzoli, IOR) and Dr C Zorzi (Ospedale Sacro Cuore Don Calabria, Negar, VR); and in Spain by Dr E García Cimbrelo and Dr C Rodriguez Merchán (Hospital Universitario La Paz, Madrid), Dr E Saura Mendoza (Hospital General Universitario, Elche), Dr A Lizard Utrilla (Hospital General ‘Virgen de la Salud’, Elda), Prof. J Couceiro Follette (Hospital Clínico Universitario, Santiago de Compostela) and Mrs S Burrelli and Ing. Paolo Dalla Pria (Scientific Adviser and Implant Designer, respectively, Lima Lto).

Ceramic knee arthroplasties are providing good results from both the functional and reliability point of view.14–16,18,34 The strong tribological characteristics of these implants are now becoming evident and, with the support of other clinical results, it will hopefully be possible to expand the indications for their use. Today, research and development have definitely resolved the limitations caused by the brittleness of the ceramic.