ASPECTS OF CURRENT MANAGEMENT

Alumina pairing in total hip replacement

In 1971, Boutin introduced the concept of an alumina-on-alumina bearing in total hip replacement and emphasised polyethylene wear as the major limitation of a metal-on-polyethylene articulation.\(^1,2\) This was further confirmed by Willert, Bertram and Buchorn.\(^3\) Many pioneers from around the world followed this initial experience but long-term results and good methodology were lacking. Recently, a number of reports\(^4-6\) have focused attention again on an alumina-on-alumina combination. More than 30 years after its introduction into clinical practice, this article considers the current information on the alumina-on-alumina combination from both experimental and clinical standpoints.

Material properties and design

The process of manufacturing alumina is critical. Experience is needed and the methods of preparing the material precisely should be appropriately controlled in order to avoid catastrophic consequences. Thus, it is still only available from a limited number of companies from Japan, Austria, Germany, the United Kingdom and France. The alumina (Al\(_2\)O\(_3\)) used in modern arthroplasties is a dense, polycrystalline ceramic, obtained from aluminium oxide powder and pressed in a mould at a very high temperature (1600˚C). It is a very stable material which will have to endure in vivo conditions. The precise stresses which a material will have to endure will follow specific physical laws. The material will have to be chemically stable and inert material, unlike zirconia which is almost twice that of stainless steel. This hardness makes alumina resistant to scratching. The main characteristics of alumina and their evolution during the last 30 years are shown in Table I. From a mechanical viewpoint alumina is very resistant to compression but it is also brittle. Brittleness is an engineering term which means that the material will follow specific physical laws. The mechanism of fracture is related to the phenomenon of crack propagation. It is possible to calculate when a given material will fracture if the size of its largest flaw is known. A crack starts from the flaw and propagates through the material at a given speed depending upon the applied load, porosity, and the presence of other flaws. For a long time this brittleness prevented the clinical application of ceramics.

With more modern alumina ceramics the physiological loads are less than the level required for a crack to propagate. Jumping, running and strenuous activities are allowed in those patients whose arthroplasties are of modern design. Flaws in the material can be avoided by well-controlled manufacturing standards and strict quality control. However, this is batch control rather than total control, and the risk of fracture cannot be completely eliminated. The precise stresses which a material will have to endure in vivo are not known and may differ from those studied in a laboratory setting. Consequently, a number of guidelines should be observed: 1) a 32-mm femoral head is safe, although modern manufacturing processes appear also to allow the safe use of 28-mm heads; 2) the connection between the head and the taper, or between the acetabular shell and the alumina insert, must allow a large contact area which is slightly roughened but perfectly clean. Perfect circularity of the taper, and a smaller 12/14 size rather than 14/16, combined with the design of the inner aspect of the alumina femoral head, are also critical; 3) the thickness of the alumina acetabular insert must be at least 6 mm with a minimum outer width.
diameter of the acetabular component of 50 mm for a 32-mm head. A smaller acetabular component needs a 28-mm femoral head. The thickness of the metallic shell should also be controlled and adapted. 4) Different options are available for the angle of the taper, 5.4° (Ceraver-Ostéal, Roissy, France) or 16° (Ceramtech, Flochigen, Germany). It is our view that the larger contact area provided by the 5.4° taper is safer for long-term use.

The operative technique must also take material characteristics into consideration. In order to avoid initiation of a crack the use of a hammer to impact the femoral head onto the cone should be avoided. The placement of the acetabular component should be chosen to maximise surface contact between the bearing surfaces, and a more horizontal placement with an angle of abduction of < 45° is preferable.²

**Tribological properties**

The superb tribological properties of an alumina-on-alumina combination depend upon both the properties of the material and the manufacturing processes.³ Alumina is a wettable material. This can be measured with the contact angle, which describes the shape of a liquid on a solid surface. The contact angle of alumina is 44°, whereas the contact angle of polyethylene is 80°. This property plays a major part in the lubrication process.

In order to achieve optimal tribological performance, a proper manufacturing process is crucial for both the femoral head and the acetabular component. Modern manufacturing processes allow the production of an extra-smooth material with a sphericity of less than 1 μm. Clearance between the femoral head and the acetabular component must be perfectly controlled in order to achieve optimal lubrication. This clearance should be between 20 and 50 μm. When these conditions are met, experimental data show that minimal wear will occur.⁶-¹² Wear performance of an alumina-on-alumina combination follows a biphasic behaviour, with a run-in period which lasts less than one million cycles followed by a steady-state phase. Oonishi et al,¹² in an experimental study of 28-mm femoral heads, calculated a mean wear during the run-in period of approximately 1.2 mm³ per million cycles, whereas the mean wear during the steady-state phase was only 0.02 mm³ per million cycles.⁶ In vivo, several authors have found a linear wear rate of 0.025 to 5 μm when the acetabular component was secure.¹³-¹⁵ Under similar circumstances the wear rate of a metal-on-polyethylene combination was 100 to 200 μm. Volumetric wear is, therefore, between 2000 and 4000 times less for an alumina-on-alumina combination than for metal-on-polyethylene.¹⁶ Recent data highlighted a specific wear pattern with a limited area of stripe wear which is thought to occur during edge loading activities such as rising from a chair or climbing high steps.¹⁷ Dennis et al measured separation in vivo by fluoroscopy while Tipper et al showed experimentally that, when microseparation was introduced, they were able to reproduce stripe wear and that wear increased from 0.1 mm³ per million cycles to 1.24 mm³ per million cycles. The quality of the alumina is also vital. As it improved with time, Prudhommeaux et al and Nevelos et al demonstrated from retrieval studies that a decrease in grain size and a reduction in porosity correlated with a lower rate of wear.

Recently, Hatton et al analysed the wear debris produced by an alumina-on-alumina combination. They demonstrated a bimodal distribution with sizes of particle between 5 and 90 nm and between 0.05 to 3.2 μm. They suggested two different mechanisms of production, the first occurring under normal articulating conditions and the second from microseparation in the presence of intra- and intergranular fractures. However, analysis of periprosthetic tissues consistently showed that there was a thinner synovial layer, fewer macrophages and a lower production of osteolytic substances around ceramic-on-ceramic prostheses when compared with metal-on-polyethylene joints.²¹-²⁴

The wear pattern of an alumina-on-alumina combination is a multifactorial process where the quality of the alumina, component design and surgical technique all play a major role. An error in any one of these features may lead to catastrophic failure.

**Limitations of a metal-on-polyethylene combination**

Alumina-on-alumina bearing surfaces were developed because of the perceived limitations of the conventional metal-on-polyethylene combination. Data from the Swedish register show that the results for conventional hip arthroplasties do not improve with time in active patients under the age of 55 years. There are different interpretations of this. However, as the most frequent cause of failure is aseptic loosening because of wear debris, it is likely that the limiting factors relate to the combination of metal and polyethylene. Clearly, alumina-on-alumina is not the only possible solution. Both metal-on-metal and highly-cross-linked polyethylene have been developed with the aim of improving the survival of total hip arthroplasty in young, active patients.

**Clinical results of an alumina-on-alumina total hip replacement (THR)**

Despite an extensive literature, the advantage of an alumina-on-alumina combination on the outcome after THR is not yet established. The many reports are confusing because of a diversity of prosthetic designs and the different methods of acetabular and femoral fixation. Interpretation of the results must include all these features and it is difficult to draw conclusions. For example, the German and American experience with the alumina-on-alumina Mittelmeir prosthesis (Osteo AG, Selzach, Switzerland) was disappointing. Most failures were due to aseptic loosening, the weakest link being the prosthetic design rather than the bearing surfaces. In the French experience, fixation of the acetabular component was initially disappointing,
and different designs were studied. The cemented plain alumina acetabular component which was used by Boutin \(^1\) from 1971, and by our team between 1977 and 1984, had a survivorship of 88.6% at ten years. The main cause of failure was an acute debonding at the implant-cement interface.\(^2\) Failure of this fixation was confirmed in a longer follow-up of Boutin’s patients by Hamadouche et al,\(^2\) who found a survivorship of 61.2% at 20 years. Finite element analysis showed that stress protection, secondary to the high rigidity of the ceramic led to weakening of the cancellous bone which supported the cement mantle and caused the debonding.\(^2\) Subsequently, a plain press-fit alumina socket acetabular component was used. Hamadouche et al\(^2\) studied two different series of patients and found a survivorship of 93.2% at six years and 85.6% at 20 years with two different designs, with and without pegs. Retrieval of one acetabular component 12 years after its implantation showed it to be surrounded by a thin layer of fibrous tissue; no bone was directly in contact with the implant.\(^2\) Recently, Bizot et al\(^2\) reported the results of a hybrid system comprising a press-fit cementless cup with an alumina insert and a cemented stem. This combination showed encouraging results with a survivorship of 97.4% at a minimum of five years when aseptic loosening was considered as the end-point. The Italian\(^2\) and Austrian\(^2\) confirmed that fixation of the acetabular component was the weakest point in the early years. The initial American studies, including short-term randomised trials, showed that alumina ceramic was safe with similar results to a conventional metal-on-polyethylene combination.\(^4,5\)

From these various reports, particularly the older ones, it appeared that osteolysis was minimal with an alumina-on-alumina combination. This observation has been further supported by experimental and retrieval data, analysing the reaction to ceramic wear debris.\(^21,24,35,36\) Considering the excellent long-term results of a conventional metal-on-polyethylene combination in older patients, as demonstrated by the Swedish register,\(^25\) an alumina-on-alumina combination is useful in the younger population because wear is minimal and osteolysis is rare, making revision surgery easier, even after many years.\(^29\) Hamadouche et al\(^29\) found that in the long-term revision requiring allograft was necessary in three of 25 hips. In addition, seven hips with moderate acetabular osteolysis were relatively easily revised using a component which was only 4 mm larger.\(^29\) Fye et al\(^27\) reported a very limited osteolysis with the Mittelmeier prosthesis.

**Clinical issues**

Fracture of the femoral head, impingement and ease of revision after a failed ceramic-on-ceramic THR are three specific issues which need to be addressed before using this type of surface bearing.

**Fracture.** Fracture of ceramic components has been, and remains, the main fear for both patient and surgeon. In the early development of the ceramic hip, the rate of fracture was unacceptable, being up to 13.4%.\(^37\) With improvements in the quality of the alumina and quality control, the rate of fracture was reduced. Recently, Willmann\(^37\) reported the results of the Biolox femoral head (Ceramtec), for which the first-generation fracture rate was 0.026%, declining to only 0.004% after 1994. Despite this dramatic improvement, the risk of fracture for a ceramic component still exists and will probably never be completely eliminated. Maher et al\(^38\) emphasised that fracture of a ceramic liner was not necessarily related to direct impact as, even after 20 impacts at 12 kN, large in comparison with physiological forces on a hip during a fall or stumble, no liner fractured; this was also true for the femoral head. It is clearly vital that any change in the manufacturing process or design of a well functioning component must be taken very seriously, a point highlighted by Hannouche et al\(^39\) who found that minor changes in the design of the acetabular liner led to an increased rate of fracture. Hasegawa et al\(^40\) reported similar findings for a modular acetabular component with a sandwich insertion which included alumina ceramic, polyethylene and titanium. However, recent reports of alumina-on-alumina combinations from the United States did not report any fractures of the component.\(^4,5\)

**Impingement.** Impingement between the femoral neck and the acetabular component has been considered as a major problem, especially with the Mittelmeier, Autophor (Osteo AG) and Xenophor (Osteo AG) prostheses which were introduced into the United States in the 1980s.\(^40\) Impingement can lead to an inadequate range of movement, fracture of the ceramic, dislocation and wear of the prosthetic femoral neck with the production of metallic wear debris. A prosthetic design which takes into consideration the neck diameter/head diameter ratio, and a well designed rim to the ceramic liner are both mandatory, as well as a precise surgical technique to avoid either insufficient anteversion or too vertical a placement of the acetabular component.\(^7\)

**Revision surgery.** Revision surgery after a failed ceramic-on-ceramic total hip replacement has received little attention in the literature. However, several key points need to be addressed during these procedures, specific to this material. Fracture of ceramic can lead to the spread and synovial inclusion of alumina debris which may then act as an abrasive; several cases have been described of massive wear of a metallic head after revision surgery for a fractured ceramic head.\(^41,42\) Recently, Allain et al\(^43\) described the outcome of 105 revision operations for fracture of a ceramic femoral head and reported a survival rate of only 63% after five years, mainly because of aseptic loosening and osteolysis. The factors which improved the outcome were a complete synovectomy, the use of a ceramic or a cobalt-chrome head and an exchange of the acetabular component.\(^43\) The latter was considered important because microscopic ceramic debris may become embedded in the polyethylene and act as an abrasive. A new cobalt-chrome or, even better, a new ceramic head were considered sufficiently hard to resist
ablation while the synovectomy may have reduced the number of available debris particles. However, the authors were unable to determine the best approach for the morse taper. Theoretically, a damaged taper may have a limited zone of contact with the new ceramic head and then act as a stress riser with a risk of further fracture. Moreover, secure fixation of the head on a damaged taper may be impaired with a theoretical risk of massive wear from abnormal movement between the head and taper. To our knowledge, there is no published data which addresses this issue. In our practice, when undertaking revision procedures for aseptic loosening, we have performed 54 simple exchanges of the femoral head on a used taper. No recurrent fractures or abnormal wear has been seen after a mean follow-up of seven years. However, if any doubt exists about the condition of the taper at surgery, a complete implant exchange should be performed.

Conclusion
An alumina-on-alumina combination is now safe and several teams from around the world have shown this. Fracture of the components, which was once the main fear for both patients and surgeons has declined to an acceptable level, although it can still occasionally occur. However, the advantages, such as minimal wear, minimal reaction to wear debris and lower rates of osteolysis, largely exceed the potential disadvantages. Continuing evidence is required to compare its performance with metal-on-metal or the improved polyethylenes. The younger, more active patients are the target population as they require an extended survivorship for their arthroplasties.

References