Ceramic - ceramic and Metal / Polyethylene Friction Couples in Total Hip Prostesis

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Our objective was to compare 2 friction couples: ceramic/ceramic and metal/polyethylene in total hip prosthesis. Between 2005-2007, 64 patients with primary osteoarthritis of the hip were enrolled in a prospective study: 32 cases underwent arthroplasty with uncemented total hip prosthesis with a friction couple ceramic/ ceramic (Group1), while the other 32 cases underwent arthroplasty with uncemented total hip prostheses with a friction couple of metal on Ultra-High Molecular Weight Polyethylene (UHMWPE) (Group 2). Group 1 was considered the test group and group 2 was designed so that the two groups to be similar in terms of gender and age distribution. We followed: the emergence of osteolysis areas, component loosening to a degree requiring revision, clinical outcome quantified by Harris score. The radiological aspect was determined by several radiological check-ups: immediately after operation, at 6 weeks, at 3 months postoperatively and then annually. Mean follow-up time was 5.2 years (ranging from 3 years and 2 months to 7 years and 8 months). The presence of osteolysis areas was observed in a single case in the ceramic/ceramic group (3.12%) and in 4 cases in the metal/polyethylene group (12.5%), the difference not being statistically significant (p>0.05). In Group 1 we performed one revision which required replacement of both components (3.12%), while in Group 2 there were 2 such kind of interventions (6.24%) - the difference being not statistically significant (p>0.05). Harris Score evolved in Group 1 from 52.34 ±6.36 preoperatively to 94.32 ±8.82 at the end of the follow-up period (p<0.01), and in Group 2 from 51.52 ±7.21 to 92.44 ±9.24, respectively (p<0.01).

Keywords: ceramic, friction couple, hip prosthesis

The ideal prosthetic implant should be biocompatible, resistant to cyclic mechanical solicitations for a long period of time, should not wear/erode/corrode and should not form microparticles, which can determine an inflammatory response from the host tissues.

In order to fulfil these goals, different materials have been tested and used for the friction couple: from the combination of metal (femoral head) and polyethylene (acetabular cup) introduced by Sir John Charnley along with his first total hip prosthesis to have stable results over time, to the modern metal/metal or ceramic/ceramic couples. Metal on Ultra-high-molecular-weight polyethylene (UHMWPE) is the most common friction couple. The main problem is that it has the highest rate of occurrence for microparticles, which generates a periprosthetic inflammatory reaction, leading, in time, to osteolysis and loosening of the prosthetic components. Cross-linkage of polyethylene reduces microparticles formation, but at the same time it somewhat diminishes the mechanical properties of polyethylene.

The metal/metal friction couple also ensures a significant reduction in wear of the sliding surfaces, and thus, in the production of microparticles, but it may lead to hypersensitivity reactions. Besides, the effects of blood and lymphatic dissemination of metal microparticles are not yet fully known and understood.

A friction couple which drastically limits the wear of the bearing surfaces while also limiting the production of microparticles has two major advantages.

It postpones for as long as possible the occurrence of osteolysis areas and also the prosthetic components loosening, which inevitably leads to revision surgery for the prosthesis (replacement of arthroplasty implants with more sophisticated types, by means of a complex and demanding surgery for both patient and surgical team).

It allows the use of large diameter femoral heads which increase the amplitude of possible movements and decrease the risk of dislocation of the prosthesis.

Ceramic/ceramic total hip prosthesis could fulfil these goals, but previous experience with other friction couples showed that the introduction of new implants can lead to unforeseen complications over time. The results of experimental and clinical studies with this type of implant arthroplasty are encouraging, but they still need to pass the test of time.

Experimental part

Material and methods

Between 2005-2007, 64 patients with primary osteoathritis of the hip were enrolled in a prospective study: 32 cases underwent arthroplasty with uncemented total hip prosthesis with a friction couple ceramic/ceramic (Group1), while the other 32 cases underwent arthroplasty with uncemented total hip prostheses with a friction couple of metal on UHMWPE (Group 2). Group 1 was considered the test group and group 2 was designed such way so that the two groups to be similar in terms of gender and age distribution. We followed: the emergence of osteolysis areas, components loosening to a degree requiring revision, the clinical evolution quantified by Harris score [1]. Harris score is a clinical score developed from several criteria: the existence and the characteristics of pain, patient's ability to perform usual activities (walking, climbing stairs, ability to sit, ability to put on shoes, presence of limping,

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need for support - crutch, stick, frame, etc.) and also hip mobility. Its values ranges from 0 to 100 points. Depending on their numerical values, the results are considered as low (<70 points), satisfactory (70-79 points), good (80-89 points) or excellent (over 90 points). We calculated the Harris hip score preoperatively, one year postoperatively and then annually. We recorded the preoperative values and those taken during the last visit. The radiological evolution was determined by several radiological check-ups: immediately after operation, at 6 weeks, at 3 months postoperatively and then annually. Mean follow-up time was 5.2 years (ranging from 3 years and 2 months to 7 years and 8 months).

Results and discussions

The presence of osteolysis areas was observed in one case in the ceramic/ceramic group (3.12%) and in 4 cases in the metal/polyethylene group (12.5%), the difference not being statistically significant ($p>0.05$). In Group 1 we performed revision of both components in one case (3.12%), while in the second group such an intervention were carried out in 2 cases (6.24%) – a statistically non-significant difference ($p>0.05$). In group 1, the Harris score evolved from 52.34 ±6.36 preoperatively to 94.32 ±8.82, at the final visit, and in Group 2 from 51.52 ±7.21 to 92.44 ±9.24, respectively. The differences between the preoperative and postoperative scores are statistically significant in both groups ($p < 0.01$), but not when analysing the differences between the two groups, in any of the temporal segments ($p>0.1$). Ceramic materials are crystalline structures that are very resistant mechanically, with a hard structure, chemically and biologically inert and biocompatible. Their resistance is due to the strong ionic and covalent bonds between the component atoms. Ceramics would prove to be excellent as articular surfaces for different types of endoprostheses if the surface is processed to become supersmooth.

Two ceramic materials are used in the process of manufacturing ceramic prostheses – alumina, which is aluminium oxide (Al_2O_3), and zircon, which is zirconium oxide (ZrO_2). These two have the characteristics of being chemically and biologically inert also being biocompatible and very stable in vitro and in vivo. The hydroxyl groups on the surface of the ceramic material attach water molecules and thus contribute to the process of surface lubrication – an ideal asset for the preservation in time of the friction surfaces and to minimize formation of microparticles.

The main disadvantage of this material is that it is somewhat brittle - high intensity shocks can cause cracks within its structure, which propagate and destroy its macrostructure. From this point of view, metallic materials - various types of stainless steels for medical use - are superior to ceramic. Microscopic defects (pores, microcavities or microcracks) of ceramic undergoing cyclic stress, can develop into a crack disseminating throughout the material mass leading to the entire destruction of the prosthesis. In a similar context (the presence of microdefects and cyclic mechanical loading), metallic materials are deformed plastically , dissipating the stress throughout the whole structure, without cracking. Biological factors (obesity, intense physical activity, major trauma, etc.) were cited as risk factors for cracking of a prosthetic component, but the most important factor, in fact, is the quality of the ceramic material and of the implants.

In order to avoid the development of microdefects, the structure of the ceramic material should be as dense and homogeneous as possible. The manufacturing technology of ceramic prostheses involves introducing miniparticles or ceramic powders into moulds of the desired shape and heating them to high temperatures. The quality (and therefore the strength) of the material obtained will be better if the particles added are smaller, more homogeneous in size and shape and purer. Strength also depends on the type of ceramic material and the shape of the implant. The latter must be designed in order to uniformly distribute the mechanical stresses onto its surface (concentration of these stresses in certain points can cause cracks with chipping of the edges or catastrophic destruction of the entire implant).

Ceramic is highly resistant to compressive but not to pressure load. Tension stress occurs in two areas: at the point of contact between the ceramic acetabular insertion and the metal acetabular component and at the contact between the ceramic head and metallic neck of the femoral component. In order to reduce tensions, the two components in contact - metallic and ceramic – were supposed to be excellently designed and manufactured and their intraoperative positioning to be perfect – with a

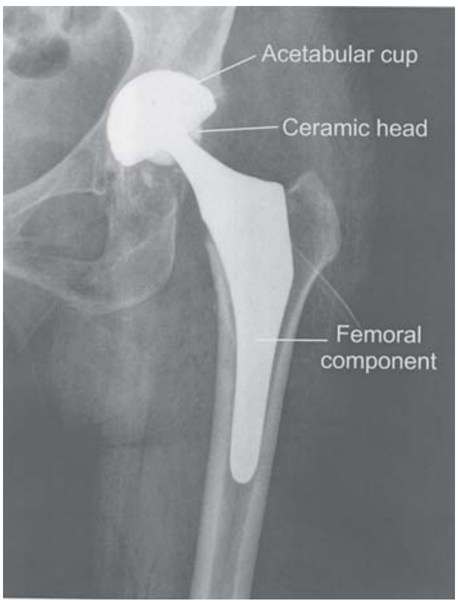

Fig. 1. Ceramic-ceramic prosthesis – postoperative antero-posterior X-ray view

Fig.2. Acetabular component – metal back and ceramic insert (alumina) – front view

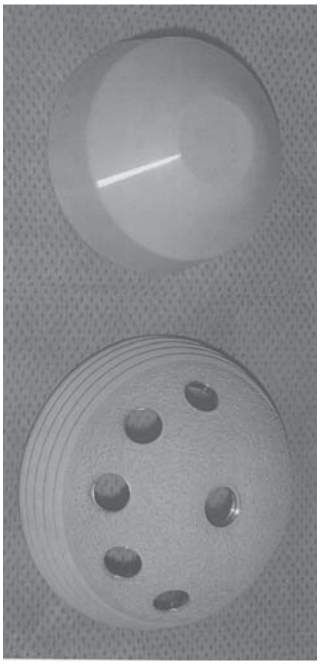

Fig. 3. Acetabular component – metal back and ceramic insert (alumina) – back view

Fig. 4. Ceramic prosthetic head (alumina) – different views

precision of less than 5 degrees disalignment. If a ceramic insert is placed eccentrically on the metal acetabular component and impacted in that position, it will break intraoperatively.

Alumina. In initial studies, despite the high expectations invested in this friction couple, the results were disappointing, as less than 70% of implants survived 5 years after surgery. These first series had poorer clinical medium and long term outcomes than the standard metal/ polyethylene implants. Over time, ceramic prostheses manufacturing methods and design improved, so that the so-feared destruction by scrapping of ceramic components has become increasingly rare. A study made by Hannouche [2] over a period of 25 years (between 1977 and 2001) followed up a total of 5500 total hip ceramic prostheses. The incidence of ceramic components fracture was 0.002% (13 cases in 5500 prostheses).

The improving technology led to the sequential emergence of three generations of ceramics for medical use. The first generation ceramic was composed of larger crystals (7.2 microns) with a lower resistance (400 MPp) and a lower density (3.94 g/cm^3) and with a percentage of impurities up to 5% of the total volume. The third generation ceramic crystals have a significantly smaller size (1.8 micron), high strength (580 MPa) and high density (3.98 g/ cm^3), and the degree of purity is incomparably better (impurities below 0.5% of the total volume)[2]. A study conducted by Willman [3] showed a femoral head fracture rate of 0.026% for the first generation of alumina, 0.014% for the second and 0.004% for the third, respectively. The risk of fracture of a third generation ceramic prosthetic component is very small. The most important step in increasing the reliability of ceramic prostheses was the introduction of the hot isostatic pressing technology (hot isostatic pressing - HIP).

Zirconia (zirconium oxide ceramic) was firstly introduced in orthopedics in 1985 as an alternative to alumina. In total hip prosthesis it is used for femoral heads and combined with acetabular components made of ultra-high-molecular-weight polyethylene (UHMWPE). The main arguments in its favour are the lower fracture risk (versus alumina) and the surface roughness (measured by the Ra index), which is much smaller than that of stainless steel (cobalt-chromium). Roughness or surface texture is quantified by the vertical deviations of the real surface from its ideal shape (the Ra index is the arithmetic mean of the absolute values of these deviations). The Ra index of CoCr metal heads is significantly higher than that of zirconia heads. Therefore, microparticles production associated to polyethylene surface friction is higher for the metal/ polyethylene couple than for the zirconia/polyethylene one.

The quality of zirconia prosthesis depends on the ceramic material (crystal structure, purity, density, porosity, particle size), on the surface roughness (also depends on the material and the manufacturing process) and the shape of the component. Zirconia crystals exist in three forms (phases): the cubic phase - cubic crystals with square facets, the tetragonal phase (prism with rectangular facets) or the monoclinic phase (distorted prism with rectangular facets). The tetragonal phase has the best mechanical properties, the ideal phase for all ceramic implant crystals. Yttria (yttrium oxide, Y2O-3) is added to the ceramic material component – about 5% of the total volume, in order to stabilize the tetragonal crystal structure at normal temperatures.

Regarding purity, the most common impurity is alumina, but its proportion should not exceed 0.5%. The ideal density is 6.1 (100%). In clinical practice, the required value is 6. Ideal porosity is 0. The closer to the ideal value, the higher is the mechanical resistance thus the smoother the surface.

To obtain best results, the ceramic femoral head should be as close as possible to a perfect sphere. The Ra index (surface roughness) should range from 0.002 to 0.003 mm.

In our study, the clinical and radiological results indicate a superior medium term survival rate for ceramic prostheses - revision incidence is significantly lower, and the presence of osteolysis areas is also significantly lower, the latter being statistically significant. The main reason of osteolysis is particles disease. During its functioning, abrasion of sliding surfaces generates microparticles from the prosthesis, which are composed of constituent material. They induce macrophage migration and phagocytosis, leading to a local inflammatory reaction. In time, this phenomenon will generate osteolysis with subsequent component mobilization and the need to replace the prosthesis. Clinically, persistent pain will occur that will increase progressively.

The inflammatory reaction depends on the rate of microparticles formation, their size and their composition. Alumina produces fewer microparticles than the metal/

Fig. 5. Ceramic-ceramic prosthesis

polyethylene friction couple and this happens due to two reasons - it is harder, and the roughness of its surface is lower. Besides, the microparticles made of alumina are chemically and biologically inert (alumina is extensively oxidized and therefore almost inactive). Theoretical calculations and in vitro determinations correspond to in vivo behaviour and clinical studies have demonstrated superior clinical results of the third generation ceramic prosthetic components.

The revision of a fractured ceramic implant is problematic. Destruction of the implant will produce numerous fragments of varying sizes. Even though most of these fragments will be removed at the revision surgery, the risk that at least some of them will remain within the periprosthetic tissue exists. These fragments, made of a very hard material can determine rapid abrasion of the sliding surfaces of the newly implanted prosthesis. If the revision prosthesis is made of metal-polyethylene, the presence of ceramic microparticles will induce a high rate of polyethylene microparticles, leading to an early particles disease associated with osteolysis and premature loosening of the revision prosthesis. Allain [4] published a study on revisions results performed for ceramic head fracture, in which he showed that revision prosthesis survival at 5 years is of 63% only. Therefore, it is highly recommended to carefully clean the prosthesis cavity in order to remove all ceramic particles and to implant a revision prosthesis of the same ceramic/ceramic couple.

If revision is indicated by the presence of a damaged ceramic component with intact metallic components, the simple replacing of the ceramic might not be the best option. The mechanical stresses to which they were subject could have produced microscopic plastic deformation of the metallic and inserting a new ceramic component can lead to incongruence and its fracture intraoperatively or shortly after. This is due to the acceptable dimensional deviations which are smaller for the ceramic prostheses and also to the well-known frailty of the material.

Ceramic total hip prostheses are generally indicated in young active patients. There is no age limit, the orthopedic surgeon being the only one to evaluate the indication. Low production of microparticles ensures prosthesis longevity, which is the main advantage in clinical practice. There are some limitations: the acetabular insert is hemispheric and comes in a certain range of sizes, and the femoral head can only have certain diameters and lengths of femoral neck. When the acetabulum is small, most often the surgeon cannot implant a ceramic prosthesis (the smallest ceramic acetabular component may prove to be too large – these cases require careful preoperative planning). An unspherical acetabulum does not match with a ceramic prosthesis, which is perfectly hemispherical. There are no semi-retention or high retention ceramic acetabular components because of the high fracture risk when mechanical stresses are concentrated in a limited area. Therefore, ceramic prosthetic implants are not indicated in unstable hips, with dislocation risk, which would benefit from a semi-retention or high retention socket. If a large femoral head or an extra-long neck are needed, we may face another design limitation of this type of prosthesis, ceramic heads can be manufactured up to a certain maximum diameter.

Conclusions

Total hip prostheses with ceramic/ceramic friction couple have a 5 years higher postoperative survival rate than those with metal/polyethylene friction couple. The incidence of peri-implant osteolysis areas is lower for ceramic/ceramic endoprostheses.

Our objective was to compare the medium term clinical and radiological results of 2 friction couples: ceramic/ceramic and metal/polyethilene in uncemented total hip prosthesis.

The subject also studied in [5].

References

1. HARRIS WH., Traumatic arthritis of the hip after dislocation and acetabular fractures: treatment by mold arthroplasty. An end-result study using a new method of result evaluation. J Bone Joint Surg Am. 1969 Jun;51(4):737-55.
2. HANNOUCHE D, NICH C, BIZOT P, MEUNIER A, NIZARD R, SEDEL L., Fractures of ceramic bearings: history and present status. Clin Orthop. 2003; 417: 19-26.
3. WILLMANN G., Ceramic femoral head retrieval data. Clin Orthop. 2000 379:22-8.
4. ALLAIN J, ROUDOT-THORAVAL F, DELECRIN J, ANRACT P, MIGAUD H, GOUTALLIER D., Revision total hip arthroplasty performed after fracture of a ceramic femoral head. A multicenter survivorship study. J Bone Joint Surg Am. May 2003;85-A(5):825-30
5. FETECAU, C., STAN, F., POPA, C., Mat. Plast., **43**, no. 1, 2006, p. 51

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