Short Term Results in Uncemented Ceramicized Metal Total Hip Prosthesis

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The objective of our study was to assess the "in vivo" wear of cross linked polyethylene in contact with different materials surfaces. Thus, we compared the polyethylene acetabular cups wear when they function in a couple with ceramicized metal heads (zirconium oxide) with those in a couple with cobalt chromium metal heads, in total hip arthroplasties. The polyethylene wear was quantified by digital measurements on standardised digital front and lateral view X-rays and the differences were statistically analysed.

Keywords: ceramicized metal, polyethylene, hip prosthesis

In the case of total hip replacement prostheses, the friction between the 2 surfaces – the acetabular cup and the femoral head - leads in time to the wear of these parts and to the formation of microparticles. Microparticle formation depends on multiple factors – the materials that the parts are made of (cobalt chromium alloy, polyethylene, ceramicized metal etc), the geometry of the prosthetic components, their more or less correctly performed implantation, the forces and mechanical stresses that they are submitted to etc. The sizes of these microparticles are very small, 90% being under 10μm, with an average diameter ranging from 0.3 to 0.5μm [1]. On the other hand, the number of particles present in the prosthetic chamber and in the adjacent spaces ranges from billions to trillions [2]. These microparticles accumulate in the prosthetic chamber and determine a foreign body type of response from the host, such as inflammatory reactions. The intensity of the inflammatory response depends on the sizes of the microparticles and their composition, but most of all on their number. The cells involved in the processes are macrophages (that migrate in order to phagocytate microparticles), as well as fibroblasts and osteoclasts. The response of the host organism involves local release of numerous enzymes, cytokines, mediators and growth factors. The local inflammatory reaction leads to osteolysis and, in time, to the mobilization of the prosthesis components (loosening), which makes necessary its removal and replacement with another one, with optimal intraosseous fixation.

The search for an optimal friction torque, which would generate fewer microparticles and thus ensures a longer use of arthroplastic implants represents an ongoing concern for biomaterial researchers, orthopaedic specialists and manufacturing companies. The most recent material to enter the array of arthroplastic therapeutic techniques is ceramicized metal – zirconia, which is used in hip and knee replacements, in combination with cross-linked polyethylene.

Experimental part

Our objective was to compare the polyethylene wear of ceramicized metal heads on polyethylene cups with that of cobalt chromium metal heads on polyethylene cups in total hip arthroplasties.

Material and methods

48 subjects with primary osteoarthritis of the hip were included in a prospective study: in the first group, consisting of 24 cases, we performed total hip replacement with uncemented prosthesis with ceramicized friction torque (zirconium – zirconium oxide)/ polyethylene, while in the second group, also consisting of 24 subjects , uncemented prostheses with a standard metal head (cobalt chromium) on polyethylene cups were implanted. Selection for inclusion in one or the other of the two groups was randomized, based on the last digit of the patient's Social Security number: if the digit was even, the patient was included in the first group, and if it was odd, he was selected for the second one. In Group 1 the average age was 41.6 years (range: 25 – 63) and the distribution based on gender was 14 women / 10 men, while in Group 2 – the mean age was 43.4 years (range: 27 – 65) and the gender based distribution was 15 females / 9 males. Average follow-up period was 2.1 years (range: 37 months - 14 months). The Harris Hip Score was determined before surgery, at one, 2 and 3 years after surgery. Standardised digital antero-posterior and lateral view hip X-rays were obtained immediately after surgery, 6 months after surgery and each year after that. Digital measurements were performed in order to quantify the linear wear between two radiological examinations.

Results and discussions

At the end of the study period, data from 19 subjects in Group 1 were available and from 17 patients belonging to Group 2. The Harris Score increased in Group 1 from a preoperative 54.71 +/- 5.61 to 94.32+/-3.86 at the final check-up, and in Group 2 from 53.46 +/- 6.37 to 91.65 +/- 4.36. The difference between the Harris Hip Scores in the two Groups at final check-ups was not statistically significant ($p>0.1$). The linear wear 1 year postoperative was 0.02 mm in Group 1 (range: 0 – 0.05) and 0.07 mm in Group 2 (range: 0 – 0.15) (statistically significant difference, $p<0.05$), while at 2 years after surgery the linear wear

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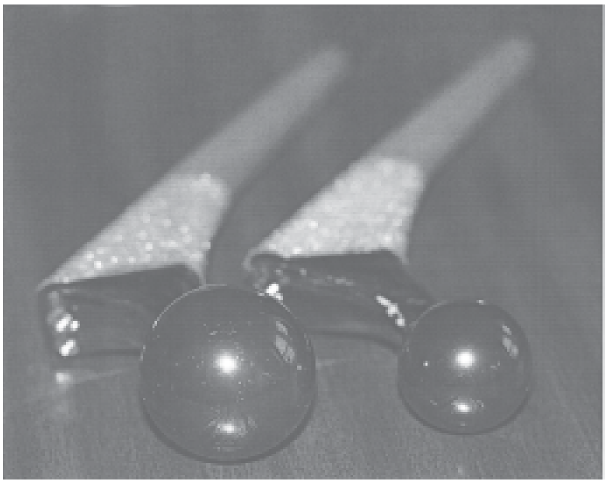

Fig. 1. Heads with ceramicized metal layer on femoral stems

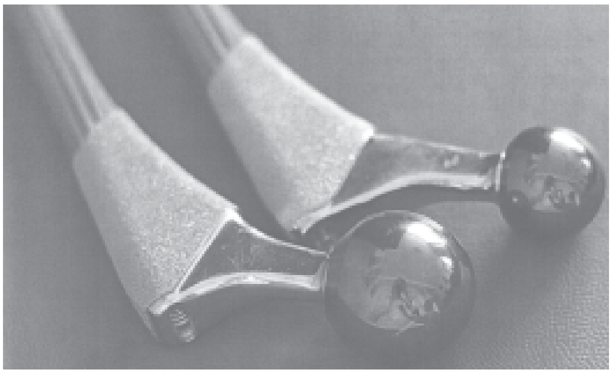

Fig. 2. Metallic femoral heads with a layer of ceramicized metal

Fig. 3. Zirconia / polyethylene friction couple (metallic femoral head with a zirconia layer in an acetabular cup – the metal back was cut-off in order to visualize the polyethylene cup inside it)

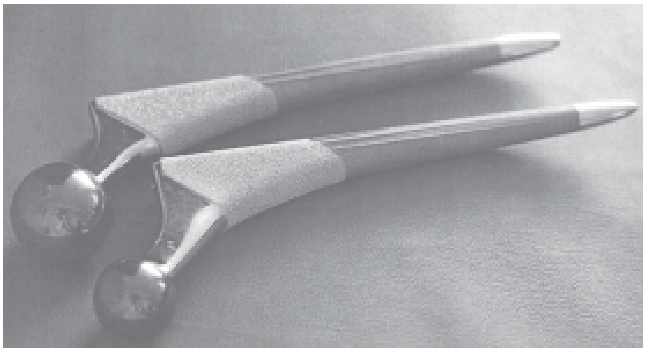

Fig. 4. Prosthetic femoral component with metallic heads (with ceramicized metal layer) of different sizes and different necks lengths

was 0.07 (range: 0 – 0.11) in Group 1 and 0.18 mm for Group 2 (range: 0 – 0.25) (statistically significant difference, $p<0.05$).

Zirconia is a ceramic compound consisting of zirconium dioxide (ZrO_2). Zirconium is a strong transition metal, with an atomic number of 40 and atomic mass of 91.224. It is one of the most biocompatible metals available (titanium, zirconium, vanadium and niobium). The biocompatibility of these metals is ensured by their resistance to corrosion, and by the fact that they have no evident role in the living world.

Hip prostheses with a ceramicized metal/ polyethylene friction torque have a layer of zirconia (brand name – oxinium - Smith & Nephew Inc, 1450 Brooks Road, Memphis, TN 38116, USA) on the surface of the metal femoral head (fig. 1). The metallic component of oxinium consists in 97.5% zirconium and 2.5% niobium (a metal with high biocompatibility as well). This layer is obtained by saturating the superficial zirconium metallic layer with oxygen at a very high temperature, until it becomes a layer of zirconia – ceramic material. This layer is very thin – 5 nm, but it is very strongly fixed to the underlying metal, as it is not applied to, but an integral part of the prosthetic head (fig. 2). This prosthetic head is covered by 3 layers: the superficial ceramic layer (ceramicized metal), an intermediate layer rich in oxygen, and the deep, non-oxygenated layer. In the intermediate metallic layer, the hardness of the material diminishes progressively, ensuring a systematic transition from the hardness of the superficial ceramic material to the metallic core, maintaining its elasticity.

The theoretical advantages of ceramicized metal are:

- higher mechanical resistance and hardness than cobalt-chromium alloys (theoretically it erodes and forms microparticles slower, it is not frail and not prone to catastrophic fractures – like usual alumina ceramic);
- smoother surface with superior lubrication – the surface is hydrophilic (it forms fewer polyethylene microparticles through abrasion); the friction coefficient of zirconia/ polyethylene is approximately half of that of cobalt-chromium alloy/ polyethylene (fig. 3);
- it contains zirconium and niobium, metals found at the top of the biocompatibility scale (they do not determine hypersensitivity reactions like those inflicted by chromium or cobalt);
- allows the manufacturing of femoral heads with a wide range of sized necks (fig. 4) (which is also possible in the case of standard cobalt-chromium alloy metallic heads, but not in the case of alumina type ceramic/ aluminium oxide heads, due to the danger of breakage).

Compared to ceramic- alumina type total hip prostheses there is another advantage as well – the polyethylene cups can be manufactured in different constructive variants – with an anti-luxation ring, semi-retentive or retentive (which is not possible for alumina cups, due to the frailty of the material) (fig.5).

In order to verify if these in vitro demonstrated advantages have an in vivo correspondent, we attempted to prospectively compare ceramicized metal/polyethylene friction torque prostheses with those with cobalt-chromium alloy/polyethylene. We used clinical criteria quantified by the Harris Hip Score – the presence of pain and its characteristics, patient's ability to perform usual activities (walking, climbing stairs, ability to sit, presence of limping, need for support – crutch or stick etc.) and hip mobility. Its values range from 0 to 100 points. Depending on their numerical values, the results are considered as low (<70

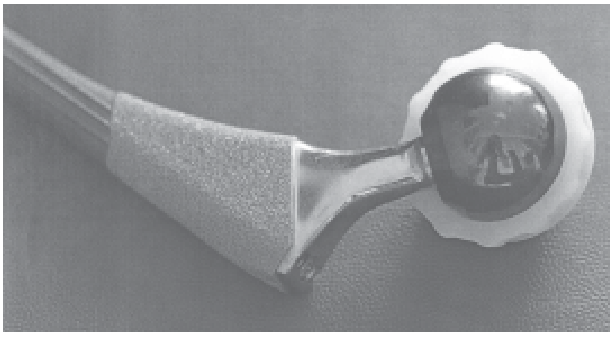

Fig. 5. Total hip prosthesis with ceramicized metal layer on the metal heads and polyethylene cup (the metal back was removed)

points), satisfactory (70-79 points), good (80-89 points) or excellent (over 90 points). Short-term results were excellent in both groups.

In terms of clinical results, there are no statistically significant differences between the two types of friction torques.

In order to determine the wear of the polyethylene cup, we used digital measurements on Dicom type images, performed under standard conditions, on the same non-portable radiological machine, for all patients. These measurements showed a more intense wear of the polyethylene cups in a torque with cobalt-chromium alloy. The differences are not statistically significant. A faster wear implies a more accelerated production of polyethylene microparticles, a more intense inflammatory response from the host tissues, osteolysis and mobilization of the prosthesis in time. It is worth mentioning that, up to the final radiological check-up, there were no periprosthetic osteolysis areas and no reinterventions required. Further follow-up of the groups will allow us to see if there is a correlation between the accelerated production of microparticles demonstrated by radiological findings and the development, in time, of osteolytic areas.

Another issue we should consider is that of hypersensitivity reactions determined by some of the metals used for arthroplastic or osteosythesis implants. Metals most frequently associated with this type of reactions include nickel, cobalt, chromium and beryllium, in this order. The incidence of sensititivity to metals among the general population is approximately 10% - 15%, with the majority of hypersensitivity reactions being determined by nickel (approximately 14%) [4]. When interacting with biological systems, metals suffer a corrosive process. As a result of this, metallic ions are released, which can spread in the entire organism, determining remote lesions or form compounds in combination with proteins, which can act as allergens, triggering an immune response from the host.

The reactions determined by orthopaedic implants are, generally, of type-IV delayed-type hypersensitivity (DTH) [5]. The antigen (the metal contained in the metal-protein compounds) activates sensitized T lymphocytes, which release cytokines and determine the recruitment and activation of macrophages [5].

Ceramicized metal hip prostheses contain only zirconium and niobium, metals with high biocompatibility, while standard prostheses contain cobalt, chromium and very small quantities of nickel. In our series there were no cases of hypersensitivity reactions to metal reported; a possible track for future research can refer to skin reaction testing for the metals contained in the prosthesis, prior to its implantation.

Conclusions

The clinical results obtained with the two types of prostheses (ceramicized metal head/ cross-linked polyethylene cup and cobalt chromium alloy head/ high molecular weight polyethylene cup) overlap, no statistically significant differences between them being reported.

The rate of polyethylene wear is significantly higher in the cases with cobalt chromium alloy/ high molecular weight polyethylene compared to those with ceramicized metal / cross-linked polyethylene.

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