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Total arthroplasty of the hip by fritted alumina prosthesis. Experimental study and 1st clinical applications☆

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ABSTRACT

A new material is proposed in total hip arthroplasty as a bearing component. The tolerance of dense ceramics was studied, as well as the anchorage of this material into bone. Physical, chemical and mechanical properties of the prosthesis were tested. Two hundred patients have already been operated on, but the follow-up is too short for any conclusion.

Total hip arthroplasty is not new: as Leinbach [1] pointed out, it was implemented by Gluck in 1890 [2], with ivory acetabulum and head fixed using colophane cement, pumice stone and plaster. The first genuine prosthesis, however, was developed and implemented in the UK by Wiles [3] in 1938. In 1939, methyl methacrylate was introduced for fixation purposes by Habouch [4]. The technique, however, really began to take off in 1959, when Charnley [5] introduced a Teflon acetabular component receiving a stainless steel head, with methyl methacrylate bone fixation; he soon substituted high-density polyethylene for Teflon, due to the toxicity of the wear debris. Mac Kee and Watson-Farrar [6], in 1960, introduced a metal-metal design in chromium-molybdenum-cobalt alloy, also using acrylic cement fixation. Everyone knows what success these two prostheses had in France, and Charnley [7] could proudly declare that "it is very nice to know that they are both British!"

Since then, many designs based on one or the other model have been developed, notably in Europe. As early as 1956, however, in the Soviet Union Siwash [8] was using a bimetal prosthesis with direct bone anchorage, both components having holes and slits allowing bone ongrowth. This prosthesis, which was first produced in chromium-molybdenum-cobalt alloy, is now made of much lighter titanium.

This brief history of total arthroplasty thus highlights the considerable improvements made in recent years. Production has moved from the craft workshop to the factory floor, with all the controls that entails: material resistance, rugosity index, circularity, friction coefficient, wear, etc. – all of which is hardly surprising as manufacture involves the metallurgy of alloys and of titanium, production of plastics and, finally, state-of-the-art ceramics.

The surgeon's objective is to approximate the intrinsic qualities of the joint as closely as possible and, in theory, to replace only surfaces that have undergone wear: i.e., the cartilage and subchondral tissue, at least in most cases.

Achieving perfect bonding between biomaterial and living bone is perhaps the trickiest question if replacement is to be lasting. Hitherto, prostheses replaced more than was necessary – and even so fixation proved hard to ensure. The advent of porous (Lyman-Smith [9]) and fritted materials (Galantie et al. [10]) will doubtless allow another step forward to be taken.

Equally worrying is the question of tolerance for these implants, which operate under stress and are subject to wear. The long-term impact of these complex molecular chain plastics remains to be seen. That of the metal alloys is better understood: they are well tolerated, but not free of microcorrosion, as demonstrated by Ferguson et al. [11]. Aragon and Hulbert [12] showed the same to be true of titanium. Microcorrosion is simply the natural tendency of the alloy components to revert to their prior status by oxidation. This combines with what Fink and Smaico [13] called stress corrosion, with a risk of implant cracking and breakage, accelerating the process of metal fatigue fracture.

This is why many authors consider that most of the substances that are implanted in the organism, which is a corrosive environment varying in pH, especially after trauma or surgery, cannot be tolerated indefinitely. Corrosion, stress and chemical degradation induced by the action of bodily fluids and tissues combine to modify implant properties and, moreover, the resultant substances may themselves be toxic, inducing intolerance toward the implant, with aseptic and then septic phagocytosis (so, at least, we think).

It is very important to take these considerations into account in developing joint prostheses, which are intended to be definitive, unlike osteosynthesis material. Thus, alongside the issue of lasting tolerance is that of the bond between the biomaterial and the bone. The use of ceramics may lead to progress here.

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The first step of the present study consisted in producing an alumina implant, and we shall present its mechanical properties and tolerance. In the second step, in the light of American findings, we shall examine the possibility of direct bone anchorage.

1. Alumina total knee replacement

In April 1969, when we considered alumina as a candidate biomaterial in implantology, we were thinking purely in terms of its excellent mechanical properties, with a view simply to replacing the currently used materials. It was to be what could be called a traditional implant, with acrylic cement fixation.

1.1. Physical characteristics of alumina

Aluminum oxide or alumina ($AL_2\ 0_3$) comes in the form of fine white powder. After compression in a mold, the part is sintered in an oven at a temperature lower than its fusion temperature of 1700 °C. This produces a very dense agglomerate of small crystals of about 30–80 microns. The density (3.92) is close to that of naturally occurring monocrystalline aluminum oxide, whether pure or colored (sapphire, ruby).

Spectrography reveals an almost pure substance, with 99.3% alumina and:

- 0.6% MG O;
- 0.04% SI O_2;
- 0.03% NA O;
- 0.01% $F_2\ O_3$;
- 0.005% CA O.

The mechanical characteristics are of especial interest. Resistance to 4000 kg cm^2 flexion and 2000 kg cm^2 traction is much poorer than most metals such as stainless steel; but in contrast, alumina's resistance to compression up to 24,000 kg cm^2, is excellent. It is, moreover, remarkably hard, graded 9 on the Mohs scale, just below diamond (grade 10). This is how it comes to be used in cutting tools and for milling even the hardest metals; but it also makes trimming and cutting very difficult, requiring the use of diamond: no metal, not even tungsten, can cut it. Like a very hard alloy or hardened steel, it is breakable under direct violent shock; at the thickness used in hip prostheses, however, this is only to be feared if it received a strong direct blow. It has the advantage over metals and plastics of not being deformed by shock, heat or pressure. This dimensional stability means that there is no risk of deformation of active surfaces during sterilization, cement hardening or everyday compression. There is thus an advantage in bearing quality and a disadvantage compared to plastics in terms of elasticity.

1.2. Chemical characteristics

Being an oxide, alumina is by definition inoxidizable; it will not deteriorate or corrode. The only chemical able to attack it is hydrofluoric acid, which is why this inert neutral foreign body is so well tolerated. Nevertheless, in our patients, spectrographic alumina urine assay performed by the Toulouse toxicology laboratory was positive in some cases and negative in others.

The explanation may lie in wear tests: 300 hours' simulation produced 10 microns of wear. This research needs to be continued, to determine whether, after prolonged implant use, spectrography continues to find traces of aluminum in the urine: the causes of potential error are multiple.

Aluminum urine assay was performed by emission spectrography on dry residue calcined at 400 °C.

Twelve of the 28 urine samples analyzed to date showed significant levels of aluminum; in the other 16, the level was below the assay sensitivity threshold (200 μg/liter).

Centrifugation and ultra-filtration (0.3 μ) tests were performed on samples after several days' refrigeration.

Qualitative spectrography of the centrifugation pellet revealed high levels of aluminum. Quantitative analysis after centrifugation found that the levels had considerably fallen.

However, these experiments have yet to determine the nature of the solid compounds fixing the aluminum: alumina (aluminum oxide) or aluminum phosphate, for example.

We are planning characterization tests:

- by X-ray diffraction;
- and by differential solubility.

Note that the glomerular filter blocks particles greater than 75 Å.

To clarify possible interaction between alumina and the organism, the following experiments are being conducted:

- *in vitro* action of plasma on the ceramic used in the implant;
- implants using this material in Wistar rats sacrificed at 8 months, to study the distribution of alumina in underlying tissue.

1.3. Tolerance by the organism

In 1969 and 1970, several implantations were practiced ahead of clinical implementation. We then learned of a study performed back in 1963 by Lyman-Smith and which demonstrated tolerance, allaying our concerns.

Mazabraud implanted a trimmed and polished ball of dense alumina under human abdominal skin for 3 months; on removal, a sclerous shell of parallel collagen fibers was found, surrounded by adipose tissue without notable inflammatory reaction.

After implantation of dense alumina sticks into the trochanters of several dogs, there was no macrophagic foreign-body reaction or lymphoplasmocytic inflammatory reaction.

We also fixed high-rugosity ceramic fragments; after a few weeks, anchorage was very solid but with a fairly violent macrophagic reaction. Similar results were found with alumina powder implanted under the skin in dogs. There was, even so, no intolerance rejection.

1.4. Description of the implant set

We therefore adopted alumina for the development of the first prosthesis, with alumina head and socket and a metal stem (Fig. 1). Engineers consider flexion resistance insufficient for the entire diaphyseal-cervical-cephalic component to be in alumina.

The alumina socket (48 mm diameter) includes an anchorage design etched into its convex side, for the cement. The hemispheric hollow (31 mm diameter) receives the alumina head (4/5 sphere). The two bearing surfaces are trimmed by a diamond grinder to ensure sphericity and good contact.

The alumina head has a lodge for the axis of the implant stem, fixed with epoxy resin, which is not in contact with any tissue although, as demonstrated by Lyman-Smith, it is well tolerated and inert with respect to the usual chemical agents.

The implant can be sterilized in a steam sterilizer, like any surgical instrument, by immersion in antiseptic, or by γ ray, which will not affect the molecular chains, as could happen with plastics.