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 had 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 (Galante 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 Hubert [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 Smaco [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 (Al₂O₃) 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 monocristaline aluminum oxide, whether pure or colored (sapphire, ruby).

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

- 0.6% MgO;
- 0.04% SiO₂;
- 0.03% Na₂O;
- 0.01% F₂O;
- 0.005% CaO.

The mechanical characteristics are of especial interest. Resistance to 4000 kg cm⁻² flexion and 2000 kg cm² traction is much poorer than most metals such as stainless steel; but in contrast, alumina’s resistance to compression up to 24,000 kg cm², 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.

Alumina 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 trochanter 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-ccephalic 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.
1.5. Study of prosthetic bearing

The bearing couple was studied by the hydromechanics and friction laboratories; to quote from their report:

- description of simulator (Fig. 2):
  - a gear motor induces rotation in a vertical axis joined at one end to a diagonal arm at 30° to the vertical,
  - within the arm is a second stem, put in rotation by a set of pinions, with the head that is to be tested fixed to the end of the stem,
  - the fixation axis of the head is displaced laterally in a revolution cone with a peak angle of 60°,
  - each revolution lasts 1 second,
  - this movement combines with a movement of relative rotation between pivot and socket around the fixation axis of the head,
  - a device (preloaded spring) exerts loading in the axis of the tested parts,
  - the two parts are placed in a tank with a constant volume of physiological saline, circulated by pump and filtered and recovered for recycling;
- test conditions:
  - head axis revolution in a solid angle of 60° at 60 rpm,
  - relative movement of rotation between head and socket,
  - 100 daN loading in pivot axis,
  - test tubes immersed in a tank of salted distilled water (9/1000),
  - round-the-clock testing, with measurement every 300 hours;
- measurements and examinations:
  - at each disassembly:
    - head and socket dimensions and weight,
    - head rugosity, on Talysurf rugosimeter,
    - head and socket surface replication micrography;
- results:
  - dimension and weight measurement found wear in the head: 10 microns over the first 300-hour period, falling to only 3 microns in the second period and to zero from 600 hours to end of testing at 2100 hours (Fig. 3). This was doubtless a question of remodeling between the contact surfaces.

In contrast, there was no acetabular wear, dimensions and weight hardly varying at all.

Head rugosity index showed significant improvement during this remodeling period:

- from 0.15–0.3 to 0.10 μ (Ra CLA [arithmetic rugosity, center line average]) in the first 300 hours;
- from 0.10 to 0.06 μ (Ra CLA) in the second period;
• and stabilizing after 600 hours.

Replication micrography found no adverse surface effects (Fig. 4).

Friction coefficients, assessed on a tribometric simulator (Fig. 5), lay between 0.10 and 0.38, reproducing well the loads encountered in real life.

In conclusion, this head/socket bearing behaved well over 3 months of trials, and “the results showed that the bearing could have continued to function doubtless indefinitely”. By 600 hours, the friction surfaces were perfectly smooth and all indices showed improvement.

The sphericity and circularity indices of the alumina head were also measured after the running in period.

Circularity, measured on the maximum head diameter, showed defects of between 0 and 2 microns (Fig. 6).

Sphericity was measured as circularity in 2 parallel planes with the same center: discrepancy was 1 micron.

Finally, these initial results, while very encouraging, can certainly be improved upon.

1.6. Surgical applications

We shall not here go over the technical details of total knee arthroplasty, which have been fully described and developed by its promoters (Charnley, Mac Kee and Watson-Farrar), but
be resected if too long. In most cases, it seems unnecessary to have several lengths of neck available, as this cut almost always allows mechanically satisfactory implantation, especially as the varying hollowness of the socket and thickness of the acrylic cement layer also help correct and adjust implantation. The stems, on the other hand, come in two forms: one steeply angled at 130°, and another which is thinner and less angled, for use with narrow shafts.

Peroperatively, it is preferable not to mark the alumina by any contact with metal. Its hardness makes it a real “whiteboard” for the metal, which undergoes wear by contact. Trial models, both femoral and acetabular, are therefore desirable.

It has proved crucial not to strike the alumina directly. Fitting should be manual, and introduction should not be made difficult by the cement hardening too fast.

Between April 1970 and December 1971, 200 prostheses were implanted, using acrylic cement. Apart from one head fracture, in our fourth implantation, due to direct shock between the metal stem and the head during trial, there were no material-related complications during fitting; the entire fractured implant was immediately replaced. Otherwise, there were no fractures during implantation, and it seems unlikely that any could be caused by indirect shock. We are unable to provide details of the aspect of the implants after use, as none needed removing.

It should be stressed that no current head components can support shock without risk of loss of sphericity, which would increase the friction coefficient and accelerate wear.

1.7. Conclusions

This new biomaterial for total hip arthroplasty, dense fritted alumina, seems to have a certain number of advantages over metals and plastics, although these need confirmation. They essentially consist in its hardness, which may render it wear-free over a human lifespan, its perfectly inert chemistry, its low friction coefficient and its tolerance by the organism. On the other hand, it may, like metal, have the drawback of lacking elasticity, unlike plastic. Clinical results for the first 100 implants will be reported 2 years after the last implantation: i.e., in 1973.

2. Ceramic implants

While developing the alumina implant as a substitute for metal and plastic designs, we also studied the research being conducted on ceramics. It seems promising. The American teams are aiming at permanent tolerance and self-fixation. Natural bone is, after all, largely composed of ceramic matter with a texture resembling that of apatite [14]. Moreover, many ceramic oxides are in a state of maximal oxidation and cannot further corrode; most are also insoluble and highly inactive, making it difficult to see why so little research has been done on them.

After a few trials, as early as 1928, using plaster to fill bone cavities, in 1963 Lyman-Smith experimented with a porous aluminate ceramic impregnated with epoxy resin. It was not pure, but rather a mixture of silica, alumina, calcium carbonate and magnesium carbonate; the resultant “Cerosium” was as hard as bone, with the same elasticity index, and proved inert in a rabbit model; it was anchored so strongly by the osseous system that it could not be separated.

This research would seem to have achieved a more precise study than with any other material of the bond between an inert prosthetic part and living bone tissue.

In 1971, Hulbert et al. published an important update [14] on current research and his own experimentation. Meanwhile, Campbell [15] announced that ceramics research would soon allow total hip replacement in humans.
It is important to bear in mind that the problem of total hip arthroplasty was complicated in the USA until recent months by the FDA’s ban on the use of cement, which accounts for the success of the Ring prosthesis [16] there.

Experimentation with ceramics led Hulbert et al. to the following conclusions:

- the ceramics studied seemed highly compatible with the musculoskeletal system. This information, borne out by other researchers, showed that any inactive ceramic holds out hope as a biocompatible implant;
- the porous ceramics studied proved able to adapt to considerable bone growth when pore size reached at least 150 microns, with bonding pores of 100 microns;
- a ceramic coating on a metal implant thus seemed a possible solution to the problems of tissue adherence found with metals, deserving further study.

These conclusions are those of a series of very precise studies: research on bone ongrowth in porosities is made very difficult by the hardness of ceramics. The authors succeeded in making cross-sections of about 75 μ thickness, using a precision diamond cutter, which they colored in thin slices so as to observe the ongrowth of Hawers canals in the pores. They also used microradiography, enabling microscopic study of radiographs. And finally, they also used electronic microprobes.

Clinical applications are presently altogether isolated; to the best of our knowledge, no total joint prostheses have yet been implemented.

Alongside the work of Lyman-Smith and Hulbert et al., we would cite that of Peterson et al. [17], Galantie et al. [10] and Welsh et al. [18], looking for anchorage in porosities or rugosities in ceramics or in ceramics and metals.

In the light of these studies, we looked into the feasibility of direct anchorage of prosthetic parts.

2.1. Direct anchorage

Dense fritted alumina is virtually non-porous, making direct anchorage improbable. Moreover, manufacturing techniques cannot at present easily produce parts with an active surface in dense alumina and anchoring surface in porous alumina. We therefore sought to get round this by artificially creating irregularities on the convex surface of the dense alumina socket.

Hemispheric alumina balls with a pattern etched deeply into the lamella of the convex surface were implanted into the trochanter in dog models (Fig. 8). The concavity was hollowed out without heating, by curette. At month 3, fixation was such that a hammer and chisel were needed to remove the balls. Histology found good tolerance, with very fine separation tissue between bone and biomaterial. At month 6, other hemispheric balls were removed with even greater difficulty, as the cancellous bone that had grown back between the lamellae could not be detached from the ceramic in part of the convex surface of the balls.

Mazabraud concluded from histologic examination (Fig. 9a and b) that:

- the multiple samples taken show osteogenesis filling the scratches on the implant. This ongrowth shows a saw-tooth aspect in the bone tissue.

Although the study was limited by lack of movement or stress on the balls, anchorage on dense non-porous alumina was proven, allowing a direct anchorage socket to be envisaged. The same, however, does not hold for the femoral head: the metal stem on which it is mounted would not seem to be able to be fixed directly without cement – although, as everyone knows only too well, some Moore self-blocking implants can be very difficult to remove, held strongly in the bone.

Since we learned of Hulbert et al.’s recommendation for a layer of porous ceramic over the metal, we have undertaken further tests:
such a layer not only provides anchorage but also creates an inactive barrier, eliminating the risk of stress corrosion of the metal.

2.2. Direct anchorage acetabular component (Fig. 10)

This prosthesis differs from the previous one in its convex surface with a deeply etched lamellar pattern and a protuberance which also has a lamellar surface. A channel is drilled in the bottom of the socket to align the hollow which has to go down to the cancellous bone.

This technique is only feasible if the bottom of the socket is thick enough. The part is then implanted after 48 mm reaming to achieve hard friction penetration.

The concave hemisphere, alumina head and metal stem resemble those of a cemented prosthesis.

2.3. Clinical applications

Only 20 acetabular components of this type were implanted, in patients with osteoarthritis of the hip who had been informed of the need to observe at least 3 months’ non-weight-bearing. Stability is difficult to assess, X-ray study being imprecise in this regard: probably, only time will tell.

2.4. Conclusions

The permanence of component fixation by stable bonding between biomaterial and bone tissue should be our prime concern, and we considered it worth sharing our research, its first applications and the hope it inspires in us.

Disclosure of interest

Authors’ disclosure of conflict of interest was not requested when the article was originally published.

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References

[15] Campbell. Department of ceramic engineering, The Ohio State University; 1971 [Personal communication].

Fig. 10. Cementless direct anchorage acetabular component. Postoperative aspect and at 6 months.