AN OVERVIEW OF IMPLANT MATERIALS

by J. P. SIMON and G. FABRY

Materials used for implant manufacture may play an important role in implant fixation. The choice of a material influences rigidity, corrosion characteristics, biocompatibility and tissue receptivity. The surface morphology of the implant affects its stability within the skeleton or within the surrounding cement mantle. This paper summarizes materials used in orthopedic implants, including metals and metal alloys, polymers and ceramics.

Keywords : surgical implants ; metals and alloys ; polymers ; ceramics.
Mots-clés : implants chirurgicaux ; métaux et alliages ; polymères ; céramiques.

SAMENVATTING

J. P. SIMON en G. FABRY. Een overzicht van implant-materialen.

Materialen gebruikt voor het vervaardigen van orthopedische implantaten spelen een belangrijke rol in implantfixatie. De aard van het materiaal bepaalt de rigiditeit, de corrosiebestendigheid, de biocompatibiliteit en de weefselreceptiviteit van het gebruikte implant. De oppervlaktemorfologie beïnvloedt de stabiliteit in het been of in de omgevende cementmantel.
Dit artikel geeft een overzicht van de belangrijkste materialen gebruikt voor het vervaardigen van orthopedische implantaten. Deze materialen omvatten metalen, metaallegeringen, polymeren en 'keramische' materialen.

RÉSUMÉ

J. P. SIMON et G. FABRY. Aperçu des matériaux utilisés dans la fabrication des implants.

Les matériaux destinés à la fabrication d'implants jouent un rôle important dans la qualité de leur ancrage. Le choix du matériau influence la rigidité, les caractéristiques de corrosion, la biocompatibilité et la réceptivité par les tissus environnants.
La morphologie de la surface de l'implant influence la stabilité dans l'os ou dans le manteau de ciment. Cet article présente un aperçu des matériaux utilisés en orthopédie pour la fabrication d'implants. Ces matériaux sont soit le métal et ses alliages, soit des polymères, soit des 'céramiques'.

INTRODUCTION

Both biological factors and prosthetic design features influence the performance of total joint prostheses. The interface between the implant and surrounding tissues is influenced by the size and shape, materials, and surface characteristics of the implant. Stable components rely on both macroscopic and microscopic interaction with the adjacent skeletal structures. Both modes of fixation are to a certain extent dependent on the materials composing the implant itself. These materials include metals, polymers and ceramics.

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IMPLANT PROPERTIES AND TISSUE RESPONSE

Biocompatibility is a prime requisite in orthopedic and other implants. Biocompatibility means that the implant does not interact adversely with the physiological environment or vice versa (6). A biological reaction to an implant does not always involve an adverse effect. A positive response may be associated with the use of some new implant materials such as hydroxyapatite (7, 9). Successful long-term implant fixation requires a stable interface between the prosthesis and the surrounding tissues (11). Each application of load through a prosthesis as well as each application of muscle force through the skeletal structures generates stresses and strains at the interface. The size, shape, surface properties and stiffness of the prosthesis all affect these stresses generated in the junctional tissues. A mechanically stable interlock occurs when forces applied to the junctional tissues are balanced by the strength of this interlock (11). If this condition is not fulfilled the structure may break, an undesirable tissue response can occur and the implant may loosen.

Chemical and electrochemical processes at the interface also affect the longevity of an implant. Contemporary implant metals have extremely low levels of corrosion, but nevertheless all metal implants are subject to corrosion at some level (3, 6). The constituents of body fluids such as water, lipids and oxygen may alter the mechanical properties of some polymers such as polymethylmethacrylate. Cell and tissue response to biomaterials is partly dependent upon the choice of materials as well as on surface characteristics ; for instance the positive cellular response to some ceramics makes them attractive candidates for bone ingrowth (7, 9).

MATERIALS USED FOR ORTHOPEDIC IMPLANT MANUFACTURE

There are three categories of materials presently used in prosthetic devices : metals, polymers, and ceramics. Nearly all have been used for various surface morphologies.

Metals

Biometals used in orthopedic implants include surgical grade stainless steel, cobalt-chromium alloys, titanium, and titanium alloys.

Stainless steel is not suitable for a permanent implant because of its poor fatigue strength and liability to undergo plastic deformation. The poor corrosion resistance has precluded the use of this metal as a porous coating for modern biologically fixed implants (6, 12).

Stainless steel is still commonly used for nonpermanent implants such as internal fixation devices for fractures. In the latter the malleability allows 'preshaping and prestressing' during the operation.

Before the use of titanium, cobalt-based alloys (Co-Cr-Mo and Co-Cr-Ni) had largely replaced stainless steel as materials for permanent implants. These alloys are generally more corrosion resistant owing to the formation of a durable chromium-oxide surface layer, the so-called passivation layer. Despite the good corrosion resistance, ion release *in vivo* is still of some concern. Chromium and nickel are known carcinogens, and cobalt is a suspected carcinogen. Chromium, nickel and cobalt are not only found in the tissues surrounding the implant, but also in blood and urine samples, often at levels higher than in individuals professionally exposed to these metals (3). Also worrisome are recent reports emerging to support the possible association between the formation of neoplasms and the long-term presence of metallic implants.

Co-Cr-Ni alloy which was initially developed for aeronautics has been in use in orthopedics for several years. It has superior mechanical strength compared to Co-Cr-Mo. However, the nickel content of Co-Cr-Ni alloy is twice that of Co-Cr-Mo (3). In view of the above mentioned ion release this obviously is of some concern. Moreover the high nickel content presents potential problems in corrosion resistance and tissue compatibility.

Although rare, there have been reports on Co-based implant fracture (12). This has led to the development of so-called supermetals or superalloys. A special forging process (compression under high pressure) increases the fatigue strength of these metals. This process reduces the grain size

and thus minimizes material defects. It is nevertheless difficult at the present time to make porous-coated prostheses by this method. Moreover the sintering process tends to decrease the fatigue strength significantly. Therefore a porous layer should be avoided at critical stress regions on the prosthetic surface. Stems of Co-Cr alloys have an elastic modulus of 221,000 MPa., which is about twice the stiffness of titanium implants (110,000 MPa) and roughly 10 times the stiffness of cortical bone (21,000 MPa.) (8). This property may decrease stresses in the cement mantle but makes these implants less suitable for cementless applications. This finding has led to the use of titanium alloy for cementless prosthetic devices. However, even titanium alloy does not have a sufficiently low modulus of elasticity. Although bending stiffness may affect processes such as stress shielding the importance of the choice of the implant metal should not be overemphasized since the stiffness of an implant increases with the fourth power of its diameter.

A somewhat smaller Co-Cr prosthesis may have a bending stiffness similar to that of a larger titanium implant. Furthermore, the stiffness is affected by the geometry of the prosthesis. The type of stiffness (axial, torsional, bending) that is important remains to be defined.

Titanium used in orthopedic implants involves pure commercial titanium and titanium alloys such as Ti-6Al-4V, Ti-6Al-7Nb and Ti-5Al-2.5Fe. These metals have been demonstrated to be highly biocompatible. Nevertheless some concern remains as to the effect of vanadium which is known to be cytotoxic, and aluminium, which has been incriminated in Alzheimer's disease. Titanium and its alloys are more corrosion resistant than cobalt-chrome alloys because of the formation of titanium oxide, which is in fact a ceramic, on the surface. This layer, however, may be porous and rather friable. Abrasion of this titanium oxide layer can lead to release of particles into the surrounding tissues ; titanium debris has been demonstrated in bone. Although titanium implants have been considered to be the most biocompatible, these debris particles may well cause an undesirable tissue response with eventual long-term aseptic loosening of the implant.

Many Co-Cr alloy and titanium prostheses are used as cementless implants. Bone bonding to these porous coated metals has been reported to a certain extent (5). The clinical success, however, of many of these orthopedic implants probably results more from their intrinsic mechanical stability at a macroscopic level than from the microscopic interlock of ingrown bone (6). It is suggested from the work of Linder that osteointegration should be regarded not as an exclusive reaction to a specific implant material, but as the expression of a nonspecific and basic healing potential in bone (10).

Polymers

Polymers are formed by linking a large number of basic elements (the monomer) through chemical reactions. In organic polymers the monomer is an organic molecule with a central carbon atom (1, 4).

The most popular polymer used in orthopedics is ultra-high molecular-weight polyethylene (UHMWP) or high-density polyethylene (HDP). Thus far polyethylene is the best material for articulating with metal or ceramic. The two most important factors of concern are creep and progressive wear. Creep is a slow, temperature-dependent deformation under load with time. Unlike biometals, where creep is virtually nonexistent at body temperature, creep is a major problem in polymers. Metal backing has been demonstrated to lessen the creep of HDP. However, metal backing decreases the effective thickness of HDP, making plastic deformation more worrisome in *in vivo* applications, such as the thinner tibial components in total knee arthroplasty.

Wear of polyethylene is of major concern. During the gait cycle polyethylene debris particles may be "pumped" into contact with the endosteal surface of the femur. Such debris may account for localized bone lysis finally leading to aseptic prosthetic loosening.

Carbon fiber has been utilized for reinforcement and improvement of the mechanical strength of polyethylene (2). Although creep and tensile strength could be improved, resistance to surface

wear was decreased. Moreover the use of carbon-fiber-reinforced polyethylene resulted in contact stresses that were higher by as much as 40 per cent in tibial components (2).

In spite of the increasing implantation of cementless devices, the use of self-curing bone cement (which is an acrylic polymer) remains widespread. Modern cementing techniques are responsible for the much improved clinical outcome of cemented prosthetic implants.

It should however be emphasized that cement does not act as a glue, but merely as a filler which allows mechanical anchoring (macro- and micro-interlock) of the implant and transfer of load from the prosthesis to the bone. Compared to cortical bone, polymethylmethacrylate is relatively weak with respect to nearly all mechanical properties (14). Its low modulus of elasticity appears to be an advantage in that it allows a gradual transfer of stress to bone.

New classes of bone cement have been introduced in an attempt to improve the strength of this polymer. These include butylmethacrylate in methacrylate matrix and ethylmethacrylate in methylmethacrylate matrix. The former bone cement has been shown to creep to a much greater extent than conventional PMMA bone cement. When used with femoral stems of suitable design this could provide a clinical advantage. The latter type of bone cement has a lower setting temperature and possibly a lower grade of post-curing shrinkage. However, clinical trials indicated that it is more difficult to achieve good compression with this cement.

As bone cement is viscoelastic in nature, it is subject to stress relaxation and creep (1). According to many authors this may adversely affect the stress-bearing capacity and may contribute to loosening and failure of total joint replacements. However when used with specific implant designs, this property of creep may be very advantageous in that it allows subsidence of the femoral component without causing fractures in the cement mantle.

It is important to emphasize that there is no significant difference in the mechanical properties of irradiated and normal cement, and postoperative irradiation may be safely used after fixation of pathological fractures without fear of adverse effects on the mechanical properties of cement (14).

In attempting to solve the problem of cement disease (the aggressive osteolytic response to cement particles) one can consider replacing the PMMA mantle around the femoral stem with a different polymer mantle. Research focusing on these coatings started in the 1960's (15). One of the first materials investigated was a porous polytetrafluoroethylene (Teflon®) carbon fiber composite (PTFC), called Proplast®. This substance was initially intended for bone ingrowth. Later it was claimed to provide a very low modulus interface that permitted uniform stress distribution. The same concept applies to a more recent investigation of polyethylene terephthalate (Dacron®) velour as a coating for tibial plateau prostheses (15).

Another higher strength polymer, porous polysulfone (UDEL®), was introduced in the mid-1970's. Because of the short follow-up time, definite statements about the efficacy of PPSF-coated stems cannot be made.

Two types of porous polyethylene were developed for biological fixation : porous polyethylene, produced by sintering particles of this polymer to the implant, and another form, by sintering fibers of the material to the prosthesis. However an extensive clinical trial with a porous polyethylene-coated device (sintered fibers) showed it to be unsatisfactory because of pain. The mechanical strength of the porous polymers is variable. It is questionable whether low-strength polymers such as Proplast® are strong enough to support load-bearing prostheses (15). Reports have appeared in the literature stating that the coating had insufficient strength to withstand normal weight-bearing loads.

The wear properties of polymers and composites are extremely important in evaluating these materials for total joint prostheses. Wear particles are a potential result of abrasion in press-fit designs and may have long-term adverse effects. Another disadvantage of these coatings is the fact that they must be factory-made and supplied to the surgeon already affixed to the stem. Thus high surgical skill is required to shape the medullary canal to exactly match the prefabricated implant. At the present

time the clinical experience with polymer implant surfaces has been rather narrow. The biological tolerance and the mechanical strength of these polymers are still under investigation.

Ceramics

The ceramics used in orthopedic implants include aluminium oxide and calcium phosphates. These ceramic materials are very resistant to compression, but weak under tension and shear, and brittle (7).

Aluminium oxide ceramics are formed by hot-pressing, the simultaneous application of pressure and temperature to a powder (comparable to squeezing snow to make a snowball). This process leads to a final product with high density, small grain size and good mechanical properties.

Bioceramics have a high modulus compared to bone (330,000 MPa.). This may result in fracture of bone or early loosening of ceramic acetabular sockets because of the high noncompliant elastic modulus.

Although *in vitro* tests revealed excellent results as to tribology and wear for the combination of alumina-to-alumina (head and socket), unacceptable wear after some years of clinical use has been observed (12). Another reason for discontinuation of its use is the low resilience (the resistance to sudden impact loading) of this ceramic. This property may adversely influence impact crack initiation and propagation. Instead, ceramic to high-density-polyethylene articulating surfaces are being used.

Calcium phosphate ceramics are particularly attractive as implant coatings because of their high biocompatibility and bioreactivity (7, 9). Titanium and titanium alloys are coated with hydroxyapatite using several methods. The plasma- or flame-spraying method is used most often for prosthesis applications. The thickness of the HAP coating varies between 150 µ and 250 µ. These calcium phosphate implant coatings have been shown to result in strong early porous implant fixation and early bone ingrowth. At present HAP coated prostheses for human applications are being investigated in several clinical trials.

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