Biomaterials, Part I

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Editors: **Björn Albrektsson,** Gothenburg
Tomas Albrektsson, Mölndal
Lars Lidgren, Lund

Material properties

Mechanical behavior of materials

K. B. Broberg

Lund Institute of Technology, S-221 00 Lund, Sweden

A schematic overview of the mechanical behavior of materials was presented (Figures 1–3).

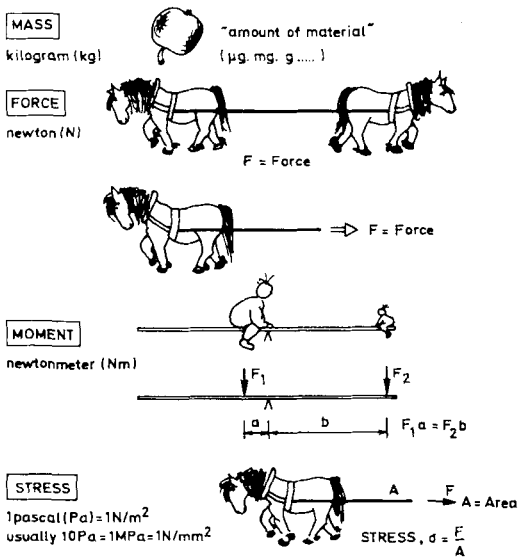

Figure 1. Basic mechanical concepts of mass, force, moment, and stress.

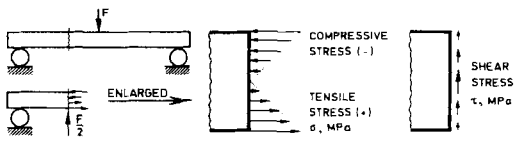

Figure 2. Normal stresses and shear stresses at a cross-section of a beam.

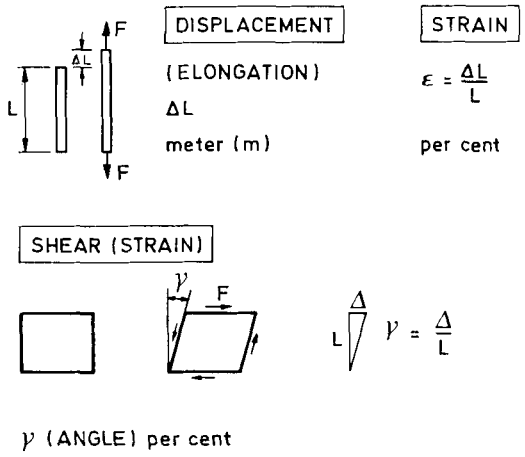

Figure 3. Basic kinematic concepts of displacement, strain, and shear (or shear strain).

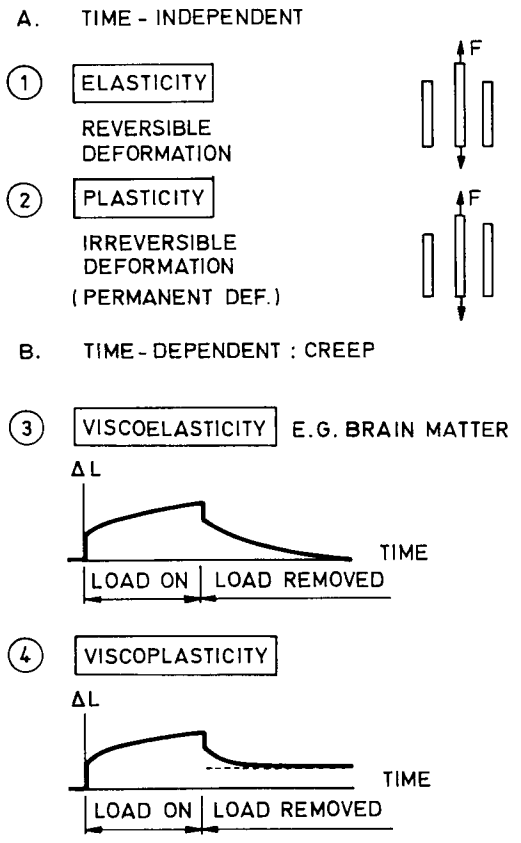

Figure 4. Constitutive relations between stresses and strains, which may take different forms.

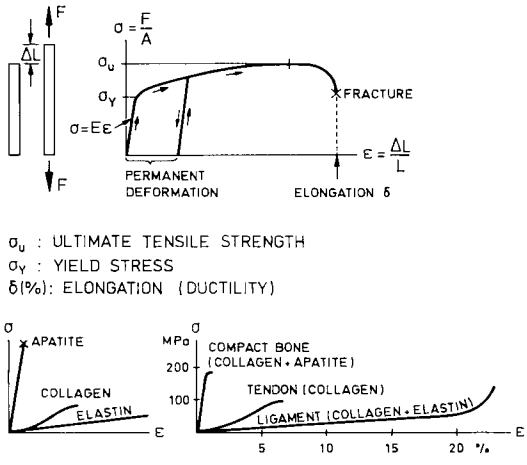

Figure 5. Stress-strain curves, showing constitutive relations for a time-independent material.

Hardness

There are several different measurements of hardness – Brinell, Rockwell, and Vickers – and these are based on records of indentations on material surfaces. Hardness is expressed as the ratio between the force exerted by the indentor and the corresponding area of the indentation. Difference among these measures of hardness are calculated on the basis of a) the shape of the indentor (sphere, pyramid, etc.), b) the associated area of the indentation, and c) the magnitude of the force used. A harder material can be used to make a scratch on a softer one.

Fracture toughness

Fracture toughness is a measure of a material's sensitivity to the presence of a crack. A more modern measure is the J-integral, which is essentially the square of the fracture toughness. Knowledge of the fracture toughness or the critical value of J for the material enables estimation of the largest crack that can be allowed in the structure. Very few structures are completely free from cracks.

Fatigue

At repeated loading fracture can occur at a low level of stress. This phenomenon is called *fatigue*. A microcrack is formed and advances gradually, one small step at each load application, until fracture occurs.

Materials

Three classes of solids are generally recognized: metals, ceramics, and polymers. The binding forces in metals and ceramics consist of attraction between electrical charges – negatively charged electrons and positively charged ions. The difference between metals and ceramics is that the binding electrons move freely around in a metal, acting as a glue and holding the ions together, whereas the binding electrons in a ceramic (glass, diamond, etc.) hold pairs of ions together, i.e., each binding electron is "ear marked" for the same two ions all the time. This difference implies that large deformations are possible before fracturing in a metal, but not in a ceramic. In a polymer the binding consists primarily in the entangling of long molecular chains.

These differences in material structure imply that some materials are brittle, e.g., ceramics; some are ductile, e.g., metals; and some are comparatively soft, e.g., polymers.

Microstructure of inorganic biomaterials

Jukka Lausmaa

Department of Physics, Chalmers University of Technology, S-412 96 Gothenburg, Sweden

The wide range of properties exhibited by different solid materials is due to differences on a microscopic (i.e., atomic) level of resolution. We will adopt here such a microscopic view to discuss the properties of inorganic solid materials (polymers are, however, not treated here). Because the mechanical behavior of different solids is treated elsewhere in this proceedings, my emphasis is on the chemical properties of solids and how they interact with the environment. Such a treatment will naturally focus on the surface properties since all direct chemical interactions between biomaterial and host tissue take place within a distance of about 1 nm from the outermost atomic layer of the surface. A more extensive treatment on the subject can be found in a recent review (Kasemo and Lausmaa 1986).

Microstructure and bonding in solids

The basic difference between solids, on the one hand, and liquids and gases on the other is that the atoms (or molecules) in a solid are bonded to one another and are essentially immobile, whereas those in a liquid or gas can move freely with respect to one another. The type and strength of *bonding* in a solid is determined by the atomic species present (i.e., the chemical composition) and will strongly influence the mechanical and chemical properties of the material. Materials with a given chemical composition will, however, also exhibit quite different properties because of differences in their *microstructure*, i.e., the way the atoms are arranged with respect to one another.

Most inorganic solids are *polycrystalline*, i.e., they are composed of a number of randomly oriented crystallites (so-called grains), where each grain is an ordered arrangement of atoms. The type of geometric arrangement within each grain (the crystalline structure or phase) and the size of the grains may vary for a given material and will strongly influence the properties of the material. Different types of crystal *defects* (vacancies, interstitials, impurity atoms, and dislocations) will also influence especially the mechanical behavior of a material.

Materials that are noncrystalline are called *amorphous* materials. In these materials the atoms are arranged in a less ordered way, almost as in a liquid, but with much less mobility. Glasses, for example, are amorphous materials.

The two main classes of inorganic solids are the *metals* and the *ceramics*. Most of the differences between these two classes of materials can be traced back to differences in bonding types. In metals the atoms are held together by so-called metallic bonding, which (in a very simplified picture) consists of the electrostatic attraction between positively charged metal ions periodically situated in a "sea" of freely moving electrons. The free electrons give rise to typical metallic properties, such as high thermal and electrical conductivity. Many metals also possess favorable mechanical properties, such as high strength, ductility, and machinability due to the nondirectional nature of the metallic bonds. One important property of metals is that they are chemically reactive. Exceptions to this are the noble metals (Au, Pt, Pd, etc.). One consequence of this reactivity is that most metals are covered with surface oxides (see next section).

Many nonmetallic materials, such as oxides, nitrides, and carbides, are formed as chemical compounds between metals and other elements. These are examples of ceramic materials, and they exhibit quite different properties than metals. The atoms in ceramics are held together by ionic or covalent bonds (often a mixture of both). These are strong bonds, and they have a high degree of directionality. As a consequence many ceramics are hard and wear resistant (but often also brittle). In contrast to metals, ceramics are chemically more stable materials, i.e., they do not readily react with the environment. Examples of ceramics are titanium oxide, nitride, and carbide (TiO_2, TiN, and TiC), alumina (Al_2O_3), and the calcium phosphates.

Surface properties and processes

Independently of which type of material is chosen as an implant material, it will be its surface that comes into contact with the host tissue. It is thus easy to realize that the surface properties of any biomaterial are of crucial importance because they will determine, for example, the biocompatiblity and the corrosion resistance of the material. In joint prostheses the tribologic requirements (low friction and high wear resistance) are also closely related to the surface properties of the implant material.

The basic concepts of microstructure and bonding discussed above also apply to surfaces. Usually, however, the surface of solids is very different from the corresponding bulk of the material. The most important differences are due to changes in the chemical composition of the surface. Such changes may occur without any interaction with the environment, by so-called segregation. Segregation is the process when a bulk impurity of low concentration diffuses out to the surface, resulting in a surface concentration that is considerably higher than that of the bulk. Especially alloys can have a dramatically different surface composition than the bulk, due to preferential accumulation of one alloy

constituent on the surface. One important example of this is stainless steel, which is corrosion resistant due to a thin, but highly stable, chromium oxide (Cr_2O_3) that forms on the surface as a result of preferential surface accumulation of Cr.

The major reason for change in the surface composition is, however, due to the fact that *all the surfaces interact with the environment* (usually a gas or a liquid). This interpretation leads to *adsorption* of molecules (or atoms) on the surface, i.e., molecules are bonded to the surface. Depending on the nature of the surface (its chemical composition and microstructure) and the type of molecule in question, the interaction will have different results. If the surface is reactive the adsorption may be accompanied by a chemical reaction between the adsorbed species and the surface atoms to form a new chemical compound on the surface. The oxidation of metals is one example of such surface chemical reactions. This oxidation occurs on most metals (except the noble metals) and results in a 1–5-nm-thick surface in air at room temperature. On many metals, such as, e.g., Ti, Zr, Ta, and Al, and in not too aggressive environments, this surface oxide is quite protective and prevents direct contact between the metal and the environment. Consequently, for these metals it is mainly the properties of their surface oxides that will determine how the material will interact with the host tissue when used as an implant. In this context, it is worth noting that the suface oxides on alloys are, in general, not identical to those of the corresponding pure metals. For example, the surface oxide of Ti6A14V alloy consists of TiO_2 and Al_2O_3, whereas that of pure Ti consists mainly of TiO_2.

Metals and ceramics are thus quite similar from a surface chemical point of view despite the fact that their bulk properties are very different. When used as implant materials, one can thus expect many metals to behave similarly in many respects to implants made from the corresponding bulk oxide ceramics. It is, however, important to realize that the surface chemical composition and microstructure of either type of material will strongly influence the chemical interactions that will take place at the biomaterial-biosystem interface. Therefore, in order to understand the different tissue responses to different biomaterials, it is necessary to characterize and study the properties of biomaterial surfaces on an atomic level of resolution.

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Metal corrosion in the tissue environment

Karl-Gustav Strid

Nobelpharma AB, P.O. Box 5190, S-402 26 Gothenburg, Sweden

Corrosion implies an interaction between a structural material and its environment that results in degradation of the material. Besides weakening of the structure, corrosion may entail release into the environment of unwanted, e.g., toxic substances.

Corrosion mechanisms

Corrosion of a metal involves an oxidation (anodic) process, i.e., the formation of metal ions associated with the release of electrons. For oxidation to proceed, electrons must be removed, either by electric conduction or by a simultaneous *reduction* (cathodic) process, e.g., the formation of water from oxygen. Chemical processes embracing the transfer of electrons are termed *redox* reactions.

However, corrosion forms an intricate pattern of interdependent redox, acid-bases, solubility, and complex-formation reactions. Thus, in an aqueous solution, acidity will influence the redox properties and displace the states of solubility and complex-formation equilibria.

If oxidation and reduction occur at the same location, rather uniform corrosion will result (general electrochemical corrosion). The process may go on until the metal is completely dissolved. Quite often, however, e.g., with surgical-grade alloys, the metallic surface will be covered by a protective layer of insoluble corrosion products, resulting in *passivation* of the surface.

If, on the other hand, oxidation and reduction take place at separate locations, connected through an electric conductor, the metal will be locally attacked at the oxidation site (local electrochemical corrosion). If such is the case, the corrosion products may not act to protect the surface. In a water droplet on a metallic surface in air, oxygen will be reduced at the contact metal-water-air. This will promote, paradoxically, dissolution of metal locally in the center of the droplet, where no oxidant is present.

Corrosibility regions. The corrosive properties of an aqueous medium are primarily determined by its redox potential and acidity, represented by pe and pH, respectively. In certain pe-pH regions, the surface will remain unattacked; *immunity* is then said to prevail. In other regions a protective layer of corrosion products will prevent further oxidation: *passivity* occurs. Again in other regions, the stable state comprises a metal ion in solution, implying the metal to be consumed indefinitely.

Manifestations of corrosion

Because corrosion ensues from deviations from chemical equilibrium, its various manifestations depend on the detailed nature of such deviations.

Galvanic corrosion. If two metals of different nobility are brought into contact in the presence of an electrolytic medium, the less noble one will undergo oxidation, and thus be corroded away.

Corrosion due to concentration elements. Chemical forces act so as to equalize any inhomogeneities in a reacting system. Thus, if the oxygen tension varies in a medium in contact with a metal, reactions will occur to consume oxygen in regions of high tension: an "aeration element" is formed causing electric current to flow, and metal will be dissolved in regions of low oxygen tension. Cavities in implants, e.g., crevices between fixing screws and osteosynthesis plates are regions where corrosion is likely to occur. Corrosion processes may cause the pH to drop considerably in crevices, so that, e.g., stainless steels may be attacked due to the acidity *(crevice corrosion)*.

Outside a metallic surface in a redox medium, metal ions will appear. If the ions are locally removed, e.g., due to flow in the medium, a concentration element results that acts to equalize the difference in ion concentration. Thus, metal will be consumed in the region of flow *(erosion corrosion)*.

Inhomogeneities in the metal composition will similarly give rise to electric currents, resulting in, e.g., *grain-boundary corrosion* of alloy surfaces or localized corrosion of amalgam tooth fillings.

Stress corrosion. In a mechanically stressed surface, microscopic cracks will act as origins of corrosion processes. Moreover, nonuniform stresses may cause variations in the chemical activity of surface atoms. The various factors will result in increased local corrosion of stretched surface regions, as compared with compressed ones.

Fretting corrosion. When a metallic part moves in contact with another component, the passivating layer is abraded, leaving the metal suface exposed to further oxidation. Even micromovements between implant components will result in enhanced corrosion.

The tissue environment

Blood and interstitial liquor are aqueous electrolytic media ("1 percent NaCl solution") at constant temperature (37° C), of about neutral or slightly acid reaction and a moderate redox character that varies with acidity and oxygen tension. Moreover, organic species present may act as strong complex-forming agents.

Implant materials

Candidates for implant materials are found among the transition metals. They fall into three categories:

(1) Noble metals (Rh, Pd, Ir, Pt, Au), which are immune to oxidation in the tissue environment.

(2) Metals of groups 4A and 5A of the periodic table (Ti, V, Zr, Nb, Ta), per se quite nonnoble, but readily forming impenetrable surface oxides that result in passivity. In the case of Ti in tissue, the oxide layer slowly grows with time, which may be of significance in regard to implant integration.

(3) Alloys of metals of groups 6A-8, which form passivating surface oxides. Iron- and cobalt-based surgical materials fall into this category. Transient corrosion will occur for a few days up to 1 month while oxide formation is taking place.

As to tissue reactions, metals of category (2) seem to be the most promising ones.

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Physical and mechanical properties of implant metals

Björn Albrektsson and Tomas Albrektsson

Orthopedic Clinic, Mölndal Central Hospital, and Department of Handicap Research, University of Gothenburg, Gothenburg, Sweden

The selection of biomaterials for orthopedic reconstruction procedures is based on knowledge about material properties of various solids optimized for implant use, and also on long time experience of their behavior as load-bearing structures in the body. Metals in the form of iron-, cobalt- and titanium-base alloys or in the form of commercially pure (c.p.) titanium are preferable to polymers and implant ceramics, mainly due to a combination of strength, elasticity, and ductility rendering a capacity to absorb high amounts of energy without mechanical failure. Nevertheless, material-related failures of metal implants have been reported. These have been traced back to mechanisms, such as wear, overload, fatigue, failure of bonding, and untoward tissue reactions. On the basis of increasing knowledge about the causes of material-related failure, improved techniques for alloying, manufacturing, and surface treatment of metal implants for orthopedic purposes have been developed.

Each of the aforementioned metals represents an attractive combination of properties with respect to the general requirements on orthopedic implants:

1. C.p. titanium because of its superior tissue tolerance and corrosion resistance, its low modulus of elasticity claimed to allow transfer of physiologic loading forces to bone, and its ductility, which facilitates forming and shaping procedures.
2. Stainless steel because of its good mechanical properties, its ease of machining, and low price.
3. Co-base alloys because of high strength, excellent wear characteristics, and good corrosion resistance.
4. Ti-base alloys because of the unique combination of high strength and low modulus of elasticity.

The most important mechanical criteria for the applicability of a surgical-grade alloy are the *deformation behavior* in terms of its elongation and elastic modulus, and the *strength behavior* in terms of its yield strength and ultimate tensile strength. The balance between strength and resistance against deformation determines the toughness, i.e., the amount of energy required to produce mechanical failure by fracture. Very strong and stiff materials, such as alumina ceramics, run the risk of brittle fracture, whereas weaker materials, such as polymers, may creep. The surgical grade alloys represent good compromises with maximum possible safety against overload failure (see Table 1).

Single heavy loads are, however, not the most obvious hazard for a metallic implant. Metals like other solids show a time-dependent failure behavior called fatigue, which implies a decreasing strength with time. The resistance against fatigue can be determined in dynamic rotating bending tests, and may be expressed as the endurance limit or as the fatigue ratio (fatigue strength – ultimate tensile strength). In graphic representations of fatigue (Wöhler diagrams), nominal stress values are plotted against load cycles, and the stress level below which the metal may undergo cyclic loading indefinitely is defined as the endurance limit. However, it is almost impossible to simulate the complicated loading and unloading conditions an implant component undergoes in vivo. Joint simulator studies and other simulated

Table 1. Mechanical properties of implants metals

Alloy	Condition	Yield strength MPa	Ult. tensile strength MPa	Elongation %	Fatigue strength MPa
FeCrNiMo	wrought				
	annealed	290–340	480–	40–	250–320
	cold-worked	–800	860–	12–	350–415
	Ortron (Charnley)	810	1150	15	
CoCrMo	cast (Protasul-2)	450–600	665–1000	8–25	190–400
	wrought	500–800	1000–1200	10–15	500–860
	annealed (Protasul 21)	500–800	1000–1200	10–15	500–860
	hot-forged (Vitallium)	860–930	1200–1280	15–	500–750
CoCrNiMo	wrought				
	Protasul 10 (Müller)	1000–1600	1200–1700	10–15	500–800
TiAlV	wrought				
	Protasul 64	900–1000	1050–1100	10–15	500–660
C.p. Ti	wrought				
	ASTM grade 1	170–200	240–280	35	200–240
	ASTM grade 4	460–490	–550	15	300–480

service tests aimed at the determination of security against failure or service life are therefore to be looked upon as merely screening tests. With this reservation in mind, values for fatigue strength of implant materials in the rotating bending test can be compared (see Table 1).

It should be emphasized that the fatigue resistance of an implant is determined not only by material properties and component designing, but also by processing methods including shaping and surface finish procedures. The complicated interrelationship between all these factors makes it impossible to calculate the fatigue resistance of a specific implant merely on the basis of known mechanical properties of the material. If, however, a well-known implant component with a typical and generally accepted design as that of the anchorage stem of a hip prosthesis is considered and if it is presumed that the manufacturing conditions are optimized, the following strength values can be looked upon as a guideline for clinical applicability, as summarized by Semlitsch (1984):

1. The yield strength should be at least 450 MPa to keep the risk of permanent deformation to a minimum.
2. The ultimate tensile strength should be at least 800 MPa to keep the risk of stem failure by overload fracture to a minimum.
3. Elongation as the measure of the capacity for deformation within both the elastic region and the plastic region should be at least 8 percent. Elastic deformation ensures transmission of physiologic stresses to bone, so that the risk of local osteoporosis due to stress shielding is reduced. In cases of very heavy nonphysiologic loading, a limited plastic deformation should be feasible as a safeguard against overload fracture.
4. The fatigue strength should be at least 400 MPa to keep the risk of fatigue failure to a minimum.

These threshold strength values are valid for the anchorage-stem application, which represents the most heavily loaded group of orthopedic implants. The minimum requirements on strength values are significantly lower when more compact-designed and less heavily loaded implants are considered.

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Biomechanical considerations on fracture stabilizing implants

J. Steen Jensen

Department of Orthopedics U, Rigshospitalet, University of Copenhagen, DK-2100 Copenhagen Ø, Denmark

As exemplification of the problems involved in the biomechanics of fracture stabilization, the hip fractures are used. Fracture instability is related to bone defects on the compression side of the fracture line. For trochanteric fracture, this means extruded fragments either medially at the lesser trochanter and calcar femorale or posterolaterally from the greater trochanter and posterior wall. For the femoral neck fractures, comminution is often encountered posteriorly leading to problems with exact reduction of the femoral head. In both cases the strong outwards rotators will bring the thigh into outwards rotation until contact is obtained between major fragments. Moreover, weight bearing and muscle pull will tend to bring unstable trochanteric fractures into a varus position.

Fracture fixation is a balance between the quality of reduction and the strength of the bone or the implant.

Biomechanical studies of devices for trochanteric fractures can be made as laboratory tests on the implants. McLaughlin and Jewett designs are proved to be insufficient because of failure in their designs. For femoral neck fractures a need for laboratory tests of the combination fractured bone/implant is apparent.

It is demonstrated that the laboratory set-up is of great importance for the results. A femoral shaft inclination is necessary to imitate nature, and the interpretation of the results depends on the position of the implants in relation to cortical bone, as well as the cross-sectional area of the beam created by the devices.

Furthermore, the effect of poor bone quality is demonstrated through pull-out tests with threaded devices.

Polymer orthopedic implant materials

Jan-Fredrik Jansson

The Royal Institute of Technology, Stockholm, Sweden

Polymers of different kinds have been used in medicine and health care as long as these materials have existed. The applications are rapidly expanding and the market is diversified; moreover, there is no indication that this trend of development will change. Polymers have been a necessary condition for modern medical technology.

The unique properties of the polymers present many advantages. Many applications would never have been developed if polymers had not been available. On the other hand, however, because polymers represent a relatively new class of materials, the knowledge about their behavior in biological environments is limited.

To resolve this dilemma, integral research and development programs on long-term properties, etc., have to be undertaken. Some of the basic questions to be answered are as follows:

1. What is the absolute toxicity of the different polymeric materials?
2. What is the long-term chemical, physical, and mechanical behavior of the various types and blends of polymers?
3. What differences exist between the various grades of the same polymer made by the same or different manufacturers?
4. How should one select a material for maximum safety?
5. What test procedures have to be used for screening prospective materials?

Advantages of using polymers in medicine

1. Possibility to modify the basic polymers a) by reinforcement: The strength and stiffness, creep behavior, impact resistance, etc., can be considerably enhanced – the thermal expansion, hardness, etc., changed by the addition of fibers, fillers, and the like; b) by plasticizing: the stiffness and elastic deformability can be changed dramatically by the addition of plasticizers; c) by surface modification: The surface of the polymer can be changed by radiation, grafting, etc., to produce hardness, chemical and biological activity, biocompatibility, etc.
2. Noncorrosive: Many polymers have excellent corrosion resistance in a biological environment, although their properties might be influenced in different ways.
3. Density close to material tissues
4. Single forming: Polymers can generally be amply formed also into varying complex structures
5. Usable as adhesives.

Disadvantages of using polymers in medicine

1. Low stiffness and strength compared with most metals, time-dependent mechanical properties: Although the properties can be enhanced considerably by fiber reinforcement, the strength and stiffness is generally low for the basic polymers.
2. Biodegradable: Many polymers are more or less attached in different ways by the environment.
3. Temperature dependence: For most polymers the mechanical and other properties are strongly reduced already at a moderately elevated temperature.

In vivo chemical stability of polymers

Stable	
Epoxy	EP
Polyester (Dacron etc.)	PET
Polyethylene, high density	PEHD
Polyether urethanes	
Polypropylene	PP
Polytetrafluorethylene (Teflon)	PTFE
Silicone rubber	SiR
Semistable	
Chlorosulfonated	PE
Epichlorohydrin	
Natural rubber	NR
Polyamide (Nylon)	PA
Polycarbonate	PC
Polymethylmethacrylate (acrylic)	PMMA
Polyethylene, medium density	PEMD
Unstable	
Acrylate rubber	
Polyester urethane	
Polyethylene, low density	PELD
Polyvinyl alcohol	PVOH
Polyvinyl chloride	PVC

Polymers for joint repair

The safety of joint replacements is limited by the risk of infections, loosening, fracture, wear, etc. The dominating problems of joint repair are 1) infection, wear, corrosion and their products, 2) mechanical instability (loosening and fracture), 3) complicated dynamic loads and moments, and 4) difficulty in replacing the joint a second time.

Figure 1 shows the relative probability for these types of failure mechanisms for conventional hip joints as given by Dumbleton 1977. The statistics point out that the accumulated probability for failure due to infection, loosening, and fracture is more than 75 percent within 15 years.

A large number of polymers have been used for different purposes in the replacement of joints.

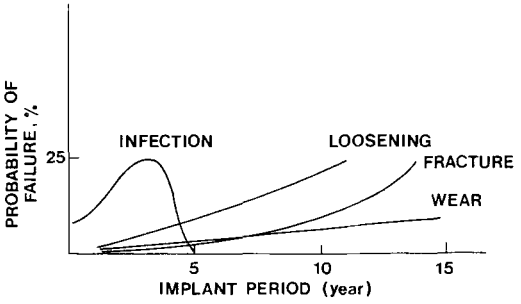

Figure 1. Failure of hip joint replacement (after Dumbleton, 1977)

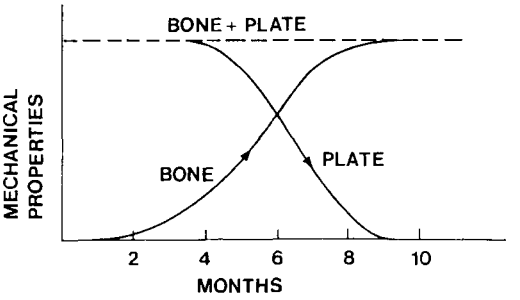

Figure 2. Resorbable bone-plate system

Polymer	Properties
PTFE (Polytetrafluorethylene)	+Corrosion resistance +Low friction −Bad wear resistance −Cold flow
ACRYLIC	+Acceptable stiffness and toughness −Deterioration in bioenvironment −Excessive wear
HDPE UHMW (High density polyethylene with ultra high molecular weight	+Low friction +Corrosion resistance +Low wear (wears out faster than metal) +Wear particles minimal tissue irritation
PYROLYTIC CARBON	+High stiffness +More durable than metal − HDPE UHMW joints −Brittle
POLYACETAL	−Excessive wear

The best friction and wear properties between ball and cup have been obtained by 1) Stainless steel/HDPE UHMW, 2) Cobolt-chromium alloy/HDPE UHMW, and 3) Pyrolytic carbon /HDPE UHMW.

The prosthesis is generally fixed by acrylic bone cement, which gives a number of disadvantages: 1) The monomers and accelerators are toxic. 2) The polymerization reaction is exothermic and causes temperatures of 60–65° C. 3) The bond is mechanically unstable.

A superior behavior is obtained by porous materials (pore size 200 μm or larger) that are infiltrated with osteoid tissue.

Controlled-surface active glasses, glass/ceramics and ceramics give direct chemical bonding.

Fixation devices

It is generally accepted that to hold the parts of a broken bone together during the healing period plates, screws, pins, nods, etc., should be used. However, metallic elements may cause inflammation and infection by their corrosion products or stress concentrations due to the large difference in stiffness (E_{bone} = 6–20 GPa, E_{metal} = 100–200 GPa) present the sound healing of the bone by stress protection of the bone, etc.

Reasonable materials are used today, the mechanical load carrying ability of which is reduced with time. The idea is demonstrated in Figure 2, which shows the diminishing stiffness of the plates adjusted to increasing strength of the bone.

Production technique for metal implants of stainless steel and cobolt alloys today and in the future

Kjell Gunnarsson, MITAB, Sjöbo, Sweden

Among the most usual metal materials in orthopedic surgery, stainless steel and cobolt-chromium alloys are the oldest and most often used today.

Specification and properties

Minimum demands for material properties are specified in a number of international norms (ISO) or national norms, such as ASTM, DIN, BS, and AFNOR. So far, there are still no Swedish or Scandinavian norms for metal implants.

Stainless steel occurs mostly as forging steel. The structure of steel 316 is austenitic; it is nonmagnetic; it becomes hard when cold-formed, with increase of yield point/tensile strength; and it cannot be tempered. Cobolt-chromium casting alloys are commercially called *vitallium*, *stellite*, etc., and can vary somewhat in composition. The castings are difficult to forge with acceptable results, and become hard and crack when cold-formed.

The mechanical properties of cobolt-chromium material are superior to stainless steel with respect to corrosion and fatigue. Different mechanical properties can be obtained by varying the content and manufacturing methods.

Production methods

Production of metal implants does not in principle differ from other industrial production. Today, the only casting method that is suitable for implants is the lost wax investment casting method. The structure of the crystals in the cast is always relatively coarse, i.e., the crystals are large. The size of the granules and their spread or growth are thoroughly checked by studying the temperature of the smelt and shell, as well as the hardening. Naturally, the quality of the alloying material will influence the end result. If there are several components in a casting – which is often the case – the final alloy may be nonhomogeneous.

Where the material is thicker, blisters and cavities may occur, which could impair the strength, in particular the impact value.

Coarse granules can be refined after treatment of the cast by heating. Unevenness in the composition can, to a certain extent, be smoothed out by solution heat treatment and subsequent quick cooling. Blisters/cavities can also be partly removed by HIP-ing (hot isostatic pressurization), which is generally used for compressing metal powder, but has also proved to be effective for casting. The implant is heated to about 1,200° C at 1,000 bars for a few hours in a protective gas (argon) and is then slowly cooled off.

By rolling or forging a material, the coarse casting structure is broken down into a finer structure, and blisters and cavities are welded together, which gives better mechanical properties.

Long/thin products often require strength characteristics that are difficult to achieve in a casting process. Forging or rolling is suitable in such cases. Semifinished goods of metal sheet, wire, or tubing are manufactured by rolling, drawing, or extrusion.

Drop forging, the most commonly used forging method, means that the piece is formed in a mold consisting of two or more parts in an excentric press.

When working with the implant, it could be hot in order to reduce the resistance to deformation, but it must not be so hot that intergranular melting occurs. Cold processing has some drawbacks, mainly because of a rapid increase in the yield points and breaking limits, as well as the increase in the hardness.

Drop forging gives a rapid and exact molding with good surface uniformity, which is better with a cold piece than with a warm one. Consideration must be taken to shrinking (0.5–1.5 percent). Good clearance in the direction of the hammer is necessary for the release of the piece, as well as for facilitating the floating of the material.

Both the stainless steel and cobolt-chromium alloys are usually relatively difficult to process by cutting as the hardness increases with the deformation. The cutting tool gets damaged by heat, i.e., more than 500–600° C at the tip. Effective cooling/lubrication is thus required.

The grinding and polishing methods do not differ from other materials. The joint surface-contact areas must have an extreme surface finish. Electromechanical polishing is often used on implants with shiny surfaces. Full surfaces are achieved by blasting with sand or small glass balls.

The products are optically controlled continuously during the manufacturing process, and are also given a final check when finished. Measurements of size and roundness are carried out. The method of further control is chosen according to whether one wants to examine superficial or deep-lying defects. On implants with high demands on strength, such as joint prostheses, radiography and penetration tests are generally used. Apart from blisters and crevices, radiography can reveal abnormal concentrations of granules in the casting.

Penetration tests mean that the details are sprayed with a colored fluid with a low surface tension. The fluid seeps into all the cracks and pores, is rinsed off, and then is dried with powder (developer), which sucks out the remaining fluid. The size of the defect can be determined by looking at the size of the colored area.

When casting, a test rod can be made at the same time or taken directly from the product. This is tested for tensile and breaking limits, extension, and fatigue.

Documentation and marking of the finished product has to be carried out and kept in such a way that the "charge" and the different operations on the product can be traced.

Future developments

Further automation and use of robots in the casting, as well as in cutting processes, will permit a more economical and standardized production.

CAD/CAM, i.e., computerized construction and production, particularly of special implants, is now being rapidly introduced worldwide.

Implants made of molded metal powder are being developed, and will probably be less expensive than cast products, and will have better mechanical properties. Welding and joining of material with different characteristics are already in production, but will be improved further.

Production techniques for metallic implants Titanium and titanium alloys

Karl-Gustav Strid

Nobelpharma AB, P.O. Box 5190, S-402 26, Gothenburg, Sweden

Titanium (Ti) is the ninth most common element in the Earth's crust, where it forms oxidic minerals (rutile, ilmenite, sphene). The pure element is a lustrous white metal with a density of 4,500 kg m−3., and is malleable when not contaminated by oxygen. It is very reactive; indeed, it is the only element that burns in nitrogen. However, the metal rapidly becomes coated with an oxide layer, making it resistant to most chemicals, and it is considered physiologically inert.

At room temperature, Ti metal forms a hexagonal close-packed structure (α-Ti), which at 882° C is transformed into a body-centered cubic structure (ß-Ti), which in turn melts at 1,678° C.

Metallurgy of titanium alloys

Being a transition metal, Ti forms solid solutions with most elements up to ± 20 percent difference in atomic size. The addition of alloying elements either stabilizes the hexagonal α-Ti structure or promotes the existence of the cubic ß-Ti structure at room temperature. The phase diagrams are generally complex.

Alpha alloys. Alloying Ti with, e.g., oxygen or aluminium results in a material of ß-Ti structure with improved mechanical properties, its tensile strength increasing by 35–70 percent for an additional 1 percent of alloying element. The material is strengthened by solution hardening. However, for an aluminium content in excess of 9 percent by weight, the alloy is embrittled due to the precipitation of Ti_3Al. Also, brittle fracture may ensue from the formation of TiH_2, especially in mechanically stressed regions.

Commercially pure (c.p.) Ti is, indeed, a range of Ti-oxygen alloys, characterized by relatively low tensile strength. Any hot processing must take place below 882° C, as stress hardening will otherwise result. The strength of the alloys depends on the grain size, increasing with reduced grain diameter.

Near-alpha alloys containing small amounts of ß-Ti stabilizers present improved forgibility.

Alpha-beta alloys. The problem of Ti_3Al formation can be circumvented by adding ß-phase stabilizers, so as to obtain, after final heat treatment, a composite of α-Ti and ß-Ti. Thus, Ti-6Al-4V, making over 50 percent of the world Ti production, presents high-tensile strength in conjunction with improved formability. On the other hand, resistance to creep above 400° C and weldability are impaired. Hardening may be carried out by water quenching, especially with alloys rich in ß stabilizers.

Beta alloys. Materials richer in ß stabilizers can be cold-forged more readily than alpha-beta alloys and subsequently heat treated to produce solution and age hardening. Thus, Ti-13V-11Cr-3Al is hardened at 480° C to yield 1,300 MPa tensile strength. However, the weldability of beta alloys is poor due to the precipitation of not fully elucidated phases, which cause severe brittleness.

Table 1 gives examples of titanium alloys of the different categories.

Table 1. Typical mechanical properties of titanium based materials. Alloys are designated by contents of principal alloying elements *in %*; ELI = *extra low interstitial content*

Material	Maximum content: Oxygen (%)	Maximum content: Iron (%)	Yield strength (MPa)	Ultimate tensile strength (MPa)	Elongation (%)
Alpha alloys					
Commercially pure titanium:					
grade 1	0.18	0.20	170	240	24
grade 2	0.25	0.30	275	345	20
grade 3	0.35	0.30	380	450	18
grade 4	0.40	0.50	480	550	15
Ti-5Al-2.5Sn	0.20	0.50	800	870	16
Ti-5Al-2.5Sn ELI	0.12	0.25	750	820	18
Alpha-beta alloys					
Ti-5Al-2.5Fe			850	950	15
Ti-6Al-4V	0.20	0.30	920	1000	13
Ti-6Al-4V ELI	0.13	0.25	840	920	15
Ti-6Al-7Nb	0.20	0.25	950	1050	13
Beta alloys					
Ti-11.5Mo-6Zr-4.5Sn			1250	1350	10

Fabrication

Ti is used in engineering as wrought (99 percent of production) or cast alloys. The ingots obtained from metallurgy are sensitive to cracking and are therefore usually hot-press forged prior to further processing. Above 550° C, Ti readily absorbs oxygen, hydrogen, etc., and thus has to be processed under a protective atmosphere (argon).

Primary shaping

Casting. Due to the high affinity of molten Ti for oxygen, nitrogen, and hydrogen, and its reactivity to most oxidic and carbidic refractories used as molding materials, casting is expensive and finds rather limited application, mainly in the production of heavy pieces.

Powder metallurgy. By production from powders, parts may be manufactured close to their final size, thus reducing machining costs. The two common methods are hot pressing followed by sintering and hot isostatic pressing. Powder-produced goods are chemically homogeneous and show no crystallographic texture, which implies quite uniform mechanical properties throughout. Proof stress and tensile strength may be improved in comparison with wrought alloys, albeit at the price of reduced ductility and toughness.

Plastic shaping

Cold forging. Cold working is possible only to a limited extent, since the material becomes hard and has to be followed by stress-relieving annealing at 650–700 °C. Due to the anisotrpy of the hexagonal α phase, textural effects may be pronounced for α-rich alloys, resulting in directional variations in strength parameters.

Creep forming. Slow isothermal forming (creep forming) is carried out at a moderate pressure, 0.1–1 MPa, applied during 0.25–4 hours at 900–950° C.

Joining

Welding. Alpha alloys and alpha-beta alloys containing less than 20 percent of ß-Ti may be welded in protective atmosphere by arc methods using consumable (MIG) or nonconsumable (TIG) electrodes or by electron-beam, plasma-arc, or laser processes.

Due to the formation of brittle intermetallic compounds, Ti materials cannot be welded to conventional structural metals (e.g., steel) spontaneous cracking being almost inevitable.

Diffusion bonding. Because surface oxides are readily dissolved in the bulk material, Ti alloys may be diffusion-bonded at 850–950° C. Bringing the pieces to be joined into contact at 1 MPa pressure for 0.5–1 hour will usually result in a joint strength exceeding 90 percent of the bulk strength.

Brazing. Ti-based materials can be brazed at 1,000° C in a protective atmosphere using silver, copper, or Ti-15Cu-15Ni as the filling material.

Machining

Most standard procedures for machining engineering materials may be applied to Ti and its alloys. Of special interest is the possibility of using computer-controlled tooling machines to shape the often complicated surfaces of prosthetic implants.

Cutting. Milling or turning Ti-based materials presents specific problems similar to those of machining austenitic stainless steels. The low thermal conductivity of Ti implies high cutting temperature, causing tool life to be drastically reduced. Moreover, the chips tend to stick to the cutting edge or the work piece. The machining time for Ti-based materials may amount to 10 times that for steels, entailing increased cutting cost. Thus, the machining parameters require careful optimization.

Electro-discharge machining. Irregular shapes may be conveniently produced by electric-spark cutting, preferably in a paraffin bath. Due to the evolution of heat, the spark-cut surface will present a recast layer covering a thermally modified zone. In most cases the surface properties will not be changed unfavorably.

Laser milling. In very thin pieces, slots or grooves may be produced by laser methods. However, laser-cut edges may be very coarse, which necessitates deburring.

Production and sterilization methods for polymer implants

Ernst Johnsson

MITAB, Sjöbo, Sweden

In the orthopedic field, numerous materials made of polymers have been tested and used for the last 50 years. The most successful polymers in use today are the groups made up from polymethylmethacrylates, polyethylenes with ultrahigh molecular weight (UHMWPE), and silicone elastomers.

Materials to be used in weight-bearing articulating surfaces have to be resistant to wear. UHMWPE has very good wear characteristics and is the dominating material in all types of implants with a weight-bearing surface.

The molecular weight of UHMWPE is about 1 million, and in the solid state it is a tough material with a very high impact, high tensile, and flexural strength, good wear resistance, and a low friction when in contact with other materials.

The wear rate in clinical use for an acetabular cup is estimated to be around 0.1 mm/year. Fractures of the UHMWPE cup have only been reported in a few cases, mainly due to cold creep (Moreland and Jinnah 1986). Rose et al. (1980) have investigated the wear rate of acetabular cups and found a correlation between the molecular weight of UHMWPE and the wear rate. Low molecular weight polyethylene gave a higher wear rate.

Because UHMWPE has a very high melt viscosity, the raw material present in the powder form is plastified mainly in presses that may be heated and cooled. This process requires the use of a tool that is constructed as a mold consisting of a female and a male half, and which is of the required height. For the preparation of faultless slabs, it is expedient to additionally heat and cool the frame of the tool. The powder is filled into the pressing tool, the cone of bulk material is spread by means of a doctor blade and is compressed in the cold state for 5 to 10 minutes under a pressure of approximately 1,400 psi. The air enclosed in the powder is expelled. To bring about fusion, the press must be heated to 400–425° F. This temperature should be maintained until the powder is completely plastified throughout the entire cross section. During this process the pressure need not be higher than 300–700 psi. For an approximately 1-inch-thick slab, a faultless melting requires a heating period of about 3 hours. For the preparation of finished articles from UHMWPE, predominantly machining processes are used. It may be sawed, turned, planed, milled, drilled, pierced, and stamped without any difficulty using machines that are commonly used for machining metals or wood.

For sterilization of polymeric materials, such as UHMWPE, the preferred method is gas sterilization with ethylene oxide at temperatures of 30–50° C. Sufficient aeration time to reduce the residual toxic gas in the material is necessary.

Sterilization with ionizing radiation is also a low temperature method that is suitable for many polymeric materials that do not degrade by radiation. UHMWPE has, however, been reported to degrade at higher dosages (Rose et al. 1984).

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Modification of the surface of metal implants, particularly with respect to stainless steel and cobolt alloys

Kjell Gunnarsson

MITAB, Sjöbo, Sweden

There are a number of factors that place demand on the surface of an implant. All implants must be trimmed, degreased, and cleaned after processing.

When motion occurs in joint prostheses, a high demand is placed on the surface finish to minimize friction and wear. Grinding and polishing with diamond paste of the weight-bearing surface has to be carried out.

In order to improve the anchorage of noncemented prostheses, the surface could be given an irregular structure, either directly on the metal of the detail, by adding a structured coating with heat sintering or by plasma coating. The added surface can either be in the form of small beads of 50–500 μ or 1–2 mm short-cut threads in an irregular pattern – a so-called wire mesh.

A problem that can arise with the adding of an irregular surface is that there may be an unfavorable effect on the fatigue strength due to local stress concentration, as well as to changes of the microstructure caused by the thermal processing.

Moreover, there will be an up to 10-fold enlargement of the surface area with possible metal leakage, especially if the passivated surface is repeatedly damaged by micromotion.

A highly polished surface free from sharp edges, transitions, pores, cracks, and scratches improves the durability of the implant with respect to fatigue fracture and will give less corrosion.

Fewer corrosion products

Metal alloys in the body are broken down by an electrochemical reaction. The rate of corrosion increases when there is simultaneous mechanical loading, so-called stress corrosion. With respect to both strength and corrosion, concentration of stress should be avoided when designing an implant.

The surface layer of stainless steel or chromium-cobolt is improved in the body during the formation of a resistant chromium-oxide layer, so-called self-passivation. This layer can become damaged/scratched, but it gradually repairs itself.

By pretreating an implant by passivation, the excretion of corrosion products from the surface could be, to a large degree, reduced during the initial postoperative period. This means treatment in an oxidating solution for about 30 minutes.

Surface coating and modification of metallic implants

Jukka Lausmaa

Department of Physics, Chalmers University of Technology, S-412 96 Gothenburg, Sweden

There are a number of different methods available today that offer a possibility to improve certain properties, such as wear or corrosion resistance of metal surfaces. In this article the principle of some of these techniques is briefly described, and an attempt is made to bring up the advantages and drawbacks of each technique. Some of these methods can be regarded as *surface coating techniques*. The two most well-established surface coating techniques, physical vapor deposition (PVD) and chemical vapor deposition (CVD), are presented here. Considerable improvements in surface properties may also be obtained by modifying (chemically and/or microstructurally) the original surface. Three examples of such *surface modification techniques,* ion implantation, anodic oxidation, and plasma oxidation, are treated here. For a more thorough treatment of these and other methods of surface preparation, the reader is referred to a recent review on the subject (Dumbleton and Higham 1984) and the references given in the text. The subject of surface preparation and characterization has also been discussed in a wider perspective by Kasemo and Lausmaa (1986).

Surface coating techniques

Physical vapor deposition (PVD) is an acronym used for several different techniques (Bunshah 1982, Vossen and Kern 1978). All of these methods are based on the principle that the coating material is vaporized and subsequently allowed to condense onto the substrate surface. The coating material is either heated in a vacuum (resistively or by electron beams) until it reaches a certain vapor pressure, or alternatively energetic ions are used for vaporizing the material (so-called sputtering). Because the condensation occurs atom by atom, a dense coating is formed that is intimately integrated with the surface. PVD processes require vacuum conditions (10^{-6} to 10^{-7} tor) in order to ensure that the evaporated atoms (or molecules) reach the substrate without suffering gas-phase collisions, which can cause reactions with the environment. There are, however, PVD processes in which the vapor is allowed to react with a well-controlled ambient (gas or plasma) to form a new compound that then condenses on to the surface. One example is the deposition of titanium nitride (TiN), which is performed by sputtering titanium in a nitrogen plasma discharge.

Because PVD is a line-of-sight process, certain geometries cannot be uniformly coated. In principle, any coating substrate combination is accessible, but the adhesion strength can vary considerably for different coating/substrate combinations and also depending on substrate pretreatment. The deposition rates may vary in the range 0.1–10^4 nm/min, depending on the material and type of evaporation source used. Coatings of a few micrometers are usually the practical upper thickness limit.

Chemical vapor deposition (CVD) techniques are based on chemical reaction between two gaseous compounds on a heated substrate surface (Vossen and Kern 1978). By choosing suitable gases, the chemical reaction will have the result that the desired coating is formed at the surface and remains there, whereas the other reaction product is a volatile or gaseous compound that can be pumped away. One well-known example of a CVD process is the formation of titanium carbide (TiC) through the reaction:

$$TiCl_4\ (g) + CH_4\ (g) \rightarrow TiC\ (s) + 4\ HCl\ (g)$$

Because this is an endothermal reaction, it requires that a certain amount of energy (i.e., heat) is supplied. The required amount of energy is lower at the surface than in the gas phase and therefore the reaction can be restricted to the surface. This process is performed at pressures in the millitorr range and at temperatures around 1,000° C.

CVD has the advantage that it is not a line-of-sight process and therefore not prone to shadow effects. However, CVD is not as versatile as PVD, since the type of coatings that can be produced are limited by thermodynamic constraints, and since the range of substrates is restricted to materials that can stand the high temperatures required. Despite this, CVD is the most widely used method for producing very hard and very wear-resistant coatings, such as Al_2O_3, TiC, and SiC.

Pyrolytic deposition is a method that is closely related to CVD. With this method the coating is formed by thermal decomposition of a suitable gaseous compound at the substrate surface. Examples of pyrolytic processes are the production of different amorphous carbons, which exhibit a high degree of chemical inertness and wear resistance.

Surface modification techniques

Surface modification techniques have the attractive feature that the desired surface layer is formed more or less within the substrate, thus eliminating the problem of poor adhesion, which may occur for some coating/substrate combinations. *Ion implantation* is possibly the most promising tool for sophisticated surface modification available today. The principle of this method can briefly be described as follows. The ions to be implanted (which in principle can be of any element in the periodic

table) are accelerated to high energies and directed towards the sample. When they hit the sample, the ions penetrate into the material, lose their energy in a number of collisions with the sample atoms and finally come to rest at a certain depth. The implantation depth depends on the ionic species used and their energy, as well as on the sample material. The implantation can thus be controlled by controlling the energy of the ions. The concentration of implanted ions is controlled by counting the charge introduced into the sample. The maximum implantation depth is restricted to a few tenths of a micron, and the maximum concentration that can be implanted is 20–50 atomic percent.

Ion implantation has proved to be especially useful for improving the wear and corrosion resistance of metals. The improvements in surface properties are due to the combination of two different effects. One effect is the change in chemical composition in the implanted layer, which if suitable ions are used can result in a compound that is hard and/or chemically inert (such as, e.g., TiN or TiC). The other effect is associated with the damage induced by the ion radiation, which gives an amorphous surface microstructure. One recent example shows that N-implantation is a very promising tool for improving the wear resistance of Ti6Al4V alloy in joint prostheses (Williams and Buchanan 1985).

The properties of metal surfaces can also be modified to some extent by changing the properties of their surface oxides. *Anodic oxidation and plasma oxidation* are two methods that offer such possibilities to control the chemical composition and microstructure of the surface oxide.

Anodic oxidation is an electrochemical method. The sample to be treated is made an anode in an electrolytic cell and when a potential is applied on the sample a current will flow through the electrolyte (due to ion transport). The transport of oxygen-containing ions through the electrolyte leads to the formation of an oxide layer on the sample surface. Because the oxide grows by oxygen ion diffusion to the oxide-metal interface and by metal ion diffusion to the electrolyte oxide interface, it will become a continuous part of the substrate material. If the oxide layer is passivating, the current will eventually decay at a certain oxide thickness determined by the anodic potential. Anodic oxidation thus offers the possibility to control the thickness of the oxide. By a proper choice of electrolytes, the chemical composition can to some extent be controlled, for example, by incorporation of anions. The crystallinity and morphology of the oxide can also be varied by using electrolyte, potential, and temperature as parameters.

Plasma oxidation is closely related to anodic oxidation, but instead of a liquid electrolyte an oxygen plasma (i.e., ionized oxygen gas is used. This method offers essentially the same possibilities to control the properties of the oxide, but has certain advantages to anodic oxidation. Because plasma oxidation is performed in a controlled and confined environment (i.e., a vacuum chamber), it can be used to prepare extremely clean metal oxide surfaces.

This article has only dealt with a few of the different surface coating and modification techniques that are available today. Most of these can readily be applied to those metals that are presently used as implant materials. Because the surface properties of any biomaterial are of crucial importance in most implant applications, one can expect that surface coating and modification techniques will play an important role in the future development of biomaterials. It should be realized, however, that in order to use these methods to their full potential, they should be combined with methods that allow a careful characterization of the prepared surfaces.

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Anchoring of metal implants with various surface structures

Helge Rønningen, Ludvig Fjeld Solheim and Elin Barth

N-2044 Frogner, Norway

Weight-bearing skeletal implants are anchored to the hosting bone by means of various principles of mechanical interlock. A strong biocompatible material interlocked in bone with an intimate contact at the bone-implant interface has proved to be able to fix implants to serve various mechanical functions for many years. Any irregularities on the surface of the implant – screws, nails, wire, methacrylate cements, fenestrations, and microscopically sized pores – make interlock fixation feasible. In this respect, fixation of artificial joints in clinical orthopedics has been a great success, with hundreds of thousands of treated patients. But within this success, certain problems have been recognized that

have been identified to be cement-related, and which have propelled research into fixation systems where cement problems can be circumvented. The principles of these systems are interlock by means of inert implants, fitting exactly into a prepared site or interlock created by the hosting organism by means of bone ingrowth into surface irregularities of the implants.

Interlock at the macroscopic level, such as screws, wire, etc., serve very well for temporary implants like those applied in fracture immobilization. However, it has not been that successful for permanent implants in orthopedic surgery (e.g., fenestrated femoral stems). The Brånemark group has been very successful with interlock at an intermediate level using threaded dental impants. By means of an extremely exacting and atraumatic technique for implant-site preparation, they have been able to implant a vast number of dental implants that have been in service for more than 15 years with a low failure rate. Their system has set the international standards for fixation of dental implants. Permanent implants in orthopedic surgery apparently need interlock at the microscopic level to be securely fixed. This has been accomplished by using implants with pores sizes in the 100–400 μm range on the surface of the implants. The large surface exposed to tissues by these structures require that only the biocompatible metals from the Co-Cr-Mo and titanium groups can be used. Fixation and integration beyond physical interlock by means of chemical bonding has its advocates, but is still at a very experimental stage, and has been so for a long time.

Porous ingrowth systems have been promising in many experiments and clinical trails. Research is expected to provide information that will be decisive as to what extent ingrowth systems will survive in the future.

Pores are usually being applied by two different methods: sintered microspheres or powders and kinked, compacted, and sintered wires. The standards for the ideal porous coating have not yet been set. The kinked wire system has a definite advantage in mechanical strength because it will not fail completely by cracks as a porous microsphere system will do. Instead, it will fail by tearing of individual wires and bonds. A metal-tovoid space ratio of 1:1 has been found to allow ingrowh of viable bone and yet provide sufficient strength. It has been found that interconnected pores in the 100–400 μm range will allow remodeling to haversian systems in the ingrown bone.

Galante and Rostoker (1973) pioneered the application of porous fiber metal implants. Ingrowth of immature bone will occur within 3 weeks after implantation. The bone will eventually occupy the entire void space of the meshwork and appears to stay completely vital for an indefinite time. Clinical experience is so far limited, but Kuo et al. (1983) reported positive experiences from a clinical trial of ingrowth-fixed prostheses in patients with bone tumors. Gustilo and Kyle (1984) reported encouraging results 12–36 months after revision arthroplasty in 12 patients who had received custom-made prostheses with inlays of porous fiber titanium.

The porous ingrowth systems require that the implantation sites are prepared using very exacting techniques that allow primary fixation by press fit. In addition, the technique must be atraumatic to secure the viability of the tissue adjacent to the implant that is to produce the new tissue that can invade the pores. Ducheyne et al. (1984) experimented on the primary press-fit fixation of tibial components furnished with porous mesh-coated prongs. They found that loads similar to those encountered in daily activities caused translocations of the prosthesis smaller than half the diameter of a pore. They conclude that the primary fixation is sufficient until bone ingrowth secures permanent fixation. Mechanical tests have demonstrated that more than one layer of porous material will improve the strength of the fixation. Thus, it has been found that the ultimate shearing stress for 50 percent void space implants will be in the range of 50 percent of that of the hosting bone site, as might have been expected theoretically (Clemow et al. 1981). During ingrowth the mechanical strength increases exponentially with increasing mineralization of, and linearly with the amounts, of the ingrown bone (Barth et al. 1985).

Eventually, the invading bone has a normal mineralization and a high blood flow. Metabolically, chronologically, and morphologically the events in ingrowth follow the same pattern as a normal fracture healing (Rønningen et al. 1984). Hence, factors such as the health condition of the host and bone-graft procedures known to interfere with fracture healing supposedly determine bone ingrowth identically.

An implant usually has deformation characteristics that differ at least one order of magnitude from those of the hosting bone. Load transmission by a composite structure implies that the stress is mainly carried by the stiffer of the components, whereas the flexible one is subjected to stress shielding. Stress shielding of bone may have severe long-term consequences for the bone. It is not yet known if the porous ingrowth systems will increase this problem by providing a level of fixation not seen before for the cement systems. Thus, Galante (1983) recommended that the femoral components of hip prostheses designed for ingrowth fixation should have only porous inlays proximally. This will subject the proximal part of the bone to stress during loading. Also, removal of the prosthesis, which is an essential requirement, become feasible.

A workshop on the bone-implant interface agreed that reliable fixation of implants can be achieved by bone ingrowth instead of cement fixation (Lewis and Galante 1985). However, the quality and extent of

ingrowth is difficult to control. It has yet to be shown that the ingrowth interface is superior to the cemented one.

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Cells, vascularization and structure of bone with an implant

Aspects of bone dynamics and bone circulation

Cody Bünger

Institute of Experimental Clinical Research, University of Aarhus, Aarhus, Denmark

Bone cells

The cells mainly responsible for *bone resorption* are the osteoclasts, which are large multinucleated cells found within the Howship's lacunae. At ultrastructural level the osteoclasts have a central ruffled border, with many cytoplasmic extensions, which appear to infiltrate the disintegrating bone. During bone resorption the solid mineral is made soluble, the glycosaminoglycans of the ground substance are depolymerized, and the collagen fibers are broken down into small peptides. The latter process is probably undertaken by mononuclear cells, which secrete collagenase. During pathologic bone resorption adjacent to rheumatoid pannus, enhanced osteocytic demineralization may take place and facilitate bone absorption by the collagenase secreting mononuclear cells.

Bone formation occurs in two stages – bone matrix formation and mineralization. The cells responsible for bone formation are the osteoblasts, which are columnar or cuboidal cells with basophilic cytoplasm arranged in a continuous epithelial-like fashion. They lie immediately adjacent to a 8–10 μm seam of osteoid. Matrix formation takes place at the interface between osteoblasts and osteoid, whereas mineralization occurs between mineralized bone and osteoid. The time lag from osteoid deposition to its mineralization is 10–20 days during which the matrix undergoes maturation. Gradually the osteocytes become embedded in bone. Cytoplasmic processes extend through canaliculi in bone to join adjacent osteocytes. Thus, an internal transport system for the bone homeostasis is provided.

The BMU theory

The biomechanical competence of bones is maintained by a continuous replacement or turnover of whole volumes of bone tissue (Parfitt 1983). Together with their precursor cells, the osteocytes and osteoclasts make up the so-called bone remodeling system, which involves both cortical and cancellous bone. The organization of these cells into special functional units was designated the basic multicellular unit (BMU) by Frost (1973).

The bone remodeling occurs in "packets" and in a linked sequence. After a competent local stimulus, the BMUs are activated by proliferation of both local and blood-borne precursor cells into a group of osteoclasts, which work together in the unit. They excavate the bone to a certain depth and disappear. After a quiescent interval of variable duration, a coordinate unit of osteoblasts lays down osteoid, which is subsequently mineralized. There are some quantitative and qualitative differences between BMU in cortical and cancellous bone. In cortical bone the osteoclast unit arises within the haversian or Volkmann's channels and extends in mainly a longitudinal direction. Behind the advancing resorption, a peripheral osteoblastic apposition of new bone takes place until a new secondary osteon has been formed and a normal haversian canal diameter is reached. In cortical bone the number of BMU/mm^2 is 0.08 compared with 0.2 in trabecular bone (Parfitt 1983).

In trabecular bone the relationship between osteoclast domain, quiescent resorption, and arrested resorption is not so well defined as in cortical bone. Likewise, the spatial outline of the BMU is less well defined in trabecular bone.

Remodeling appears at appreciable levels of activity primarily in large and long-lived vertebrates that display skeletal maturation. Mice, rats, hamsters, and, to some extent, rabbits lack appreciable remodeling and are considered invalid models for the study of bone remodeling.

In growing bone fundamentally different dynamic relationships exists; there is a net gain in bone mass and a continuous sculpturing process, e.g., bone modeling.

In bone repair secondary to gross physical injury, activation of BMU can be expected in adjacent bone resulting in approximately 10 percent and 20 percent loss of cortical and cancellous bone, respectively (Nilsson and Obrant 1983). At the site of injury, another series of events is initiated starting with granulation tissue invasion and osteoblast formation and ending in humans after 2 to 4 years with replacement of calcified bone matrix by a haversian type remodeling lamellar bone. In certain types of bone healing when the fracture gap is very small and stability is provided, a direct invasion of the fracture area by cutter heads of BMU may take place, e.g., primary bone healing or healing by creeping substitution.

Bone circulation

The vascular supply of bone has traditionally been divided into periosteal, medullary via the nutrient artery, metaphyseal, and epiphyseal. Their relative importance was recently reviewed by Albrektsson (1985). The primary function of bone vasculature is to serve as a transport route for nutritional, metabolic, and hormonal compounds necessary for bone growth, hematopoiesis, and body homeostasis. The blood supply of long bones show high regional variation and probably parallels the metabolic needs within the different regions. Accordingly, a significant change in regional blood flow patterns takes place from childhood to adultness. Regional blood flow (RBF) measurements with tracer microsphere technique in immature dogs have demonstrated RBF rates as high as 100 $ml \times 100g^{-1} \times min^{-1}$ in the calcification zone of the growth plates, whereas RBF rapidly declines to 10–20 $ml \times 100g^{-1} \times min^{-1}$ on both sides of the growth plate. Estimation of microvascular volumes by ^{51}Cr-tagged red cells and I^{125}-fibrinogen showed the largest volumes in the metaphyseal compartments, and also the most prolonged transit of blood components reflecting the highest capillary density (Bünger et al. 1986). In adult bone the highest flow values are found in metaphyseal bone particularly in the femoral neck region (35 $ml \times 100^{-1} \times min^{-1}$) in contrast to RBF rates of 1–2 $ml \times 100g^{-1} \times min^{-1}$ in adult cortical bone (Tøndevold 1983).

Bone blood flow control

The main control mechanisms are of neural, humeral, and metabolic origin. Bone blood vessels are richly supplied with both myelinated and nonmyelinated nerve fibers. There is a central resting sympathetic tone in bone blood vessels that can be modified during pathophysiologic conditions, such as hypotension and hypoxemia. Lumbar sympathectomy causes a 25 to 60 percent increase of RBF of 2 to 3 weeks' duration.

The humoral control of bone blood flow has not yet been firmly established, but hormones like calcitonin exert a direct effect on vascular smooth muscle in bone and causes vasoconstriction. There is a local predominantly metabolic control of both cortical and cancellous bone. Postexercise tardive hyperemia in cortical bone has been measured in both immature and mature dogs. This might reflect a change in bone metabolism. Likewise, an increase in venous outlet resistance is accompanied by a tardive arterial vasodilation. The nature of the local mediators of vasodilation in bone apart from carbon dioxide and H^+ has not yet been established. We found no major change in subchondral bone blood flow regulation following prostaglandin synthetase inhibition; however, this does not preclude an important effect on vascular permeability in bone as suggested by Nannmark et al. (1984).

Bone blood flow in repair

Also in bone repair, RBF appears to be closely related to the metabolic activity. In experimental tibial fractures, RBF could be related to the mechanical stability in stable and less stable osteosyntheses as an indication of prolonged increased bone metabolism in the less stable fractures. In both groups, there was a peak in RBF approximately 20 days following fracture (Kelly 1984). In cancellous bone autotransplants in dogs vascular ingrowth was present after 1 week. RBF rates closely paralleled the new bone formation and peaked after 3 weeks (Lucht et al. 1986). Manipulation of bone metabolism by indomethacin treatment during fracture healing in rabbits showed poor healing and prolonged elevation of RBF at the fracture site following indomethacin in contrast to a decreased early RBF response (Keller et al. 1986). This signifies the role of prostaglandins in the early inflammatory response and endothelial proliferation in bone repair.

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Mechanical properties of cortical and cancellous bone

Paul Lereim

Sophies Minde Orthopedic Hospital, University of Oslo, Oslo, Norway

There are several reasons why orthopedic surgeons need knowledge of mechanical properties of bone tissue. We should know the highest load a bone can resist before fracture, how external loads create internal stresses, the effect of age, disease, and other factors. Better knowledge of bone as a material makes it easier to understand some basic problems in implant surgery. Will corresponding mechanical properties of implant and bone at the interface, for instance, diminish the problem of prosthetic loosening?

Bone occurs in two forms: trabecular or cancellous bone and dense and compact cortical bone. Bone with a volume fraction of solids less than 70 percent is classified as cancellous bone, that over 70 percent as cortical bone. The basic bone material is a composite of collagen and hydroxyapatite, which can resist compression, tension, and shear forces. This is important because bone is continuously subjected to multiple forces.

Bone is superior to all other materials because it has the unique ability to repair itself and adapt its mechanical properties to external forces according to Wolff's law.

A prerequisite for understanding the mechanics of a material is a knowledge of some technical terms. To the basics belong the concepts of stress and strain. Strain is a term that is use to describe the amount of deformation of an object. Stress is defined as the force per unit area that develops within an object in response to an external load. The mechanical behavior of a material is expressed in the stress-strain curve, which is a normalized force-deformation relationship. The units of stress are newtons/m^2 or pascals (Pa). Strain has no unit since it is the relationship between deformation and original form, such as F L/L. When a load is applied to an object, it deforms. In elastic materials the object will recover completely from the deformation until a critical "yield point" is reached. Deformation beyond this point causes a plastic, nonrecoverable deformation. The "failure point" is reached when the load is increased until disruption of the material occurs. Because bone is a viscoelastic material, the stress-strain curve below the yield point is curvilinear. When the load is removed the slope goes the opposite way, and a hysteresis loop is produced.

The main characteristics of a material can be extracted from the stress-strain curve. The slope of the curve in the elastic region is referred to as the modulus of elasticity (E), or Young's modulus, and is expressed in pascals. The strength of a material is the maximum load that can be sustained before failure, "ultimate failure point." The energy stored by the material at any point is proportional to the area under the stress-strain curve. Because young bone is able to store more energy than old bone, the energy released at fracture under certain circumstances will lead to a comminuted fracture, "high energy fracture."

Cortical bone

Due to its relative uniformity, cortical bone is more easily subjected to mechanical testing than cancellous bone. Specimens from cortical bone can be examined in compression and tension, as well as in bending and torsion. Due to its viscoelastic properties, a specimen of cortical bone that is rapidly loaded will have a greater elastic modulus and ultimate strength than bone that is loaded more slowly.

Cortical bone is an anisotropic material. This means that mechanical properties such as ultimate strength and modulus of elasticity are dependent upon the direction in which it is loaded. The osteons are oriented along the

Table 1. Strength of femoral cortical bone*

Loading mode	Ultimate strength (MPa)
Longitudinal	
Tension	133
Compression	193
Shear	68
Transverse	
Tension	51
Compression	133

* Mean values from Reilly and Burstien (1974). Age span of population: 19–80 years.

long axis of the bone, which makes it stronger and stiffer in the longitudinal than in the transverse direction.

Torsion tests about the longitudinal axis show that the shear strength is approximately one third of the compression strength. The longitudinal elastic modulus is 50 percent greater than the transverse elastic modulus, and the shear modulus for torsion about the longitudinal axis is approximately one fifth of the longitudinal modulus.

Table 2. Modulus of femoral cortical bone*

Longitudinal	17.0 GPa
Transverse	11.5 GPa
Shear	3.3 GPa

* Mean values from Reilly and Burstein (1974). Age span of population: 19–80 years.

Cancellous bone

Cancellous bone is a cellular material composed of an interconnecting network of rods and plates. A network of rods at low densities forms an open network, whereas as density increases more bone material accumulates in the walls transforming the structure into a more closed network of plates. The apparent density of trabecular bone ranges from approximately 0.1 g/cm^3 to 1.0 g/cm^3. The density of cortical bone is 1.8 g/cm^3. According to Wolff+s law the density of trabecular bone increases in response to the magnitude of the applied load. For example, the density of the subchondral bone of the medial tibial condyle is higher than that of the lateral tibial condyle because the forces acting on the medial side are the highest. This relationship indicates that the compressive strength of bone is proportional to the apparent density. It is also indicated that strength in compression is approximately the same as in tension. The same relationship is found regarding the modulus of elasticity in trabecular bone.

At apparent density of 0.5 g/cm^3 the compressive strength of trabecular bone is about 10 MPa and the modulus of elasticity approximately the same value. (Cortical bone in comparison: Compressive strength 200 MPa and E 17.0 GPa).

The structural behavior of a *whole bone*' is dependent upon the mechanical behavior of cortical and cancellous bone and, not least, of bone cross-sectional area and the entire shape of the bone.

Principal aspects on the bone-to-implant interface

Tomas Albrektsson and Björn Albrektsson

Department of Handicap Research and Orthopedic Clinic, Mölndal Central Hospital, University of Gothenburg, Gothenburg, Sweden

Most conventionally used arthroplasties, cemented or not, are surrounded by a fibrous tissue coat. From a biological point of view, a soft-tissue interface is a sign of an adverse tissue reaction, whether it is dependent on poor biocompatibility of the implant material, on a traumatizing surgical technique, on inappropriately controlled loading conditions, or on a combination of these factors. Clinically, such arthroplasties have been demonstrated to result in increasing failure rates with time, as well as poor results in the young individual who is prone to overloading the devices (Chandler et al. 1981). However, there may exist two types of soft-tissue interfaces, depending on the direction of the fibers: one with fibers parallel to the long axis of the implant (that theoretically would be less advantageous), the other with fibers perpendicular to the implant surface and thereby, presumably, with a better load-bearing capacity than the former type (Pilliar et al. 1981). Whether there actually are two types of soft-tissue interfaces leading to a different clinical outcome is uncertain. However, it will be most interesting to compare clinical long-term results of knee arthroplasties that have been found to be migrating either rapidly or slowly (Ryd 1986) with consecutive tissue specimens from the interface of the same joint replacements, should these become available.

An alternative way for permanent anchorage of a bone implant – to establish a direct bone-to-implant interface without interposed fibrous tissue – was introduced by Brånemark et al. (1969). Brånemark later coined the term *osseointegration* to describe this novel type of implant fixation, which at the present time has been used clinically for anchorage of dental implants over more than two decades and which has given far better results than conventionally fibrous tissue-anchored implants. In the future it is not impossible that osseointegration will prove to be a useful mode of anchorage also of orthopedic implants. However, although originally described as a clinical reality a long

time ago, the concept of osseointegration has not been properly defined to this date. Albrektsson et al. (1981) suggested that osseointegration is a direct contact, at the light microscopic level, between loaded implant surface and bone without any interposed soft tissue. Today, there are two ways of defining osseointegration, through either a *structural* or a *biomechanical* approach.

The *structural approach* is aimed at a morphologic analysis at the light-microscopic resolution level of bone-to-implant specimens where the implant has not been removed prior to analysis. It is obvious that the entire implant-to-bone interface has to be examined. For instance, a patchy direct contact between bone and implant in, let say, 1 percent of the entire contact zone cannot be used as evidence for osseointegration of an implant if the remaining 99 percent demonstrate a fibrous tissue interface. At the passage through cortical bone, minimally 90–95 percent of the implant surface should be in direct bone contact to justify the term *osseointegration*. In cancellous bone areas, there is much less hard tissue, and even if there is a tendency of bone condensation at the implant interface, a 90–95 percent bone-to-implant contact cannot, generally, be expected. In fact, the level of hard tissue contact with implants in cancellous bone seems to vary with the insertion site. In the future, it may be possible to add qualitative criteria at the ultrastructural level to the structural definition, as there is already published evidence (Albrektsson et al. 1983) that bone-to-titanium may establish a direct contact at a higher resolution level than permitted with the light microscope, and that collagen filaments may approach the surface of the foreign material to a distance of only a few hundred ångströms.

The shortcomings of the structural definition of osseointegration in cancellous bone has lead to *biomechanically based* definitions. Baier (1986) has suggested that a proper osseointegration of an implant calls for a bond strength over the bone-to-implant interface that renders it stronger than the surrounding bone tissue. So, attempts to push/pull out or unscrew (depending on implant design parameters) an osseointegrated device would lead to bone fracture (supposing the implant does not break) rather than an interfacial failure. Steinemann and coworkers (1986) have used another biomechanically based definition in stating that the proper osseointegrated implant shows resistance to shear, as well as to tear-off forces that act over the interface. They found that experimental bone-anchored implants could resist shear forces of several hundred newtons and tear-off forces of 100 N. The interfacial strength in tear off was found relatively close to that of cancellous bone. These observations may form the basis for the biomechanical definition of osseointegration.

In conclusion, if a *structural* definition of osseointegration is chosen, it may be necessary to evaluate separately the degree of bone-to-implant contact in a cortical and cancellous bone bed, respectively. Only in the cancellous site alone, it would be justified to accept a term such as "partial osseointegration" corresponding to, roughly, 50 percent or more of bone-to-implant contact. The *biomechanical* definition of osseointegration is most promising, but we need more experimental data to verify possible bonds that occur over the bone-to-implant interface.

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Biological reactions to implants

Factors that influence the tissue response

Tomas Albrektsson and Björn Albrektsson

Department of Handicap Research and Orthopedic Clinic, Mölndal Central Hospital, University of Gothenburg, Gothenburg, Sweden

Interfacial reactions to a foreign device are not determined by the biocompatibility of the material alone. Albrektsson et al. (1981) summarized six biological

factors of importance for the tissue behavior to an implanted object, the first three being related to the implant: its biocompatiblity (1), its design (2), and its microsurface (3). In addition, the status of the host bone (4), the surgical technique (5), and the loading conditions (6) were regarded as important for a proper "implant take." The individual importance of these factors is not known. Experimental attempts to manipulate one factor while the others are controlled are most probably misleading, as several individually subliminal inadvertencies may add to one another in the clinical reality. This makes the outcome of an experimental investigation under "ideal conditions" less valid as an indication whether one or more of the six related factors are to be regarded as less significant than the others.

1. *Material biocompatibility.* Albrektsson and coworkers have experimentally compared interfacial reactions to several different metals including gold, zirconium, tantalum, niobium, stainless steel, titanium alloy, and c.p. titanium. Of these, c.p. titanium showed the most nature-like tissue reactions, i.e., was regarded as the most biocompatible material (Albrektsson and Jacobsson 1986). Implants of Al_2O_3 have been demonstrated to become osseointegrated in bone (Heimke et al. 1982). However, aluminum is potentially neurotoxic and leaking aluminum from implants has been demonstrated to accumulate in the body without any tendency to reaching a plateau phase over 6 years of follow-up (Woodman et al. 1984).

2. *Implant design.* Threaded implants have the advantage of an initial stability and resistance to shear forces in comparison to porous or mesh designs where implant stability is observed first after sufficient bone ingrowth. However, a potential advantage of the porous design would be the possibility to manufacture implants of an elastic modulus comparable to that of cortical bone. More research is necessary to identify these parameters.

3. *Implant surface.* Baier and coworkers (1984) have demonstrated the importance of a high surface energy for proper cell adhesion. From a structural point of view, a surface with microirregularities has been demonstrated to result in a better "implant take" than a smooth surface (Röstlund et al. 1986).

4. *Status of the host bed .* An uninfected bone bed is important for implant success. As demonstrated by Jacobsson et al. (1985), previous irradiation is not a contraindication for implant insertion, but preferably a time of minimally 1 year should pass before implant surgery.

5. *Surgical technique.* Inserting screws for Richard's plates have been demonstrated to result in temperatures of 89° C in spite of saline cooling (Eriksson et al. 1984), whereas a controlled surgical technique need not result in any elevation above the body temperature (Eriksson and Adell 1986). The critical temperature for impaired bone regeneration seems to be in the range of 44–47° C applied for 1 minute (Eriksson and Albrektsson 1985).

6. *Loading conditions.* Premature loading of an implant will cause movements, and movements stimulate fibrous tissue formation (Uhthoff 1973). A controlled loading pattern seems necessary for the establishment of a fibrous tissue-free interfacial reaction. One way to control the loading is to use a two-stage surgical technique.

In essence, several parameters will determine the outcome of an implantation procedure. Poor control of only one of the factors summarized in the present report may lead to clinical problems in spite of if all the other relevant variables are optimized.

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Tissue reactions to ceramics and glass ceramics

Elin Barth[1], Helge Rönningen[2] and Ludvig Fjeld Solheim[2]

[1]Section of Orthopedic Surgery, Bowman Gray School of Medicine, Winston-Salem, NC 27103, U.S.A., and [2]Institute of Surgical Research, National Hospital, Oslo 1, Norway

The factors that determine the rate and degree of bioresorption of calcium phosphates remain an area of controversy and confusion (Jarcho 1980). Additionally, two different biologic resorption pathways exist; solution-mediated and cell-mediated processes (i.e., phagocytosis). Despite the limited knowledge of the factors that control the bioresorption of calcium phosphate implant materials, it is clear that both chemistry and material structure play key roles. High density implants, be they hydroxyapatite (HA) or tricalcium phosphate (TCP) or mixtures of the two, will show little tendency to bioresorb due to their small surface area. Porous TCP implants will resorb much more rapidly than porous HA of very similar structure. Microporosity may be a factor in promoting cell-mediated bioresorption. However, a bioresorption through an overaggressive phagocytosis would cause an acute or chronic inflammatory response. Tetracalcium phosphates behave like HA. The calcium phosphates ar in general extremely biocompatible and become directly bonded to bone. The reason for this may be that these materials are composed of the same ions that make up the bulk of natural bone mineral and are therefore capable of participating in calcium phosphate solid-solution equilibria at their surface.

Thus, all calcium phosphate implant materials will become coated with a microscopic layer of biologic apatite shortly after implantation in bone. The histologic sequelae associated with implantation of nonporous calcium phosphates in bone represent normal bone healing on and around the implants. At the interface of both dense and porous implants, there is direct bone deposition without an intervening fibrous tissue capsule; and at implant failure, fracture lines are propagated through the bone-implant interface. Ultrastructurally, the first evidence of the bonding zone is a 3–5-micron-thick amorphous substance on the implant surface that is deposited from differentiating osteoblasts. This amorphous zone becomes calcified with plate-shaped bone mineral crystals. Between this zone and the cells, there are loosely arranged collagen bundles. The calcium phosphates are not osteoinductive. Bone defects filled with particulate, porous calcium phosphates (HA or TCP) heal more slowly than an empty defect, but defects filled with compact, particulate HA or TCP heal as quickly as an empty defect. However, there materials are osteoconductive. When full-thickness cartilage bone defects are filled with porous blocks of HA, titanium oxide, and aluminum oxide, only the HA implant sites demonstrate regenerative healing of hyaline cartilage, whereas fibrocartilage is formed at the other implant sites and controls. When placed in soft tissue, calcium phosphates are sequestered by a quiescent, fibrous tissue capsule.

The bioactive glass ceramics (i.e., Bioglass®, Ceravital®, Apatite Wollastonite®, controlled release glasses, and sodium/silicon-oxide glasses) are postulated to bind chemically with bone, and a certain migration of sodium and phosphate ions is crucial to this chemical bonding. Although the bioreactivity of these glasses is defined as the time it takes for a known amount of glass ceramic to override a pH of 5.4 in a buffered solution and to reach an equilibrium pH of 10, recent studies indicate that the solubility cannot be directly related to their bone-bonding capability (Gross and Strunz 1985). Their tendency for uncontrolled dissolution in vivo remains an inherent problem, and an uncontrolled dissolution may elicit a continuous inflammatory response to the dissolution products with fibrous tissue encapsulation of an implant inserted in bone. The release of constituents such as Al_2O_3, Ta_2O_5, Zr_2, or phosphates from the material may inhibit normal mineralization and result in fibrous or chondroid tissue formation at the boneimplant interface. Provided the dissolution is controlled, a close apposition of bone will take place as described for the calcium phosphates.

The bone tissue response to the various ceramics/glass ceramics is reflected in their bond strength to bone. Dense HA has a failure load during push out of 2–3 MN/m^2 corresponding to the strength of the HA, and the failure occurs at the implant side of the interface. The failure load for alumina is only 0.04 MN/m^2, and the failure occurs in the connective tissue envelope. Glass ceramics fail at 0.6–2.5 MN/m^2, and the failure takes place at the interface between implant surface and bone. However, this failure load is much lower than expected from a chemical bond, which is 20–100 MN/m^2. The hypothesis of chemical bonding of glass ceramics to bone may thus be questionable.

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Tissue reaction to bone cement

Lars Linder

Department of Orthopedics, Malmö General Hospital, S-214 01 Malmö, Sweden

The normal response to bone cement is generally considered to be fibrous encapsulation, and thereby sequestration from the bony implant bed. In addition, since the soft-tissue membrane contains macrophages and foreign body giant cells, the long-term prognosis for cemented implants has been considered dubious.

Bone cement differs from other implant materials in that it is traumatizing in itself, and the thermal and/or chemical traumas have been implicated as the cause of membrane formation. However, in animal experiments, the fibrous membrane is not regularly seen, but a direct bone-cement contact has instead been demonstrated (Draenert 1981, Linder 1977). A direct bone-cement contact has also been shown when prepolymerized cement plugs have been implanted in animals.

During the last 10 years, it has become increasingly clear that a direct bone-cement contact can occur even in the clinical setting, i.e., despite the initial trauma from the bone cement itself and despite loads over the interface. So far, this situation has only been reported for the femoral side of total hip replacements. However, there is no reason to suppose that a direct bone-cement contact is a local phenomenon.

It would thus seem that the tissue reaction to polymerized bone cement is qualitatively similar in animals and in man. In an ultrastructural study (Linder and Hansson 1983) the interface anatomy was found to differ from that usually seen around osseointegrated titanium implants. Although being technically osseointegrated, the bone cement was separated from the collagen of the bone by a thick proteoglycan layer. Also, macrophages and multinucleated cells were a common finding between the areas of bone-cement contact.

The reason why this type of interface has not been seen in cancellous bone is unclear. It may be that the traumatic effects of the cement for some reason are more pronounced in cancellous bone. However it may also be that perioperative factors, for instance, loading, plays a relatively more prominent part in cancellous bone. However, all efforts to reduce the traumatic effects of the polymerizing bone cement should be encouraged.

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Tissue reaction to implant metals other than titanium

Lars Linder

Department of Orthopedics, Malmö General Hospital, S-214 01 Malmö, Sweden

Numerous studies have been undertaken to characterize the tissue reactions to metal implanted into various animal species and anatomic sites. Little if any difference has been found when present-day implant metals (pure titanium, chrome-cobalt alloy, and stainless steel) are compared. The explanation for this may either be that no differences exist or that the analytical methods have been inadequate to detect a small difference.

Two principal sites of implantation have been used in experimental research: soft tissue (subcutaneous tissue or muscle) and bone. Because the former tissues can only heal with scar tissue, a fibrous capsule will always form around the implants. In the analysis, therefore, the thickness and cellular composition of this capsule have been quantified using histology and enzyme histochemistry (Spector 1982).

Few comparative studies of the modern metalic implant materials have been carried out in bone. There are numerous reports on the reaction of bone to retrieved metallic implants, but it is difficult to evaluate the significance of some of these reports, as the implants have been subjected to widely different conditions.

The predominating finding around a removed clinical implant is a thin soft-tissue membrane between the implant surface and the bone. The mechanism behind the formation of such a membrane has been thought to be implantation trauma, microinstability of the implant, and/or implant corrosion. Histologically, the membrane

is usually made up of flattened fibrocytes without inflammatory cells, except in the case of gross implant corrosion. No difference in the reaction to stainless steel, chrome-cobalt or titanium alloy implants are seen (Brunet et al. 1986).

In recent years it has been shown by Brånemark et al. (1977) that if an implant of pure titanium is inserted into bone with a very careful and exact technique and without postoperative loading, a true bone/metal interface will be established (osseointegration). Experimentally, it has also been shown that solid implants of stainless steel and chrome-cobalt alloy will become osseointegrated if implanted with the same gentle technique (Linder and Lundskog 1975). Pull-out tests yield similar values for all materials.

All the studies on osseointegrated bulk metal implants have been done using conventional light microscopy. Transmission electron microscopy (TEM), although desirable, has not been used for methodologic reasons, but a new method conceived by Linder (1985) will make possible TEM of the interface of even osseointegrated bulk metals.

The conflicting results outlined above would suggest that at least the short- and medium-term tissue reactions to these metals are related to the conditions under which they are implanted rather than the composition of the implant materials. However, there are theoretical grounds to suggest a differentiated tissue response to the modern implant metals, even in the case of osseointegration. Events taking place on the surface of the implants probably differ, and the long-term consequences of potentially toxic corrosion products are unknown. This underlines the importance of high-resolution methods of analysis and standardized, comparative long-term studies.

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Tissue reactions after implantation of titanium and its alloys

Helge Rønningen

N-2044 Frogner, Norway

Most biomaterials are implanted in the organism to serve a mechanical function, which means that the implant will be subjected to continuous stress over a time span that no part in machine technology has ever been designed to resist. The demands on materials that are intended to function as integrated parts of the skeleton for the patient's lifetime must be entirely different from those on materials designed for temporary function. The term "integrated parts" indicates that the implant must be biocompatible, i.e., it must not attack, or itself be attacked by, the hosting tissue to any such extent that the longevity of the function is jeopardized.

Titanium has repeatedly been found to be a biocompatible metal. A comprehensive investigation led Harms and Mäusle (1980) to propose that commercially pure titanium and alumina ceramics, be recognized as reference standards for biocompatible materials. Animal experiments have shown that titanium implants can be hosted by bones for up to 10 years without detectable adverse local or systemic reactions (Memoli et al. 1983). The Brånemark group has implanted a vast number of titanium dental implants and reported of excellent tissue acceptance of this metal. Thus, Albrektsson et al. (1981) implanted commercially pure titanium and found that the titanium-bone interface, after up to 90 months of implantation, was characterized by normal lamellar bone in direct contact with the metal. Linder et al. (1983) described an interface zone of 20–50 nm between implant and bone collagen filaments that contained hyaluronic acid and chondroitin sulphate, as does normal ground substance. This kind of implant-bone interface is probably unique for titanium. Adell et al. (1981) presented remarkably good results from 2,775 dental implants that had been in service for up to 15 years. Experiments in cell cultures have concluded that titanium is well tolerated. Kawahara (1983) found that cells adhered directly onto a titanium film with the cells maintaining their normal cytoplasmic structure. The observation that the cells were unable to undergo mitoses, was attributed to their strong mechanical adherence to the metal film. Allergy to titanium has not yet been observed, despite a massive exposure since titanium oxides are common constitutents of cosmetics and vehicles in preparations used in dermatology.

Alloying titanium with 6 percent aluminium and 4 percent vanadium improves the ultimate tensile stress, endurance limit, and wear properties without serious sacrifices in biocompatibility. Unalloyed titanium is used where the biocompatibility of the implants has the

highest priority. This is particularly important for implants with a large surface area exposed to living tissues, like the porous bone-ingrowth anchoring systems.

Titanium will react with air or an aqueous environment and form an oxide film on the surface that renders it resistant to corrosion breakdown. Solar et al. (1979) concluded that titanium can be expected to resist physiologic chloride solutions at body temperature for an indefinite time. Titanium oxide is by its nature a ceramic. Thus, it has been proposed that titanium with its oxide film represents the ultimate goal for an implant material where desirable mechanical properties of a metal can be married to the inertness of ceramics. Along with this, it has been hypothesized that the oxide layer creates the environment believed to result in chemical bonding between implant and living tissue (Albrektsson et al. 1983). D. F. Williams: "Titanium therefore shows all the characteristics of the perfectly passive material so desirable for surgical use. Film breakdown and overt corrosion of titanium or the Ti-6Al-4V alloy has yet to be observed. Titanium is completely immune to pitting and crevice corrosion under physiological conditions and there is no equivalent of intergranular corrosion" (*Biocompatibility of Orthopedic Implants*, CRC Press 1982).

Titanium under certain conditions gives off large amounts of metal ions by a mechanism still not understood. This causes an impressive black discoloration of the tissue surrounding titanium implants. Fortunately, it appears that even an intense discoloration does not imply serious biological harm to the tissues. A theory of a break off of titanium oxide needles on the implant surface has been put forward to explain the discoloration.

With its record of biocompatibility, titanium was a suitable candidate for the manufacture of implants to be fixed with porous ingrowth (Galante and Rostoker 1973). Porous implants expose a large surface to the tissue compared with the solid implants. This has caused much effort to investigate what leached out metal ions mean to the biological environment. Woodman et al. (1984) analyzed tissues from baboons that had had Ti-6Al-4V implants for up to 92 months. They found that the titanium concentration in the lungs increased with time to reach a steady state level at 38 months. The aluminum concentrations in the lungs also increased with time, but did not reach a steady state within 92 months. Vanadium did not accumulate. The significance of these observations have yet to be understood.

While the need for biological compatibility of biomaterials has been evident, the need for mechanically compatible materials has not received the same attention. Recent reports have demonstrated that the load transmission across an implant-bone interface governs the remodeling of the trabecular architecture adjacent to an implant. Areas with load transmission will react by forming thicker bone trabeculae running parallel to the direction of the loads, whereas nonloaded trabeculae may gradually resorb. A mismatch between the mechanical properties of bones and implants may disturb this process due to local stress concentrations. Because titanium has an E modulus of only half of that of other implant materials, it may be more of an ideal implant material than the others. But the practical significance of this remains to be established.

The results from research on tissue reaction on biomaterials is so far largely descriptive, with a presence/absence of certain tissue appearance (denaturation: e.g., lysis of bone, influx of cells known to be associated with defence reactions) recognized as criteria for biocompatibility. The true nature of the elements that constitute this puzzle still remain obscure, and it is not known how implants interfere with the biological environment. Probably the adverse effects are exerted through disturbed immune system (allergy), biological mediators (e.g., chemotaxis), capacity of phagocytosis, bacterial adherence, microcirculation and carcinogenesis.

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Tissue reactions of corrosion and wear products

A. Ohlin

Department of Orthopedics, Malmö General Hospital, S-214 01 Malmö, Sweden

Corrosion and wear products of orthopedic implants may lead to mechanical failures, severe tissue reactions, and systemic effects. In the evolution of total joint prostheses, the metal-metal Cr-Co alloy prostheses were found to generate metal wear particles inducing metallosis of the tissues around the joint. In the tissues adjacent to the prostheses there was a foreign body reaction with formation of scar tissue, but also necrosis formation in the joint capsule, as well as in the bone adjacent to the joint (Evans et al. 1974). Increased levels of Cr and Co in hair, blood, and urine were found in patients with a total hip replacement (THR) with metal-metal articulation. The significance of these increased ion levels is not clear. Also allergic reactions were considered to be contributing to prosthesis loosening (Coleman et al. 1973). The introduction of metal to polyethylene articulation of joint prostheses has dramatically reduced the problem with wear and corrosion of metallic prosthetic components (Charnley 1979). The frequency of metal allergy is perhaps somewhat increased in patients with metal to polymer prostheses, but it is not considered a great problem (Carlsson et al. 1980). Among the three most commonly used metallic implants, stainless steel, Cr-Co alloy and titanium and its alloys, stainless steel has the least resistance to corrosion (Sutow and Pollack 1982). In the development of joint replacements, one of the great problems has been wear of the polymers and the resulting tissue reactions. In 1946, Judet's hip replacement made of polymethylmetacrylate (PMMA) was introduced. The long-term result was disastrous owing to a high implant wear rate with a pronounced tissue reaction, formation of a caseous debris material in the joint cavity, and resorption of bone adjacent to the joint (Mittelmeier and Singer 1956). In 1960, Charnley introduced his cemented THR with a metallic femoral component and a socket made of Teflon. The socket wear rate was very high with a subsequent tissue reaction with a similar formation of caseous debris material in the joint and bone resorption. In 1962, Charnley introduced a high n density polyethylene (HDP) socket. The polymer wear rate was dramatically reduced and today this principle is not surpassed (Charnley 1979).

The drawback of the metal polyethylene prostheses was considered to be the high polymer wear rate. Other designs were therefore presented: In 1970, Weber introduced a THR with a prosthetic head made of polyester articulating against a metal socket. This THR gave a poor result due to a high polymer wear rate and a similar tissue reaction as with PMMA or Teflon (Weber et al. 1974). In 1970, Christiansen presented a new THR in order to reduce the problems with friction and socket wear – in this design there was a trunnion bearing between the femoral stem and the head, also polyoxymethylene (POM) was chosen as the polymer material (Sundahl et al. 1974). In the end of the 1970's, it was realized that also this design of THR often failed (Josefsson 1980). Similar findings were made – a high socket wear rate, a foreign body reaction with formation of caseous material in the joint cavity and severe bone resorption (Ohlin and Persson 1987).

Solid silicons are used for replacement of the carpal bones, the radial head, and the base of the great toe – these being the most common sites. Severely worn implants are frequent with a concomitant similar tissue reaction (Eiken et al. 1985). In the hinged Guepar knee replacement, a silicone bumper was used; this component is prone to wear, and the poor results with this type of prosthesis are partly due to this design "refinement" (Le Nobel and Patterson 1981). Also, high density polyethylene can be severely worn with a similar result if the design is poor. Failures with the soft top protheses are best explained in the terms of a high wear rate of articulating convex polymer components (Revell et al. 1978).

For more than 10 years, ceramic endoprostheses have been used in various designs and combinations, but there are still no convincing data suggesting the superiority of ceramic prostheses, even if some experimental studies indicate that the tissue reaction of particulate alumina are less intense (Dumbleton 1981).

In the artificial joint, continuous release of wear products induces, in the new formed capsule, a proliferation of cells capable of phagocytosis. The observation that wear particles have been found at a great distance from the joint suggests that the foreign body particles are transported by the lymphatic system. If the production of wear particles exceeds the elimination rate, there will be an accumulation of particles within the joint. This results in formation of a foreign body reaction within the capsule. Granulomata with central necrosis are formed,

and the superficial border of the membrane is often covered with a thin fibrinoid necrotic layer that is projected into the joint cavity forming caseous masses of a necrotic material with wear particles. The cellular composition of the reactive tissue seems to be determined by the size of the foreign particles and in part also by the chemical composition of the worn material. The smaller particles are most often phagocytized by mononuclear histiocytes, whereas the larger particles are engulfed by multinucleated giant cells. In cases with a very large amount of wear particles, one can find granuloma and necrosis formation. The phagocyting cells eventually succumb and the indigestible material may repeatedly be phagocytized by new generations of macrophages in a vicious circle with a resulting release of proteolytic enzymes (Willert and Semlitsch 1975). The mechanism of bone resorption is not fully understood, both cellular resorption and enzymatic degradation are being discussed (Forest et al. 1985).

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Micromotion of endoprostheses

Leif Ryd

Department of Orthopedics, University Hospital, S-221 85 Lund, Sweden

Motion between endoprostheses and bone is, by definition, the measurable entity corresponding to mechanical loosening, the major problem of endoprosthetic surgery today. Accurate measurement of such motion should 1) provide a method of early differentiation between different prostheses and fixation concepts regarding the rigidity of the bone-prosthesis bond, and 2) provide further insight into the pathology behind loosening.

These statements will be supported by the following presentation of roentgen stereophotogrammetric analyses (RSA) of the tibial component in knee arthroplasty.

Conventional arthroplasty

Fifty-one conventionally cemented all-polyethylene components (27 Total Condylar and 24 Marmor) were followed for 4–5 years. Micromotion, both migration and displacement by external forces, was found for all the prostheses. All the prostheses migrated (mean 1.0 [0.2–5.4] mm) predominantly during the first year, after

which time a majority of the prostheses remained stable. A minority, however, continued to migrate during the period studied. Already after 1 year, there was a significant difference between the magnitude of the migration for the two groups. Inducible displacement (mean 0.6 (0.2–1.0) mm) was found.

Metal-supported prostheses

Twenty-six cemented metal-supported prostheses (7 Kinematic, 7 Porous Coated Anatomic (PCA), and 12 unicompartmental "Prototype") were followed for 2 years. No difference could be found between these and the former, all- polyethylene, groups regarding migration or inducible displacement.

Noncemented or partially cemented prostheses

Thirteen (PCA) prostheses were inserted without cement, and 10 were inserted with partial cement (peripheral rim). Both groups were subjected to our routine postoperative regimen, including immediate weight bearing. For the noncemented prostheses, migration (mean 2.4 [0.5–5.0] mm) and inducible displacement (mean 0.7 [0.4–1.3] mm) was found. This was larger $P < 0.001$) than for all-polyethylene prostheses regarding both modalities. The partially cemented prostheses behaved like cemented all-polyethylene ones in both respects.

Five Freeman-Samuelson prostheses migrated (mean 1.4 [0.7–3.8] mm) and six showed inducible displacement (mean 1.9 [0.8–5.0] mm), both modalities larger ($P < 0.01$ and $P < 0.001$, respectively) than for all-polyethylene prostheses.

Discussion

Absolute rigidity between protheses and bone, hitherto considered a prerequisite for lasting good results, does not seem to exist regarding the tibial component of the knee.

Migration during the first year occurs in all the cases, and probably represents physiologic phenomena during the healing of the prosthetic bed. This initial migration occurs in all the cases disregarding type of prosthesis or type of fixation. Some prostheses migrate continuously for many years. This indicates a more unstable fixation possible leading up to loosening.

Measurement of the inducible displacement is a way to mechanically characterize different types of fixation. The bond between cemented prostheses and bone is semielastic, allowing inducible displacement up to about 1.0 mm. This motion corresponds to the elastic properties of the fibrous tissue membrane (= radiolucent zone).

Metal support under the polyethylene does not seem to alter the mechanical characteristics as measured by RSA.

The fixation of the Freeman-Samuelson prosthesis is more elastic, giving inducible displacement up to 5 mm.

The noncemented PCA prostheses gives a fixation in the intermediate range allowing inducible displacement up to 1.5 mm. Such displacement rules out bony ingrowth into the porous undersurface of the prosthesis. In order to optimize the conditions of bony ingrowth, a peripheral rim of cement for initial stability was used. This decreased the inducible displacement to that found for cemented PCA prostheses, but not, however, to a degree that would be compatible with bony ingrowth.

With increasing refinement of prosthetic design, the need of sharper assessment tools becomes correspondingly more pertinent. RSA offers a unique possibility in this respect.