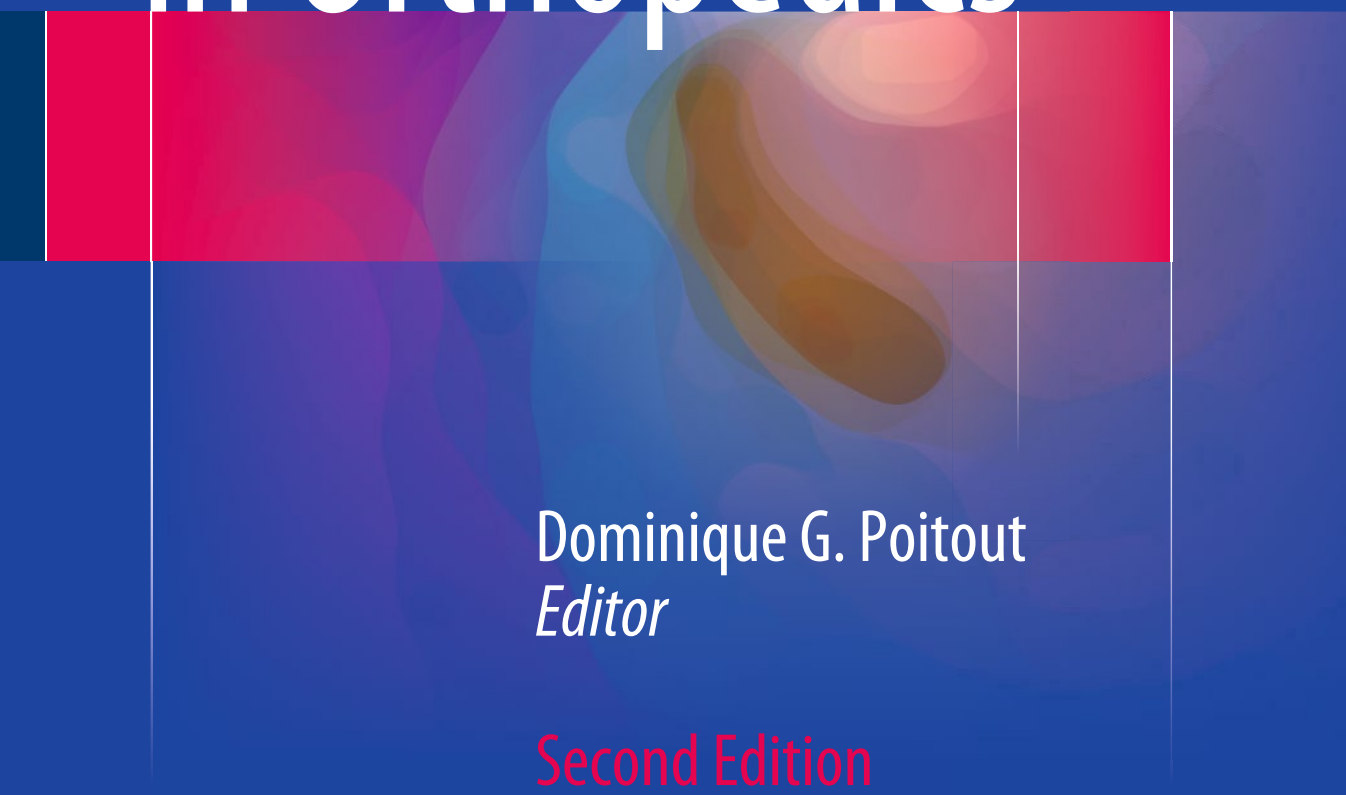
Biomechanics and Biomaterials in Orthopedics



Dominique G. Poitout
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Second Edition

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Foreword

Even before biomechanics and biomaterials were recognised as specific scientific fields, they were a major concern of the earliest orthopaedic surgeons. The basic principles of biomechanics were first approached by Wolff in 1892. The design of implants and the selection of biocompatible materials became an essential field of research following the pioneering work on the first surgical fixation of fractures by Lambotte and Lane.

Since the recognition of these specific fields, it has become necessary to understand the complex multifactorial interaction of the musculoskeletal tissues. After the difficulties encountered in establishing a common language, these areas of research grew exponentially and involved many scientific disciplines. During the 1970s, the first Biomechanics and Biomaterials Societies were founded to meet this need.

From the study of the passive characteristics of the materials to improve mechanical resistance and the neutral biochemical behaviour of the implant, they gained an active role in controlling cell and tissue regeneration.

Smart implants ensure monitoring of bone healing and interactive regulation within biological parameters. Tissue and cell engineering is being constantly developed and appears to be a promising tool in the stabilisation of the degenerative process and repair of tissue defects.

In addition to the constant evolution of implant technology, the improvement in the production of allograft and bone substitutes significantly expands the armamentarium of the orthopaedic surgeon. The recent involvement of nanotechnologies opens up the possibilities of new approaches in the development of interactive interfaces of the implant.

These fields of science represent an essential part of the knowledge and experience of today's orthopaedic surgeons and it has to be mentioned that in this publication Dominique Poitout offers an informed contemporary insight into this fast expanding domain. In 1987, he achieved this objective by the publication of a first handbook "Biomécanique Orthopédique", which was a reference for many practitioners and scientists.

Currently, there is a need to summarise and update the advancements in the different specific topics to further new applications and initiate new researches. Dominique Poitout has been able to compile the most prominent active researches in the discipline to offer young orthopaedic surgeons a

summary of fundamental skills that they will need to apply in their day-to-day work, while also updating the knowledge of older surgeons in the most advanced fields. He has successfully fulfilled this goal with this book and we thank him for this fundamental contribution.

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Part I

Introduction

Bone as Biomaterial

1

Dominique G. Poitout

Since 30 years surgery has seen striking developments in the area of biomaterials and it is becoming increasingly necessary for surgeons from various specialisms to have an in-depth knowledge of the biomechanical properties of and what happens to foreign bodies implanted in the body, whether metallic or biological such as bone. Industrial researchers have to identify and then resolve the mechanical problems which arise when using inert (metallic or plastic) or biological materials to replace joints, ligaments, or even whole bones.

Using human or animal grafts (bone, cartilage, or ligament) in certain surgical, traumatological, or oncological indications requires a combination of various types of knowledge in the areas of immunology, biology, and biomechanics which are necessary for these allografts or these xenografts to be incorporated into the body.

Human bone, whether autologous and therefore bone-forming, allogenic, and simply bone-conducting or even animal bone (xenograft), behave biomechanically in a progressive fashion depending on the extent of the demands placed on it, the rate and degree of its revascularization, and of the procedures used to preserve and sterilize it. Bone substitutes are also currently being studied, whether in the area of hydroxya-patites, vitroceramics, tricalcium phosphates, corals, or even ceramized or heated allografts or xenografts. Mixed compounds combining a massive metallic prosthesis with bone from a bone bank surrounding it are composite biomaterials, the constituents of which each have their own advantages and disadvantages.

Introduction

Biomaterials can be defined as being "natural or synthetic substances, capable of being tolerated permanently or temporarily by the human body".

Indeed, although initially doctors chose mainly precious materials, as dentists still do, the development of new materials such as ceramics, polyethylene, carbon–carbon composites, or titanium have enabled the field of application which used to be limited to joint or dental prostheses to be extended to other areas such as ophthalmology and cardiology.

The use of allografts or xenografts is not recent but progress now being made in the areas of the sterilization and preservation of these products of human or animal origin mean that

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there is fresh interest in the surgical techniques which use them.

Research in these areas focuses on three aspects:

First, the study of the mechanical, physical, and chemical behavior of the material in its biological environment, i.e., its resistance to fatigue, wear, its elasticity, its resistance to corrosion, its biomechanical behavior, and its possible incorporation into the structures of the human body.

Then the study of its biocompatibility, in particular the analysis and identification of the reactions which occur at the interface between the material and the live tissue (for example, at the interface between the receiving bone and the prosthesis or the graft which has been introduced).

The biochemical growth factors, the role of certain enzymes in the breakdown of the materials used, the problems inherent to rejection or even immunological phenomena in relation to the destruction of an implanted graft are currently the subjects of a great deal of research.

Finally, it is necessary to choose a method which makes it possible to decide on a product which can be implanted in the body and which is also relatively easy to manufacture industrially or, where bone is concerned, preserved and distributed under ideal sterile conditions and the biomechanical behavior of which is compatible with restoring satisfactory and long-lasting joint function.

The Materials Used in Orthopedics

In the field of biomaterials, research has to follow two different but complementary paths:

On the one hand the characteristics and performance alone of the material have to be studied in accordance with its role in the body,

On the other, its biocompatibility has to be studied.

The biomaterials used in orthopedic surgery have developed a great deal in recent years. We now have a better understanding of the advantages they bring and their limitations. We know that steels corrode (vitallium) and that cobalt-chromium alloys wear. The complications connected with intolerance to the debris of metallic wear have meant that metal–metal prostheses are no longer used. The combination of metal and polyethylene also produces wear debris which plays a decisive role in the physiopathology of the loosening of prostheses, and the ceramic–ceramic joint may become blocked if the slightest particle enters the interface.

Plastics, such as polyethylene, which cover the sliding surfaces of many joint prostheses, become deformed, creep, and break down, tending to limit the life of these prostheses.

Cements, made of methyl methacrylate, which are used to fix some joint prostheses in the bone, have a high polymerization temperature if they are used in large quantities (over 70 °C), and for this reason cause bone necrosis (proteins congeal at 54 °C). The salting-out product may be toxic to the heart and when first used caused peroperative cardiac arrest from which the patients did not recover.

In 10 % of cases allografts produce considerable immune reactions and are only slowly and incompletely assimilated by the skeleton. Bone substitutes are not necessarily successful in mechanical terms and at present can only be used to a limited extent.

Many materials have disappeared completely from our arsenal of therapeutic options and we may well ask ourselves what can be used in future to replace the biomaterials used at present.

Biodegradable Materials

The need to remove an osteosynthesis product which was implanted a few months or years earlier is inconvenient; it means that the patient has to be hospitalized and operated on again and leads to a search for products based on amino acid-based polymers which would break down and disappear spontaneously in the body within a few years.

Compounds made of polyglycolic or polylactic acid are currently used in the form of suture materials or parietal reinforcing plates and

produce reasonable results. Their mechanical strength and life have to be improved and the way they are implanted into the body has to be specified. However, as from now, there is hope that in future they will replace the metallic materials currently used for osteosynthesis.

Bone Replacement Materials

Bone grafts currently have a major role.

Autografts

Autografts (bone graft taken directly from the patient) cannot be used to replace large segments of bone or an osteocartilaginous segment forming part of a joint. Being bone-forming, they alone can induce the formation of new bone and help in the healing of a fracture or the assimilation of an allograft.

Allografts

Since 1979 we have turned our attention to Marseilles, to preservation in tissue banks of allogenic bone fragments (bone graft taken from another person) stored in liquid nitrogen at −196 °C with cryopreservatives.

Currently used in traumatology or in oncology, these allografts make it possible to reconstruct a bone segment which has been destroyed by a tumor or an accident. These allografts are well tolerated by the body and only in exceptional cases (10 % of cases) do immunological rejection phenomena occur. They can therefore be used easily in anybody requiring this type of operation.

Xenografts

Xenografts were used several decades ago by French teams (Judet-Sichard). The large number of rejection phenomena experienced with them (more than 50 %) led to people refusing to use them. Because of the current shortage of human grafts, new attempts using different sterilization, preparation, or treatment techniques (lyophilization, ceramization, irradiation, heating) try to mitigate the inadequacies of this type of graft.

Bone Substitutes

Derivatives of artificial hydroxyapatite (a combination of hydroxyapatite-collagen, hydroxyapatite cement, corals or madrepores, vitroceramics or bioglasses) are undergoing in-depth mechanical and experimental studies to see how well they are tolerated in-situ and how they can be used. Even if some bone substitutes really are "colonized" by the bone of the host, their mechanical properties are still inadequate and mean that large fragments cannot be used in human clinical medicine. Furthermore, these structures, which are uniquely bone-conducting, do not form new bone, and tend to break down rapidly.

Joint Replacement Materials

There are a great number of plastics including polyethylenes with mechanical properties which allow them to be used in human clinical medicine. Various treatments (irradiation of the grafts or the addition of other compounds, for example) are being used in an attempt to improve their properties and to prolong their life in the body.

Alumina ceramics have been used for more than 15 years and their mechanical properties are well known. As the manufacturing processes are now very well established, it is possible that this material has the best coefficient of friction and produces the least wear debris in the body.

Zirconia ceramics are currently being investigated. They are less hard than alumina ceramics, they are easier to shape, are extremely strong but in some cases can break. Biological tolerance studies are currently being carried out and their biomechanical behavior in use is being characterized.

Silicon carbides could be used as friction surfaces for joint prostheses because they seem to be well tolerated, as the experimental implants have shown, but their long-term fate is not yet completely understood.

The use of massive cartilaginous allografts is being proposed more and more frequently by some international teams producing surprisingly good clinical results. The assimilation of these

cartilaginous allografts is excellent as cartilage cells do not need vascularization to survive. They are sustained only by the components of synovial fluid. However, in order for the mechanical behavior of the graft to be adequate for the purpose, it is necessary for the cells contained in the cartilage, which ensure its trophicity in relation to the hydrophilia of the proteoglycans, to be protected during the freezing phase. Hence the advantages of using a cryopreservative when the temperature drops and the option of using secondary sterilization by heat, gas, or irradiation is absent. This has to be particularly rigorous when grafts are being taken and osteocartilaginous fragments are being stored so that the graft is definitely entirely sterile.

Capsuloligament and Joint Replacement Materials

The frequency with which tendons and ligaments tear directs world research towards these areas. Artificial ligaments are used more and more frequently in clinical practice but their long-term fate is unclear.

Carbon fibers sheathed in polylactic or polyglycolic acid, polyamide fibers, or high-density polyethylene threads are currently being tested for fatigue but they are already used in human surgery. Dacron or Teflon ligaments have not given good mechanical results in the medium term and have led to inflammation.

Preserving human ligaments in tissue banks is also an avenue of research which appears to be promising but comes up against the problem of how tissue banks obtain their supplies and of the mechanical behavior of the grafted ligaments while they are being revascularized.

Mineral Structure of Bone

Approximately 70 % of mature bone is made up of an inorganic substance: calcium phosphate, and 30 % of an organic matrix, the main component of which is a fibrous protein: collagen.

The exact nature of this mineral phase, which has been studied mainly by X-ray diffraction, remains unclear. Furthermore, it appears to be an established fact that the nature of this phase varies as the bone ages.

Several main components are frequently suggested:

brushite: $CaHPO_4 \cdot 2H_2O$
octacalcium phosphate: $Ca_8H_2(PO_4)_6 \cdot 5H_2O$
amorphous tricalcium phosphate: $Ca_3(PO_4)_2$
apatite, classically hydroxyapatite: $Ca_{10}(PO_4)_6(OH)_2$

The crystallites of bone apatite are small and often carry impurities. PO_4^{3-}, Ca^{2+}, and hydroxy-apatite hydroxide are replaced by carbonate, Mg^2, and fluoride respectively. Compared with mineral hydroxyapatite, these imperfect crystals are more soluble and easily dissolved during resorption in the acid environment of the brush border of the osteoclastic cells.

The smallest unit of crystalline structure of the apatites contains 18 ions and it appears probable that such a complex structure is formed de novo from ions in solution. Progression through simpler forms has been demonstrated in vitro. However, these forms are unstable and difficult to demonstrate in vivo. The fluid environments of the body are said to be metastable in terms of their calcium and inorganic phosphate concentration. More precisely, that this concentration is below that of the concentration necessary for spontaneous precipitation but well above the concentration needed for the growth of the crystal if apatite crystals are present in the solution.

This therefore leads us to consider two very different phenomena:

the initiation of mineralization or “nucleation”,
the growth of the first crystals formed.

Progression of Mineralization

It has been demonstrated in vivo that more than 90 % of mineralization takes place normally by the growth of pre-existing crystals. As far as the growth of the mineral phase is concerned, the problem here is how to control it. Indeed, once

mineralization has started in a metastable environment, it should continue until all the ions are used up. If this were the case, we would all be turned into a pillar of salt like Lot's wife. Mineral growth is therefore tightly controlled and regulated. Three factors play an important role: collagen, certain non-collagenic proteins, and proteoglycan.

Collagen

Initially considered to assist in nucleation, bone collagen essentially of type I helps in the formation of apatite in vitro and in particular organizes crystallization. The crystals are deposited parallel to the axis of the collagen fibrils and denaturing of the collagen disturbs this precipitation. Therefore, although in vivo studies tend to call into question the role of collagen in nucleation, it has an essential organizing role during the growth of the crystals.

Non-collagenic Proteins

Several non-collagenic proteins have been extracted from different calcified matrices. Two large groups have to be distinguished; the phosphoproteins and the GLA proteins (or proteins carrying gammacarboxyglutamic acid). The phosphoproteins have been isolated from bone, dentine, enamel, and calcified cartilage. Some phosphoproteins are more closely bound to collagen. Various roles have been suggested: orientation of the crystals, the control of their shape and size, or even a support role in particular in tissues which do not contain collagen, such as enamel. Osteonectin, a phosphorylated glycoprotein specific to bone tissue, is thought to help in binding calcium to collagen.

GLA proteins have been suggested as being the agent which regulates mineral growth but their role is still unclear and controversial. Their interest lies particularly in the possibility that a radioimmunological assay could be carried out on the serum, which would be a reliable and sensitive marker of bone remodeling activity.

Proteoglycans

These consist of a central protein of hyaluronic acid and of carbohydrate chains formed from the repetition of sulfated disaccharide units. Essential components of cartilage, proteoglycans have also been isolated from mineralized tissues.

Proteoglycans of bone are thought to be smaller and immunologically specific. It has been suggested that they play a role in calcification on account of the fact that there is a lower level of these in calcified tissues than in non-calcified tissues. Furthermore, in epiphyseal cartilage, the proteoglycans are thought to become smaller and fewer in number close to the calcification front. Moreover, proteoglycan aggregates inhibit the formation of apatite. The idea that proteoglycans indispensable to nucleation are transformed has therefore also been suggested. However Blumenthal has shown that the subunits, like the aggregates, inhibit mineralization. Poole et al., using immunofluorescence techniques, challenge the classical ideas of proteoglycans being reduced during endochondral ossification. In their view proteoglycans continue unchanged when mineralization starts and are only modified during immature primary bone modeling.

Bone Remodeling

Bone resorption and formation take place in a perfectly organized manner. The phenomena are most stereotypical in cortical bone. In old bone, and under influences which are currently little understood but which are certainly biochemical in nature, a population of osteoclasts appears which hollows out a resorption cavity which grows 7–9 microns a day up to a diameter comparable to that of a haversian osteon, and in particular advances into the bone, in a direction determined in particular by the mechanical constraints at a rate of 40–60 microns per day, thus producing a tunnel-like structure. After an intermediate phase (reversal phase), the osteoblasts appear on the walls of the cavity which initially deposit 8–10 lamellae of osteoid tissue and then, owing in particular to the osteoblastic alkaline phosphatases, cause the mineralization of this osteoid. Approximately 10 % of the osteoblasts remain in the bone tissue formed in this way and, when they mature they become osteocytes, reunited with each other and communicating with the cells remaining on the

surface of the residual canal by prolongations using a rich and anastomotic canalicular system. The end structure created in this way is the haversian osteon.

The resorption phase lasts approximately three weeks, the formation phenomena are spread over three months. In the trabeculae of the spongy bone the phenomena are the same but their spatial layout is different. Osteoclastic resorption takes places and advances on the surface of the bony trabeculae, forming Howship's lacuna, subsequently covered, there too, with osteoblasts transforming and then mineralizing the osteoid tissue. In this system, described by Frost, the site being remodeled is called the "basic multicellar unit" (BMU) and the cells which form it are called the "basic structural unit" (BSU), the end result of this remodeling is the haversian osteon.

Any pathological condition of the bone, and in particular diffuse conditions affecting the skeleton, is the result of an anomaly, varying in nature, of remodeling and of its elementary phenomena, with resorption always preceding its formation except in very specific cases (early stages of bony callus or ossifications of the soft tissues for example).

Morphology and Bone Mechanics in Hypodynamia

During its development each bone acquires a shape and a mass which is determined genetically in such a way that it has sufficient mechanical competence to perform the usual human activities. This acquisition requires the bone to be put into control, which allows it to be modeled during growth, followed by permanent remodeling throughout life. Physical activity therefore has a vital role to play in obtaining and then maintaining sufficient bone mass. A sedentary person will have a weaker bone mass and will be more likely to suffer fractures when making unaccustomed efforts. On the other hand, people who have been practicing a sport or an intense physical activity for a long time will have a higher bone mass or bone density than average (weight lifters, ballet dancers, tennis players) and may even thus be able to compensate for a diet which is extremely low in calcium, as is the case in some Equatorial areas.

The osteogenic stimulus therefore has a permanent effect on the bone, which continually adapts to this stimulus. Trabeculae of bone in children organize themselves in line with increasing functional activity, adopting an orthogonal arrangement according to the main force lines. This arrangement gives the system maximum strength with minimum bone tissue. On the other hand, cortical bone does not have the same mechanical requirements and its structural objectives are also different. There does not appear to be any clear relationship between the usual structure of the compact bones and the forces to which they are regularly subjected, but the ability of the bone cortices to react to a high local force is still possible (the end of a hip prosthesis, for example). Functional adaptation therefore affects the shape and mass of the bone from a basic level determined genetically, to a structurally adequate level. Nevertheless, each bone adapts itself independently; it is therefore the bone overall which adapts itself to the mechanical forces rather than specific tissue structures. The cell population of a bone is therefore able to assess the forces exerted on this bone.

Not only is the adaptation of the bone sensitive to the intensity and distribution of the force exerted, but in particular to the variations in this force. Static forces therefore appear only to have a moderate effect on bone remodeling and if they increase excessively, this can have a paradoxically negative effect.

It also seems that four daily compression cycles are sufficient to counterbalance the effect of immobilization, and that 36 daily cycles allow the maximum effect to be obtained.

Hypodynamia has a rapid and negative effect on the bone formed: the absence of forces exerted no longer allows the bone to adapt itself permanently, and opens the field to various biochemical and hormonal influences, of which adequate physical activity is the necessary counterpart. It has an identical effect on the

growing bone, which without adequate stimulation does not acquire the architecture or reach the bone mass critical for it to be compatible with normal functional activity (the sequelae of poliomyelitis, for example).

Epiphyseal Cartilage

Continuous axial compression slows down the growth of connecting cartilage. The clinical applications (epiphyseal agraffing when the length of the lower limbs is unequal) are evidence of this.

Increased axial compression leads not only to a resumption of the activity of the epiphyseal cartilage but to an even more rapid rate of growth than normal. (Bonnel's experience, growth spurts observed in children confined to bed). This hypothesis explains the apparently contradictory results for stresses on flexion. During the day, when under pressure, the part of the epiphyseal cartilage subjected to compression in the resolution of a stress on flexion grows at a reduced rate. At night, or when not under pressure, the growth rate of this same part is accelerated. The sum of these two phenomena is thought to have a positive effect on growth with, in all, a more rapid rate of growth than for the part of the cartilage subjected to traction, still in the context of flexion.

These considerations apply, of course, to stresses greater than those physiologically endured by epiphyseal cartilage but less than the pathological stresses for maintaining the biological competence of this cartilage. The effects observed combine to produce a biologically healthy epiphyseal cartilage.

Articular Surfaces and Friction

The types of friction of the articular surfaces can be of the limited type (or Coulomb's type) or of the viscous type. In the limited type, for a light load and a slow rate, friction occurs via a substance with remarkable sliding properties, absorbed in the articular surfaces.

In the viscous type, for a heavy load and a rapid rate, a continuous liquid film permanently separates the two articular surfaces. The thickness of this film depends on the stresses which are exerted normally on the surfaces and the rate at which they move in relation to each other.

These two types of friction occur in human joints. They were demonstrated experimentally by studying the way in which the oscillations of a pendulum decrease when attached to a joint: a linear decrease in the case of limited friction, an exponential decrease in the case of viscous friction.

Lubrication and Pathology

The synovial fluid of joints affected by rheumatoid arthritis has proved to be a slightly less-effective lubricant than normal fluid. The fluid taken from arthrosed joints is thought to be better, almost as good as normal fluid. In the opinion of Little et al. (1969), there is no significant difference between the coefficients of friction of normal hips and those of joints manifesting fibrillation phenomena. There is no evidence to date to suggest that a lubrication disorder is at the root of degenerative phenomena observed in clinical practice.

Finally: Tomorrow, Will Man Be Artificial?

If advances in technology continue at the current rate, it may be that many materials used today will be abandoned in years to come, but that, on the other hand, new products will appear on which the arthroplasties of the year 2000 will be based.

The reconstitution of joint cartilage by collagen, osteocartilaginous allografts, or artificial substances will allow huge strides to be made in the treatment of arthroses, the number of which increases as people live longer.

Methods of fixation for joint prostheses – biological fixation, new cements, so-called "intelligent" materials (nitinol and monocrystalline

aluminas), or even bone grafts sheathing a metallic prosthesis – will enable the prosthesis to be better tolerated by the body. However, no-one can predict how this area will develop as chemists and metallurgists will without a doubt discover some new materials which will turn the future of the science upside down.

Artificial organs are now part of the usual arsenal of medical solutions. But can we expect to see an artificial man tomorrow? The list of artificial organs which are currently available or are being created is so long that it is becoming increasingly difficult to draw up a comprehensive list of them. Artificial skin is currently being developed for very severe burns. Cell cultures of osteoblasts or chondrocytes could, in the near future, cover bone substitutes or recolonize them.

However, all these artificial organs are expensive. The cost of the worldwide use of artificial kidneys or renal dialysis, for example, is several billion dollars (and in the case of France alone, 1 % of the social security budget). It can well be imagined that the cost of creating very complex prostheses which can be used by only a small number of people could well be prohibitive, particularly for the most severely affected patients or the elderly who have relatively limited life expectancy.

Is it preferable to use grafts or artificial organs? In some cases it would be preferable to use prostheses and in others grafts. It would seem that the graft is the final element which would make it possible to save the patient, the prosthesis only allows him to wait until his graft can be implanted.

Combinations of prosthetic materials and biological materials are now used more and more frequently, whether it is a bone graft sheathing a prosthesis, or artificial skin made of human cells and cultured, or even live pancreatic cells developing within a synthetic structure.

In truth, it is worrying to think how far it could go, and whether one day it would be possible to create a wholly artificial man or carry out a succession of grafts aiming to replace the various components of the human body. For the moment it is still impossible to replace live organs with artificial organs which are as reliable, and in particular have the same capacity of self-repair as scar formation. Furthermore, their incorporation will without a doubt pose problems in the long term.

Nevertheless, the progress we are constantly making in the development of biocompatible implantable products – ever smaller circuits, ever more powerful software, and in particular live grafts assimilating perfectly into the body in which they are placed – give us real hope.

Part II

Biocompatible Materials

Biomaterials Used in Orthopedics

2

Dominique G. Poitout

The great advances in orthopedic surgery over the past few decades and the fact that it constantly out-performs itself are the result of a policy of rigor in various areas.

Rigor in the training of the surgeons in this discipline, which demands a long period of training in specialist departments.

Rigor in performing operating techniques as a result of which hazardous improvisation is excluded.

Rigor in the choice of materials, the use of which has opened up the way to progress but the quality of which determines the results.

Precision and reliability are therefore the key words of the orthopedic surgeon who is preparing and executing an osteotomy in the same way as an engineer approaches the bridges and road surfaces for the arch of a bridge. He needs a good knowledge of the laws of physics and of the rules of mechanics, but he also has to be able to apply this knowledge to living matter.

I also believe it to be important to stress that orthopedists are clinicians and care for patients and that, if clinical practices develop in a direction which is not in line with their wishes, even though the theory and the calculations are accurate, we should not try to understand how this should work but why it does not work. Indeed, there are so many parameters involved in human clinical medicine that it is often difficult, when trying to describe a movement or define the stresses on a particular material, to take all the normal physiological parameters into account.

Behavior of Biomaterials in Situ

Although the functional aspects of implanted materials can be anticipated fairly reliably, it is very often difficult to anticipate how well they will be tolerated clinically. For materials of any kind there are two aspects which have to be taken into account. They are:

on the one hand the *adhesion* between a biomaterial and the part of the human body with which it will be in contact,
on the other, the *aging* of the product implanted.

Adhesion involves all the problems of using cements and adhesives, the role of which is to transmit and distribute the stresses over the largest area of contact possible. This adhesion problem is far from being resolved satisfactorily from the practical point of view and there is still plenty of scope for the researchers to investigate. Should

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a prosthesis be cemented, screwed, or introduced with force, hoping that its irregular surface will allow the bone to grow again and for the prosthesis to be fixed into the bone? More and more surgeons are currently abandoning these latter methods because of the frequency of painful failed fixations requiring surgery to be repeated (6–8 % on average after 12 months). Cement has its drawbacks but according to the current state of knowledge seems to be the best compromise for fixing material into bone.

Aging. As soon as it has been implanted in the body, the biomaterial finds itself in an environment which is more aggressive than sea water, not least on account of its higher temperature and its sodium chloride content. Furthermore, there are also the variations in pH which may lead to a rapid breakdown of plastics and may accelerate_metal corrosion.

I would like to dwell on this problem of metal corrosion for a few moments. Some metallic materials are very resistant to generalized corrosion. This is the case for Vitallium, stainless steels, or alloys based on titanium, but they are still vulnerable to corrosion if pitted, the risk of which increases with contact friction which leads to breaks in the protective passive layer. It is also necessary to take into account the simultaneous action of the corrosive environment on the prostheses and the mechanical stresses to which they are subjected. This results in the risk of corrosion under stress, and corrosion due to fatigue which can lead to the appearance of weak points with the risk of breakage. Another well-known case of corrosion is galvanic corrosion caused by placing two different metals in contact with each other in a conducting liquid which then behave like an electric battery.

When there is corrosion, metal ions pass into the body. Therefore, some studies have shown that for austenitic stainless steel osteosynthesis plates, 9.1 mg of the alloy passed into the body 2 years after having been implanted. That is to say that there is a release of iron, nickel, and chromium in an equal proportion to that of the composition of the alloy. For example, in an individual who had had intramedullary pinning of the tibia, after 18 years he was found to have a nickel concentration in his serum, urine, hair, and nails which was up to 18 times the normal concentration, almost the same level as is found in workers in the nickel industry.

More generally, the implantation of foreign material, and particularly a metallic material, always has consequences for the surrounding biological environment. It was even possible to demonstrate a transformation of the proteins left in contact with nickel, in particular by electron transfer at the metal–electrolyte interface.

The problems listed above therefore require the practitioner to know the mechanical and chemical properties of the materials to be implanted without, of course, forgetting the sterilization conditions which can alter certain materials (such as gamma rays on plastics, ethylene dioxide absorbed by certain materials then released producing toxic reactions).

If the surgeon cannot check all the properties of the material he uses by appropriate tests, he has to rely on the manufacturer's literature to make his choice. But if he knows the properties that he can expect for a given application, the dialog will be more to the point.

That is the current direction in the area of French orthopedics.

Biomaterials Used in Orthopedics

As it would be excessive to give an exhaustive list of all the biomaterials used in orthopedics, we will only take a few examples from each of the five main classes of orthopedic biomaterials;

metals and metal alloys,
ceramics and ceramo-metallic materials,
bone replacement materials and allografts
carbon materials and composites, polymers.

Metal Alloys and Metals

First, where steels are concerned, the introduction of alloys leads to a spectacular improvement in oxidation. Molybdenum plays an essential role in resistance to corrosion caused by pitting.

Chromium also plays an essential role from the point of view of corrosion. Indeed, exposed to

the air or to an oxidizing environment, chromium allows a very thin, invisible film of chromium oxide to form – this is called the passivation phenomenon. A minimum chromium content of 12 % is necessary to give steel its stainless properties.

Other elements can be added; this is true for nickel which, when in a proportion of 10–14 %, makes it possible to obtain an improvement in mechanical performance without leading to brittleness.

Steel with a high carbon content is therefore suitable for temporary surgical implants (osteosynthesis plates, intramedullary nails) because of its malleability and its stainless properties. But its poor prolonged resistance to corrosion means that it has to be removed after a few years.

Alloys based on cobalt–chromium are shaped by microfusion or casting, which is less good mechanically, and only very rarely has it been possible to make forgeable alloys, owing to considerable additions of molybdenum, tungsten, and nickel.

Although these materials have a resistance to corrosion and a breaking load which is better than stainless steel, their elastic limit is very close to the breaking load, which prevents any possibility of permanent deformation. And, as their resistance to fatigue is low, a significant breakage rate has been seen for femoral implants.

Their modulus of elasticity is high, at around 200,000 MPa, which poses the same problems as when using stainless steels (the modulus of elasticity of a bone being less than 20,000 MPAI). Due to their great hardness, alloys based on chromium and cobalt are the best compromise to date for making prosthetic femoral heads.

Titanium alloys have high resistance to all forms of corrosion and have good mechanical properties. Their modulus of elasticity is low, 110,000 MPa, which is half that of other alloys such as stainless steels. They have excellent biocompatibility, a high breaking load, and an elastic limit close to that of the breaking load, which eliminates any problems of permanent deformation in the case of high stresses, but also limits their use as a material in osteosynthesis. Owing to the passivation phenomenon, titanium covers itself spontaneously with a protective film of titanium oxide which renders it remarkably resistant to corrosion. This can be increased even further by the chemical process of anodization. There is one negative element that should be emphasized which is that titanium alloys have poor friction properties in that it is not possible to use them as prosthetic femoral heads or in the axis of a hinged prosthesis. Current trials, aiming to improve the friction characteristics by laying down deposits of titanium nitride or carbide, have not been very successful because these deposits are irregular and thin so that the layers abrade after a few thousand cycles.

Hydrogen or nitrogen ion inclusion techniques are still at the experimental stage.

Finally, the alloy most frequently used currently is an alloy containing a combination of aluminum and vanadium; Ti_6AP_4V, which has properties clearly superior to those of nickel–chromium–cobalt alloys. This is certainly the best solution today for all diaphyseal implants, particularly femoral hip implant which is subjected to high mechanical stresses.

Other metallic biomaterials could, in future, be useful in orthopedics; more specifically zirconium, tantalem, and nobium, all three of which display excellent biotolerance. However, progress still has to be made with alloys before they can rival titanium alloys.

Ceramics and Ceramic–Metal Compounds

Ever since man discovered that fire can modify the properties of clay (hydrated aluminum silicate), ceramics have never stopped developing. New ceramics have been developed and these materials take various forms:

oxides: aluminum oxide (Al_2O_3), zirconium oxide (ZrO_2),
carbides: silicon carbide (SiC),
nitrides, bromides, and fluorides.

The science of ceramics has also meant that new textures can be created such as ceramic composites with various fibers combining metals and ceramics, which are called ceramic–metals or

even cermets. There are also controlled crystallization glasses called vitroceramics.

The New Ceramics

Sintered oxides are either pure oxides such as alumina or mixtures of oxides. When high-purity alumina is used in the medical field, the specification is extremely precise. Alumina is a hydrophilic material (unlike polyethylene which is hydrophobic), it is very hard, slightly less so than diamond (which is, moreover, used to grind and polish it), and its modulus of elasticity is 380,088 MPa, which is practically twice that of the metal alloys. Its resistance to flexion, however, is low, which limits the indications in which it can be used as an osteosynthesis rod or plate. When alumina was first used as a prosthetic hip compound, there were many failures of the femoral head when used with an acetabulum also made of alumina.

The two pieces machined for each other:

tended to jam if the slightest particle of wear debris came between them.
produced very little wear debris, certainly, but as these were crystals they led to synovial reactions comparable to microcrystalline arthritis.
prevented any isolated change in one of the pieces of the prosthesis if only one became damaged.

The existence of a high modulus of elasticity, far higher than that of methyl methacrylate and that of cortical bone, led to problems when sealing an alumina acetabulum with methyl methacrylate because unsealing occurred more frequently and usually occurred between the cement and the acetabulum and not between the bone and cement, as is normally the case. On the other hand, if the alumina acetabulum is directly screwed into the bone, the quality of the fixation is exceptional and the mobility of the implant normal because of the almost inevitable appearance of a film of fibrous tissue between the implant and the bone. The use of alumina currently, therefore, seems to be restricted to femoral heads and sliding surfaces in contact with polyethylene.

Zirconia (ZrO_2) also has excellent mechanical properties, in particular flexion, together with satisfactory resistance to wear and friction, but in some cases it breaks! We hope that zirconias stabilized by yttrium oxide (Y_2O_3) and by alumina ($R_{12}O_3$) will be used routinely as friction components in total prostheses of the hip.

Carbides and Nitrides: These new materials include silicon carbide, which appears to have greater resistance to flexion than alumina as well as a higher modulus of elasticity, but its coefficient of friction is lower than that of alumina.

Ceramic–Ceramic and Ceramic–Metal Compounds

Fiber composites are a compromise between a deformable solid (for example, carbon fibers or alumina fibers) and a matrix which resists deformation (such as alumina or silicon carbide). To date, the first experiments with mixtures of aluminum oxide and iron have not produced useful results for improving the properties of the material. On the other hand, other combinations with molybdenum and its carbide, with tungsten and its carbide, or with titanium combined with zirconium oxide, seem to improve the resilience and toughness of the material considerably.

Glass and Vitroceramics

The mechanical strength of some glasses can be greatly improved by being transformed into vitroceramics. Direct anchoring, as for conventional ceramics, can, together with glasses and the vitroceramics, be performed by mechanical or chemical processes. In the case of vitroceramics anchored mechanically the dimensions of the interconnections between the pores are sufficiently large to allow colonization by bone tissue. Unfortunately, the mechanical properties of these vitroceramics are relatively poor. Resistance to breakage on flexion remains around 20 MPa, which is far too low for use in internal prostheses.

It seems that glasses and vitroceramics anchored chemically give better results. These materials initially have better mechanical strength than those of porous materials and are better than those of bone, but these criteria do not last. On