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Challenges in Materials for Health Care Applications

Implanted Devices
Tissue Replacements
Biocompatible Polymers

By David F. Williams*

Important issues face the use of advanced materials in medical applications. It is now possible to replace or augment many tissues and parts of the body by implanted devices, but there are still severe limitations to functions they are able to perform and problems associated with their compatibility with the tissues. Biomaterials of the future need to simulate more closely the tissues they are replacing and both the current position and future outlook are reviewed in this light.

1. Introduction

In the fifty years that have now passed since the invention of Nylon by *Wallace Carothers*, we have witnessed many changes in materials science and in the contribution of materials science to the welfare of mankind. This paper will discuss and review the current status of, and future challenges for, the uses of materials in one specific aspect of this contribution, that of implantation within the tissues of the human body.

There are many reasons why it is necessary or desirable to place some of today's advanced materials within the body,[1] but it is not the purpose of this paper to review them in detail. Some of the major reasons, and the current technical advances that have been made, are now well-known (Table 1). The twin diseases of rheumatoid and osteoarthritis are unfortunately very common, but the surgical technique of joint replacement, developed to overcome the pain and disability caused by these diseases is widely practiced, and has become a familiar landmark of late twentieth century surgery. Cataracts in the eye are now effectively treated in some half

[*] Prof. D. F. Williams
Institute of Medical and Dental Bioengineering
University of Liverpool
P.O. Box 147, Liverpool L69 3BX (UK)

Table 1. Some current applications of implanted devices.

Clinical area	Implant	Tissue replaced or augmented
Orthopedic surgery	Total joint replacement	Bone, cartilage
	Fracture fixation	Bone
	Ligament repair	Ligament
Cardiovascular surgery	Mechanical heart valve	Valve leaflet
	Bioprosthetic heart valve	Valve leaflet
	Vascular prosthesis	Blood vessel
	Pacemaker	Nerve
Ophthalmology	Intraocular lens	Lens
	Keratoprosthesis	Cornea
Ear, nose and throat	Ossicular replacement	Bone
	Cochlear stimulation	Cochlea/nerve
Maxillofacial	Dental implant	Teeth
	Fracture fixation	Bone
	Mandibular reconstruction	Bone
Plastic surgery	Breast reconstruction	Soft tissue

a million patients a year by the removal of the offending clouded lens and its replacement with a polymeric intraocular lens. Dental caries and, to a lesser extent, periodontal disease, affect most people at some stage, and the various procedures of restorative dentistry used to replace or treat these tissues utilize a great variety and volume of synthetic materials. Fewer people suffer from disease of the cardiovascular and peripheral vascular system, but the problems, when they arise, are of far greater consequence and significance. One method of treatment of such disease is the surgical replacement of the affected tissue.

Within this range of uses, the precise requirements of function will also be varied. It must be noted that, at the present time, the functions performed by the materials and devices of implant reconstructive surgery are quite simple in relation to the functions of the tissues they replace. Ideally, a replacement should possess all of the functional characteristics of the tissues, but this is rarely possible. In most cases it is a simple mechanical or physical function that is obtained, very frequently the implant merely acting as a space filler. It is very exceptional for more complex functions, especially involving biological activity, to be sought or achieved. The challenge for materials in these applications is to provide more sophisticated function, including biological and pharmacological function, while maintaining the appropriate mechanical or physical performance.

2. The Functional Replacement of Tissues

If it is intended to replace diseased, damaged or otherwise lost tissue by a functionally analogous structure, it is sensible to consider the nature and characteristics of these natural tissues. At the molecular level there are many different components involved. Water is the most abundant compound; this is not a trivial comment, since virtually all synthetic materials are unhydrated. Dissolved in this water are a variety of acids and bases as well as a vast array of both soluble and structural proteins, carbohydrates, lipids and nucleic acids. Complex as these organic molecules may be, the development of materials to simulate or mimic them is not the real problem. Figure 1 demonstrates the close similarity between the repeating molecular units in a synthetic polyamide, and two common, although non-human organic molecules, silk and wool. Many other examples can be found of the essential

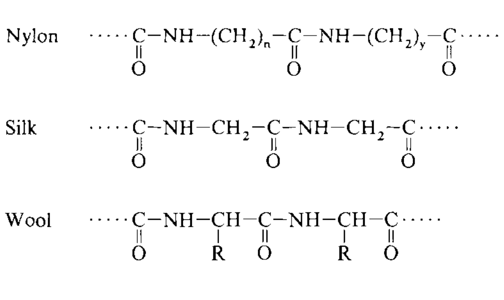

Fig. 1. A comparison of the molecular structures of a synthetic polymer (Nylon) and two natural polymers (silk, wool). After *Richardson*.

equivalence of the repeat units in natural biopolymers and synthetic polymers.

The real problem lies with the fact that these molecules constitute just the basic level in the structural hierarchy of tissues and that the higher levels are far more difficult to rebuild. The tissue itself, apart from the water, contains both cellular and extracellular structures. Cells are not only varied in their structure and function, but are also extremely complex entities whose activity is as much dependent upon the ability to receive information, for example for highly specific receptors on their membranes, as on the ability to react to this information. Perhaps the simplest cell is the erythrocyte, or red blood cell, since this consists of a thin membrane which contains a solution of hemoglobin. It has been possible to prepare structures which simulate this cell and possess some of the functions of hemoglobin transport, but the development of more complex artificial cells using conventional materials is rather difficult to contemplate.

Cells possess varying degrees of mobility. Some, notably those of the musculo-skeletal system, are essentially fixed within an extracellular matrix. This matrix often consists largely of structural proteins such as collagen and elastin and is in some cases reinforced by deposits of minerals, specifically hydroxyapatite in the case of bone, dentine and enamel. In this type of system it is as much the spatial distribution of the various components and their interfacial relationships that control the performance of the tissue, as it is the molecular nature of the components themselves.

The structure of bone provides an excellent example of this, which is, of course, very relevant to implantable devices.[3] The structural protein of bone is collagen, which has a well recognized molecular and fibrillar structure. The collagen is itself arranged with a microstructure, described in terms of a Haversian system, in which there are cylindrical, concentric layers of collagen (Fig. 2). There are lengthwise

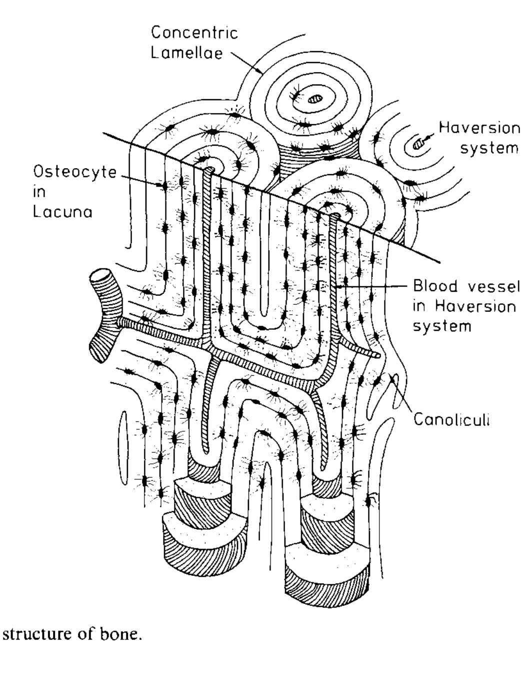

Fig. 2. The structure of bone.

canals containing blood vessels, small spaces containing the blood cells and a myriad of ultrafine canals, the canaliculi. The collagen contains a multitude of nanometer-sized crystallites of calcium hydroxyapatite.

At a macroscopic level, the bone may be arranged in a reasonably dense way (cortical bone) which comprises most of the major structural part of long bones such as the femur and tibia, or it may be arranged in a more open, porous form, known as cancellous bone, which is found in the ribs, the pelvis and elsewhere.

The mechanical and physical properties of a bone (as a structure) depend on all of the molecular, microstructural and macroscopic arrangements discussed above, making it a multicomponent composite structure, with considerable anisotropy. The functional characteristics of bone are complicated even more by its viable, dynamic nature. It does contain cells, which are in a state of constant turnover, and it does require a blood supply. Resistance to fatigue crack propagation is dependent on the vital ability of bone to blunt cracks. The relationship between the mineral phase and the collagen is controlled by mechanical stress via a number of mechanisms including piezoelectric and streaming potential effects. These and many other phenomena demonstrate the acute relationship between mechanical properties and biological characteristics which control functional performance.

Since bone, with this structure complexity, is one of the most straightforward of tissues to replace from a functional point of view, it is easy to appreciate the enormous difficulty of replacing some of the other tissues of the body. Two examples will serve to emphasize this point.

Skeletal muscle consists at the molecular level of proteins such as myosin and actin. They form long myofibrils combined to form muscle fiber which are arranged in bundles to form the muscular structure (Fig. 3). The molecular and fibrillar arrangement allows very high extensibility without excessive interatomic forces, a characteristic which is difficult to achieve in all but a few synthetic elastomers. The ability to elongate and contract, however, is not a simple passive function, but involves active movement of calcium ions, under the influence of electrical impulses, which initiates myosin and actin interactions and the sliding of myofibrils. The challenges to the functional replacement of muscle lie both within the extraordinary elastic performance and the ability to incorporate transducers in order to translate electrical impulses into elastic deformation.

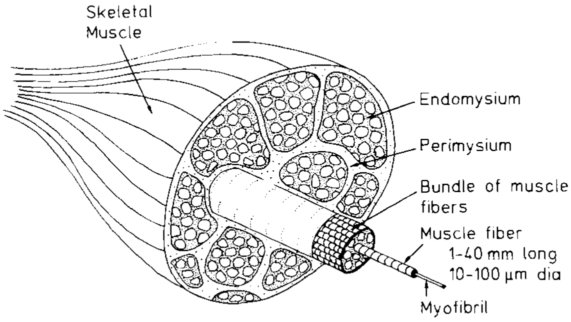

Fig. 3. The structure of skeletal muscle.

The vascular system, both in relation to the cardiac and peripheral circulation, appears to have a simple function, that of providing a series of conduits along which blood can flow, and gently assisting that flow. In reality, the mechanisms involved in producing the optimal hemodynamic conditions so that the organs and tissues receive their blood most efficiently are very complex. Considering the arterial system, an artery consists of a cylindrical connective tissue layer, a smooth-muscle layer within this, a cylindrical elastin membrane and finally, on the inner aspect, a layer of endothelial cells (Fig. 4). The functions of importance are two-fold, relating to the mechanical performance of the wall and also the interaction between the endothelial cells (or underlying connective tissue if damaged) and the blood. The mechanical performance is vital. Since it is necessary for blood to flow with laminar characteristics under pulsatile conditions, both the elasticity, compliance and geometry are important. Of equal, if not greater, importance is the need for this contact with flowing blood to take place without adverse effects on the blood. Blood is a medium that contains several defense mechanisms that can only operate under certain conditions, for example, blood has the ability to clot if the vessel is damaged. The clotting mechanism is very complex, but represents a sensitive balance between a variety of biochemical events. This balance can be easily upset and it is therefore a major functional requirement of these tissues that they do not themselves adversely interfere with these mechanisms.

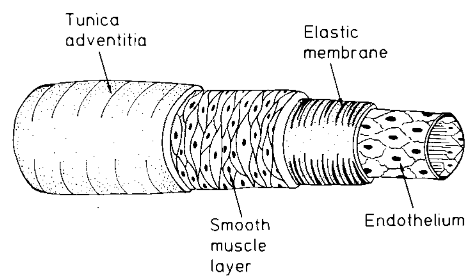

Fig. 4. The structure of an arterial wall.

3. The Characteristics of Current Biomaterials

At the present time, a wide selection of materials is used in implant surgery (Table 2) but in the majority of cases, because only a simple, single function is sought, these materials bear little resemblance to the tissues they replace. Examples include metals and alloys, such as an amalgam of mercury, silver and tin which replaces tooth structure,[4] and cobalt-based alloys, 316 stainless steel, titanium or Ti-Al-V alloys which replace or augment bone.[5] Clearly, these metallic materials have no molecular or structural similarities with

Table 2. Major currently used biomaterials.

Class	Material	Use
Metal	Amalgam	Restoration of teeth
	Titanium/Ti–Al–V	Bone replacement/repair Dental implant Maxillofacial implants Encapsulation of electronic devices
	Stainless steel	Bone replacement/repair
	Co-Cr alloy	Bone replacement/repair
Ceramic	Alumina	Bone, joint and tooth replacement
	Hydroxyapatite	Coating on bone/tooth replacement Bone augmentation
Polymer	Polyurethanes	Arteries and other blood contact devices
	Polymethylmethacrylate	Dental restorations Ophthalmology Fixation of bone/joint prostheses
	Polytetrafluoroethylene	Arteries, soft tissue
	Polyethylene	Joint replacement
	Polyesters	Arteries, sutures

the tissues. There are also some ceramics. High purity alumina and transformation-toughened alumina possess some attractive properties of wear resistance and inertness,[6] but otherwise are quite unlike natural tissues.

Polymer-based materials are widely used[7] and possess a greater claim for similarity with tissues than most materials. However, they still fall short, for although they are based, as indicated earlier, on an organic backbone, it is extremely difficult to organize their microstructure in an appropriately biological way. Current polymers in use include polyethylene and polypropylene, acrylics, polyamides, polyesters (both aromatic and aliphatic) polyurethanes and silicone polymers. Most of these are single phase structures, either thermoplastics, cross-linked polymers or elastomers, with little evidence of any structural hierarchy. In some cases multiphase structures with domains and segments are available and of course certain composites, both fiber and particulate, are emerging. Even here, however, there are still major structural differences from the anisotropic heterogeneous natural products.

4. Some Concepts in the Development of Biologically Analogous Materials

A few concepts and ideas that have emerged during the last few years are beginning to show real promise in the search for biologically analogous materials.[8] It should be said that the ultimate solution is the use of natural tissue itself. In many ways this is the most obvious and indeed oldest solution, for transplanted tissues have been used in selected cases for many years. Ranging from skin and bone grafts at one end of the range to heart transplants at the other, these materials and procedures are very variable in their success and applicability. The most successful procedures are those where simple tissues are transplanted from one part of a patient to another, but the occasions where a patient has an adequate supply of the required tissue, and when the loss from the donor site is repairable, are few and far between. The most difficult are those, such as major organ transplants, where donor and recipient are different, and although great strides have been made with immunosuppressive drugs to improve their acceptability, transplants of this type are always likely to have major problems facing their use.

Most of the technical as opposed to ethical and logistic problems associated with transplanted tissue relate to sterility and antigenicity issues. Foreign tissue generally elicits a response from the immune system and of course all tissue products transferred from one human to another have to be carefully screened for viruses such as those involved with hepatitis and AIDS. One potential solution to the dilemma of using natural tissues, but being concerned about sterility and antigenicity issues, is to take such tissues and treat them, rendering them non-viable but sterile and non-antigenic. The construction of prosthetic heart valves has employed this concept, with the use of bovine pericardium (the muscular tissue of the heart-wall of cows) or porcine valve tissue, in the fashioning of the leaflets of mitral and aortic valves, after fixation in glutaraldehyde.[9] While giving better biological performance than the alternative mechanical valves, these do suffer problems of long term calcification and degradation. It is not clear whether any treated soft tissue obtained in this way will ever be sufficiently stable for long term use in the body. Some success has been achieved with the use of bone harvested from donors and treated in some appropriate way, for example freeze-drying.

Tissue which is either transplanted in a viable state, or treated and rendered non-viable, usually retains its heterogeneity. An alternative approach to using these structurally complex tissues is to separate individual components from the tissue and use these for their specific properties. These components may be obtained by separation techniques using donor tissue or synthesized directly. Two examples are described here. First, there is considerable interest in the use of collagen preparations, especially for injection as soluble materials for cosmetic surgery.[10] Secondly, the mineral phase of bone, hydroxyapatite, may be used for bone reconstruction or bone bonding applications either in its own right as an alternative to bone graft or as a coating on a tough substrate. In the latter case there is strong evidence that synthetic apatite allows new tissue-derived hydroxyapatite to be deposited epitaxially on its surface, hence producing material–tissue bonding.[11]

As a ceramic, hydroxyapatite cannot offer all of the properties of bone itself and suffers from inferior mechanical properties. Some attempts have been made to produce composite materials that are structurally analogous to bone in the hope of finding equivalent properties. One example actually employs hydroxyapatite as the dispersed phase in a matrix of polyethylene.[12] Others, including some carbon fiber reinforced thermoplastics, are less biological in composition, but possibly better mechanically. In situations where it is desirable to apply a biomaterial which can be shaped to a prepared bone cavity or to augment a deficient bone structure, for example the ridge of the mandible in patients without teeth, the same hydroxyapatite can be incorporated into some natural polymerizable substance. Of increasing interest here is the use of a fibrin glue as a matrix for the preparation of a composite with hydroxyapatite.

The assumption that natural tissue is the best replacement material, together with the problems of supply logistics, ethics, technique and acceptability, have resulted in several attempts to encourage regeneration of the patient's own tissues. Several years ago, for example, an "artificial" artery was prepared by the implantation of a mandril into tissues and utilizing the fibrous capsule that formed around it, although this was not particularly successful.[13] More recently, porous surfaces and totally porous materials have been employed, which, by manipulation of the pore characteristics can allow tissue ingrowth.[14] This may be used to secure anchorage of an implant to tissue via a porous surface or, when using a degradable porous material, complete tissue regeneration. Since it is usually only connective tissue that is able to regenerate in this way there are significant limitations to this approach and it cannot be used for highly specialized tissue.

The concept of using the biomaterial as a vehicle or matrix to support the growth of natural tissue has been taken in a different direction through the use of biomaterial-supported cells grown in culture. It is possible for certain cells, isolated from tissue and maintained under strictly controlled conditions in the laboratory, to carry out their usual function. If cells are taken from the tissue of a patient and grown in culture to an effective condition and concentration, they may be reimplanted, with an appropriate support, where they can provide an effective 'natural' replacement. This is being used, for example, for an artificial skin, in which epithelial cells from a patient with a major burns injury can be incorporated into a suitable degradable matrix and used in place of a skin graft. Also, endothelial cells may be cultured onto the surface of a vascular prosthesis, which will present a more natural surface to the flowing blood.[15]

A combination of cells and synthetic polymer has also been employed, at least experimentally, for an entirely different reason. The application mentioned above can only work if the cells are derived from the same patient in whom they are to be used because of the problem of the immune response to foreign proteins. If the cells of interest are not readily available in that patient, problems arise. Such a situation is seen in diabetic patients, for example. They do not have the cells that produce insulin, the Islets of Langerhans, and it is not possible to transplant such cells from a donor as they would be recognized as foreign and attacked by the immune defence system. However, it is possible to encapsulate donor cells in a polymeric membrane. If the structural characteristics of this membrane are selected carefully, it can allow the transport of glucose and insulin between the cells and the surrounding tissue, but prevent the passage of the much larger protein molecules of the immune system, inhibiting their immunological rejection.[16] This concept is leading to the development of so-called hybrid artificial organs such as, in this case, the pancreas.

A final approach to be mentioned here involves the surface modification of engineering materials to provide more biologically acceptable interfaces, especially those which attempt to mimic natural interfaces. Most examples are of blood-contacting surfaces.

Blood is a highly complex and sophisticated tissue which in the healthy patient flows through the cardiovascular and peripheral vascular systems without any interaction with the vessel walls. This lack of interaction represents a delicate balance between several events and many factors play a role. One of the more important factors is the relationship between the circulating platelets and the vessel wall.[17] Platelets do not normally interact with the endothelium, largely because the cells release a variety of substances, especially prostacyclin, which inhibit such interactions. If the vessel is damaged, or if a foreign material is placed within the vessel, then the platelets recognize a non-endothelial surface, adhere to it, and initiate a sequence leading to the formation of a clot. While this is a desirable reaction in the case of vessel injury, it is undesirable in the case of a biomaterial implanted within the vascular system for reconstructive purposes. There are many different approaches to controlling these blood interactions, but in one case a synthetic analogue of prostacyclin has been attached to the material surface. Such a surface imitates the natural endothelial surface and prevents platelet deposition.[18]

5. General Conclusions

This brief review has highlighted the major problems of implanting synthetic materials for advanced applications in the human body. If we are to succeed in using materials with greater reliability and more sophisticated performance, we need to face the challenges of developing advanced materials to meet the combined requirements of functional performance and biocompatibility. The more this approach leads to a merging of the concepts of synthetic materials and of natural materials, the better the prospects.

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Panel Discussion

Improving Effectiveness in Materials Research

By Gerhard Wegner *

High temperature materials, electronic materials, composites and superconductors are featured as regularly in the business press as in scientific journals. Materials science receives heavy management attention as well as public and political interest worldwide. The Materials Research Society (MRS), founded only a few years ago in the US, is rapidly growing into one of the largest professional societies, with offshoots on other continents. Despite the obvious successes of materials science as a field of industrial relevance and academic concern, the people involved do not seem to be very satisfied. One of the key issues is finding the proper balance between industrial or market driven research and development and the necessity to conduct in depth research of a basic nature to find and understand new materials. This issue is intimately related to the role of industry in defining and supporting research areas in academic institutions. Conversely, the transfer of basic knowledge, new insights and novel methods from the ivory tower of the university to the harsh and competitive ground of the industrial world does not seem to work well and finds many obstacles.

This, in a nutshell, was the content of a panel discussion organized and directed by Du Pont's *Rudolf Pariser*, Director for Advanced Materials Science in the Central Research and Development Center at Wilmington, Delaware, USA. The panel discussion was part of an Advanced Materials Conference celebrating the 50th anniversary of Nylon and the invention of Teflon, both products being cornerstones of the commercialization of polymeric materials.

[*] Prof. G. Wegner
Max-Planck-Institut für Polymerforschung
Jakob-Welder-Weg 11, D-6500 Mainz (FRG)

A Climate of Worldwide Competition and Collaboration

"The climate in Du Pont research is characterized by increasing worldwide competition and collaboration, the globalization of business and the need to respond quickly and specifically to market needs, energy and raw materials resources and environmental issues...", Dr. *Pariser* told the audience of more than 150 invited scientists from US and foreign universities, research institutes and agencies involved in materials science studies.

Du Pont's approach to research and development reflects the change of attitude towards materials science worldwide. As little as ten years ago, the laboratories were organized to emphasize specific polymeric materials, such as elastomers or textile fibers with relatively little interaction between them. Today, research has expanded beyond polymers and includes ceramics and metals as well. The emphasis is on materials systems and systems functionality. New fields are under development based on polymer composites and structural ceramics, inorganic fibers and molecular composites. Thus, an advanced materials laboratory has been created where many materials disciplines are combined into one organization with broad functional research themes. The trend is toward multidisciplinarity among the research staff as well. In addition, Du Pont has a rapidly increasing involvement with US universities. The more than US $ 25 million which were spent by Du Pont in 1988 alone to support university research programs was a substantial part of the total US $ 630 million by which US industry supported R & D at American universities.