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Biomaterials research and development

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Abstract. This paper discusses the importance of biomaterials technology and its wide ramifications in clinical practice. The current problems in biomaterials research such as characterisation, surface modification, safety evaluation and tissue-prosthetic bonding are out lined. The need for constant access to several discipline would seem to underline the importance of large integrated centres in the development of biomaterials technology.

Keywords. Biomaterials; biocompatibility; medical aids.

1. Introduction

The explosive growth of semiconductors, glassy metals and other advanced technology materials in recent years has tended to overshadow the development of prosthetic devices whose applications numbered between two million and three million in the US alone during 1980 (Abelson 1980). An earlier report by the Science Research Council of Britain estimated the world market for medical aids at £ 11,000 million which included approximately £ 4000 million for prosthetic devices and medical aids (Science Research Council, December 1977). The corresponding figures for India are not available, but the size of our population and the rapid growth of health care services leave one in little doubt that the demand for prosthetic devices and medical aids, actual and suppressed, is very large in India.

2. Current applications

For centuries, external prostheses have been in use for rehabilitating amputees and other physically disabled, but the development of internal prostheses for replacing diseased organs dates back to recent times. Dentures, metallic plates and joints, fabric grafts and artificial valves have become so well-known in contemporary practice that the world of biomaterials and bioimplants often goes unrecognised. The current range of their applications is listed in table 1.

The challenge of biomaterials arises from their imperative need to meet the exacting functional requirements of bodily organs. A tooth, for example, must have a tensile strength of 15,000 to 20,000 psi in flexure: the leaflet of a heart valve must have sufficient flex life to enable its opening and closure 100,000 times a day. These examples can be easily multiplied.

Apart from meeting functional requirements, biomaterials must satisfy the criteria of biocompatibility which postulate that tissues and implant materials must not cause

Table 1. Applications of polymeric materials

Polymer	Applications	Polymer	Applications
Epoxy resins	Bone adhesives Pacemaker Encapsulant	Acrylics PMMA	Optical items Cure-in-place material
Poly urethanes	Surgical sponge Blood filter Sutures Blood pump	Acrylic Hydrogel	Vitreous
		Cyano-Acrylates	Tissue adhesives
Polyamides	Disposables Sutures	Polyethylene	Sutures Eye surgery Disposables
Polyesters	Velours Implants Arterial prosthesis Sutures	Polypropylene	Tissue reinforcement Heart valve Blood filter
Silicones	Implants Lubricants Tubing Membrane oxygenator	PTFE	Implants Prosthetic vessels Sutures
		PVC	Disposables
		Metals and Alloys	
		Titanium	Bone and joint replacement Heart valves
		Chrome-Cobalt Alloys	Springs Dental wires Heart valves
		Silver Amalgam	Dental filling

mutual damage (Williams and Roaf 1973). The characteristics of biocompatibility are listed in table 2.

Another equally important determinant for the successful application of a biomaterial or bioimplant is its ability to establish a stable interface with living tissues. If the adhesion between the material and surrounding tissues is poor, the consequences in terms of implant failure and tissue damage can be serious. The control of the interface has been achieved so far by such techniques as chemical reactions, alteration of microstructure or surface reactivity. However, a molecular union between living and nonliving matter continues to remain elusive and offers an important field for future research.

The development of biomaterials has been taken up in recent years by scientists, engineers and physicians who share a common concern for patient welfare. As a result, new types of materials have been created with unprecedented combination of biological and physical properties; novel methods to characterise biomaterials

Table 2. Biocompatibility

1.	Not toxic
2.	Not inflamatory
3.	Not allergic
4.	Not carcinogenic
5.	Non thrombogenic
6.	Sterilisable
7.	Non corrosive
8.	Non degradable

and study their inter-faces have been developed and optimisation of implant design advanced to a stage when its function closely parallels the physiological function of organs.

3. Priority areas for research and development

Biomaterials science offers serious opportunities for interdisciplinary research. A few will be listed. To ensure consistency in composition, each batch of candidate materials needs to be characterised fully in terms of molecular weight distribution, thermal properties etc before tissue implantation. These tests must be repeated on implants which have failed or are removed at reoperation to determine and catalogue the degree of biological degradation of materials. Secondly, chemical and physical methods such as heparin bonding and glow discharge technique need to be expanded to make prosthetic surfaces compatible with different tissues which have characteristic environments. Thridly, the long term reliability of safety evaluation methods calls for improvement since the introduction of tissue culture technique merely represents a beginning in this direction. Fourthly, new methods to stabilise the tissue-prosthetic interface must be developed to eliminate a currently vulnerable feature of bioimplants. Lastly, performance prediction for the long-term function of implants offers rich fare for the bioengineers. These examples are illustrative of the breadth, scientific potential and practical importance of biomaterials research.

The priority areas for research, development and introduction of standards in medical aids are briefly discussed below.

3.1 *Catheters, blood bags and other hospital disposables*

This group covers a large variety of devices which are in wide hospital use and range from simple intravenous catheters of polyethylene to composite blood oxygenators. Their use is essential in all types of patient care as the application of catheters, blood bags and similar items is not confined to large hospitals.

3.2 *Contraceptive materials*

The technology of contraception demands new materials either for intrauterine devices, slow release drug carriers or blockers of vas, fallopian tubes or cervix.

3.3 *Dental materials*

This category constitutes a vast market and consists of filling materials, sealants, liner, impression materials and denture bases. Ceramic-filled polymers for anterior teeth filling, a radio-opaque low cost resin of high strength for denture base, adhesives with better adhesion and chemical resistance in the oral environment are examples of the current needs. Another area which holds promise for research is the application of modern theories of fracture mechanics and tissue - prosthetic interface to the development of new materials (Ritter 1978).

3.4 *Bone and joint prostheses*

Orthopedics leads in the medical use of bioimplants. The commonly used implants include nails, plates and total joints which have large scale applications in trauma and degenerative disease. The materials extensively used in their fabrication are vitallium, titanium, stainless steel, ultrahigh density polyethylene and acrylic cement. Much work is still needed to improve the compatibility, adhesion and wear of these materials and to match the respective devices to the biomechanics of bone.

3.5 *Arterial prostheses*

Graft reconstruction of large arteries which are severely damaged by disease or trauma has been an essential part of surgical practice for many years. Woven or knitted fabric tubes of polyester or PTFE are successfully used for replacing arteries larger than 1 cm in diameter. They are employed with less satisfactory results for replacing smaller arteries. Newer forms of porous PTFE and polyurethane are currently under trial for small vessel replacement (Lyman *et al* 1977).

3.6 *Heart valve materials*

The rigid housing of the ball or tilting disc valve is made of non-corrosive materials such as stellite or titanium and the occluder from dilicone, pyrolitic carbon or Delrin. The valve is provided with a polyester or PTFE fabric skirt for surgical fixation in the heart chamber. While these devices have functioned well for many years and given a new lease on life for many patients, there is a continuing need to work for a leaflet valve with truly central flow which would emulate the natural valve in flex life and haemodynamic function.

3.7 *Dialysis materials*

In patients with end stage kidney disease, blood is dialysed against a crystalloid solution through a semipermeable membrane to remove harmful metabolic products. This procedure which is repeated several times a week is the basis for life support in such patients. The use of semipermeable membranes have applications in other areas too such as oxygenation. Further development of microporous membranes from polymers such as cellophane, PTFE, polycarbonate and silicone has great promise for the future of dialysis and the removal of toxins from blood by sorption.

3.8 *Opthalmic devices*

Ultra transparent polymeric lenses have revolutionised contemporary opthalmic practice. New hydrophylic polymers with high water content are replacing conventional spectacles technology in several eye conditions.

The above list is by no means exhaustive. It will however bear out the importance of biomaterials technology for the health of millions.

4. Integrated research centre

While individual scientists or groups can and must make innovative contributions to biomaterials science, major advances will emerge from the effort of large multi-disciplinary groups which preferably enjoy industrial liaison. This is because the combination of skills in materials science, toxicology, biomedical engineering and medical sciences which are so essential for the development of biomaterials is unlikely to be found in a conventional institution or organisation. Western societies have tackled the problem by establishing close liaison among private industries, laboratories and universities with liberal support from private and public agencies. As the Western model is inapplicable to India, what is needed in the local context are large integrated centre which will bring together scientists, engineers and clinicians with necessary equipment and facilities for research in biomaterials. The Sree Chitra Tirunal Institute for Medical Sciences and Technology represents a new effort in this direction which will have a major influence on the growth of biomaterials science and health care technology in India.

The Institute consists of a modern hospital for advanced specialities as an integral part of a developmental programme for materials and devices in medical engineering. Its research campus includes active laboratories for the technical evaluation of materials, protein-polymer interactions, toxicological studies, polymer technology, biomedical engineering and experimental surgery which are responsible for the work presented in the following papers. They are indicative of the scientific importance of biomaterials as well as their technological promise.

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