CHAPTER 1

INTRODUCTION TO BIOMATERIALS ENGINEERING AND PROCESSING — AN OVERVIEW

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The success of a material to be used as a biomaterial in medical devices, apart from biocompatibility, is often related to the ability and ease of the material to be formed into complicated shapes. This chapter provides an overview of biomaterials engineering, paying particular attention on the effect of processing methods on the mechanical properties of biomaterials. The effects of grain refinement in metals and ceramics, molding conditions on polymeric wear, and composite lamination are discussed with the aim of introducing the many interesting materials engineering techniques that have been used to enhance the mechanical properties of biomaterials. The chapter concludes by introducing the concept of tissue engineering as the new wave in biomaterials engineering of tissues and organs.

1.1 Introduction

Biomaterials engineering is concerned with the application of biomaterials science in the design and engineering aspects of medical devices' fabrication. Traditionally the study of biomaterials focuses on issues such as biocompatibility, host-tissue reaction to implants, cytotoxicity, and basic structure-property relationships [1–8]. These issues are important. They provide a strong scientific basis for a clear understanding of many successful medical devices such as the mechanical heart valve. However in biomaterials engineering, the manufacturing and processing aspects emerge as a primary concern. While it may be easy to make a one-off laboratory prototype, it is extremely challenging to produce a thousand units of identical devices with good quality control, consistent properties and having to be packed in a sterile manner for storage and easy transportation. Topics such as durability, corrosion,

and surface modification are some essential elements in engineering biomaterials for medical applications.

As an example, Figure 1–1 shows the intricate engineering mold design involved in forming a polyurethane (PU) tri-leaflet valve using a thermoforming process. The tri-leaflet heart valve is an interesting design which mimics the natural aortic valve with a central flow. First, a biocompatible PU sheet is thermoformed over the leaflet mold to yield the three-leaflet shape with a central flow. Next, the outer three sinus lobes need to be formed over the leaflet. The valve must be made without any parting lines which are often seen in two-part injection molds. The parting lines can be detrimental as they are lines of weakness and subject to thrombus formation. An engineer developed a three-part mold that allows the PU sheet to be thermoformed over the assembled tool. The latter consists of three detachable lobes which can be unscrewed after the three-sinus-lobe mold is set.

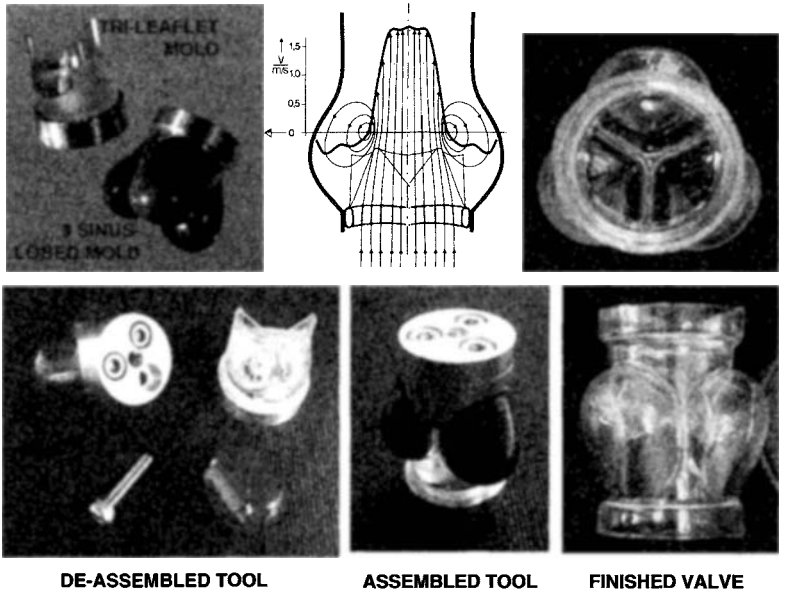

Figure 1–1 Manufacturing steps in making a tri-leaflet polyurethane valve. Note the complex die assembly needed to produce a seamless polyurethane valve by thermoforming.

1.2 Requirements of Biomaterials

Biomaterials must have special properties that can be tailored to meet the needs of a particular application — this is an important concept to bear in mind. For example, a biomaterial must be biocompatible, non-carcinogenic,

corrosion-resistant, and has low toxicity and wear [1,2]. However, depending on the application, differing requirements may arise. Sometimes these requirements can be completely opposite. In tissue engineering of the bone, for instance, the polymeric scaffold needs to be biodegradable so that as the cells generate their own extracellular matrices, the polymeric biomaterial will be completely replaced over time with the patient's own tissue. In the case of mechanical heart valves, on the other hand, we need materials that are biostable, wear-resistant, and which do not degrade with time. Materials such as pyrolytic carbon leaflet and titanium housing are used because they can last at least 20 years or more.

Generally, the requirements of biomaterials can be grouped into four broad categories:

1. **Biocompatibility:** The material must not disturb or induce un-welcoming response from the host, but rather promote harmony and good tissue-implant integration. An initial burst of inflammatory response is expected and is sometimes considered essential in the healing process. However, prolonged inflammation is not desirable as it may indicate tissue necrosis or incompatibility.

2. **Sterilizability:** The material must be able to undergo sterilization. Sterilization techniques include gamma, gas (ethylene oxide (ETO)) and steam autoclaving. Some polymers such as polyacetal will depolymerize and give off the toxic gas formaldehyde when subjected under high energy radiation by gamma. These polymers are thus best sterilized by ETO.

3. **Functionability:** The functionability of a medical device depends on the ability of the material to be shaped to suit a particular function. The material must therefore be able to be shaped economically using engineering fabrication processes. The success of the coronary artery stent — which has been considered the most widely used medical device — can be attributed to the efficient fabrication process of stainless steel from heat treatment to cold working to improve its durability.

4. **Manufacturability:** It is often said that there are many candidate materials that are biocompatible. However it is often the last step, the manufacturability of the material, that hinders the actual production of the medical device. It is in this last step that engineers can contribute significantly.

1.3 Classification of Biomaterials

Biomaterials can broadly be classified as: i) Biological biomaterials; and ii) Synthetic biomaterials. Table 1–1 shows the various classifications and some examples. Biological materials [3,4] can be further classified into soft and hard

tissue types. In the case of synthetic materials, it is further classified into: a) Metallic; b) Polymeric; c) Ceramic; and d) Composite biomaterials.

Table 1–1 Classification of biomaterials

I. Biological Materials	II. Synthetic Biomedical Materials
1. Soft Tissue *Skin, Tendon, Pericardium, Cornea*	1. Polymeric *Ultra High Molecular Weight Polyethylene (UHMWPE), Polymethylmethacarylate (PMMA), Polyethyletherketone (PEEK), Silicone, Polyurethane (PU), Polytetrafluoroethylene (PTFE)*
2. Hard Tissue *Bone, Dentine, Cuticle*	2. Metallic *Stainless Steel, Cobalt-based Alloy (Co–Cr–Mo), Titanium Alloy (Ti–Al–V), Gold, Platinum*
	3. Ceramic *Alumina (Al_2O_3), Zirconia (ZrO_2), Carbon, Hydroxylapatite [$Ca_{10}(PO_4)_6(OH)_2$], Tricalcium Phosphate [$Ca_3(PO_4)_2$], Bioglass [$Na_2O(CaO)(P_2O_3)(SiO_2)$], Calcium Aluminate [$Ca(Al_2O_4)$]*
	4. Composite *Carbon Fiber (CF)/PEEK, CF/UHMWPE, CF/PMMA, Zirconia/Silica/BIS–GMA*

1.4 Mechanical Properties of Biomaterials

The mechanical properties of a biomaterial can best be described by its modulus of elasticity, ultimate tensile strength, elongation to failure, and fracture toughness.

- Modulus of elasticity describes the stiffness of the material and is usually obtained from the slope of a stress-strain diagram.
- Ultimate tensile strength describes the ability of the material to withstand a load before it fails.
- Elongation to failure describes how much strain the material can bear before it fails.
- Fracture toughness is an important measurement of the material's resistance to crack propagation.

Figures 1-2(a) to (d) show the comparisons amongst different classes of biomaterial with respect to the four properties mentioned above. It can be seen

that metals are generally very stiff and have high fracture toughness. In sharp contrast to the metals are the polymers, which have low stiffness and fracture toughness. However the polymers have high elongation to failure. The high stiffness of metals, on the other hand, can be a disadvantage since this can give rise to "stress shielding" in bone fracture repair. Stress shielding is a phenomenon where bone loss occurs when a stiffer material is placed over the bone. Bone responds to stresses during the healing process. Since the stress is practically shielded from the bone, the density of the bone underneath the stiffer material decreases as a result.

1.5 Effects of Processing on Properties of Biomaterials

1.5.1 Effect of Post Processing and Grain Size

Numerous properties of biomaterials can be improved by processing techniques. Figure 1–3 shows the fatigue strengths of some commonly used metals. It can be seen that the fatigue strengths of forged 316L stainless steel and cobalt–chromium are significantly higher than in their cast state. The increase in fatigue strength can be attributed to the large compressive force applied on the surface of the metal during the forging process, as well as due to grain refinement. How grain refinement leads to an increase in fatigue strength can be understood from the Hall–Petch equation. The equation states that the yield strength of a material (σ_{YD}) is inversely proportional to the square root of the grain size (d):

$$\sigma_{YD} = k\sqrt{d} \quad (1)$$

where k is a constant.

For many years in the steel industry, the subject of grain refinement has been intensely pursued to help improve the yield strength of steel. Nanograin structures have been produced via severe plastic deformation with remarkable success [9]. The other common route is to use powder metallurgy where ultra-fine particles are consolidated, compacted, and sintered at elevated temperature. Figure 1–3 shows that after cobalt–chromium alloy is subjected to hot isostatic pressing (H.I.P.), its fatigue strength is almost double than that in the cast state [10]. The use of isostatic pressure also helps to reduce defects — such as voids — in the alloy.

Brittle materials — such as bioceramics — are sensitive to stress concentrations which exist around pre-existing defects, such as pores, scratches, or cracks. Under an applied tensile stress, σ, the stresses at the tip of a crack can be described by the stress intensity factor K, which is given as follows:

$$K = Y\sigma\sqrt{a} \quad (2)$$

where a is the defect size and Y a geometry factor related to the crack.

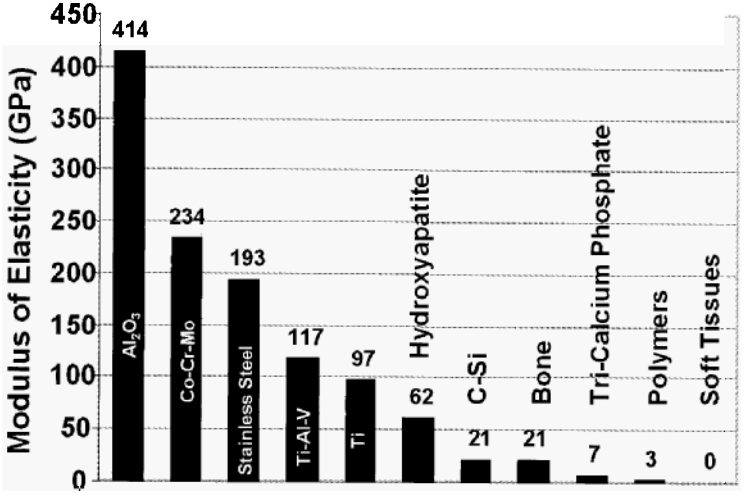

Figure 1–2(a) Comparison of moduli of elasticity of biomaterials. Note the very high values for ceramics and metals.

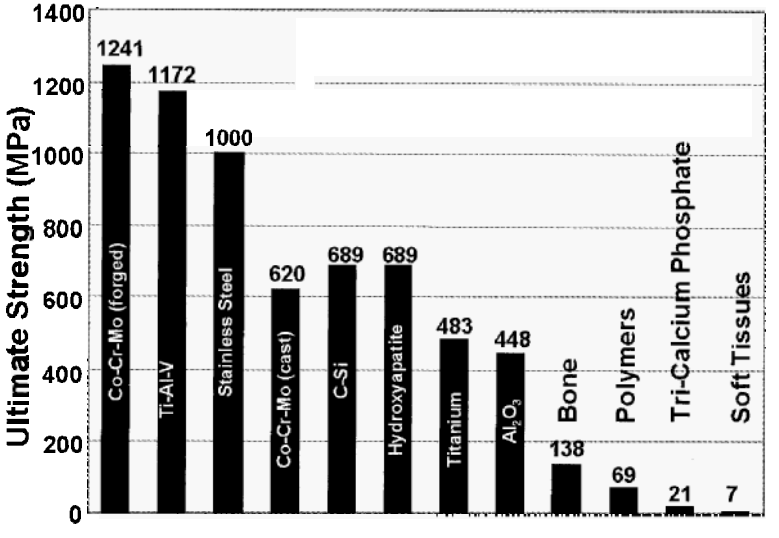

Figure 1–2(b) Comparison of ultimate tensile strengths of biomaterials. Note the exceptionally high values for metals which make the metals an ideal choice for load bearing applications.

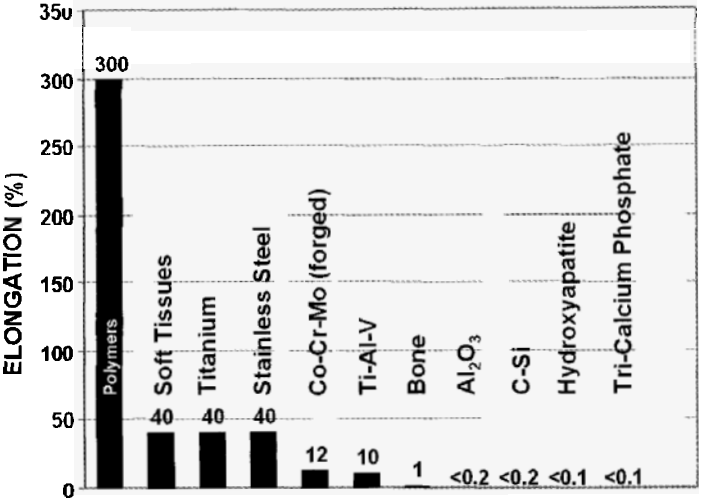

Figure 1–2(c) Comparison of elongation at failure of biomaterials. Note that polymers have exceptional elongation as compared to other materials. This is a measure of their high ductility.

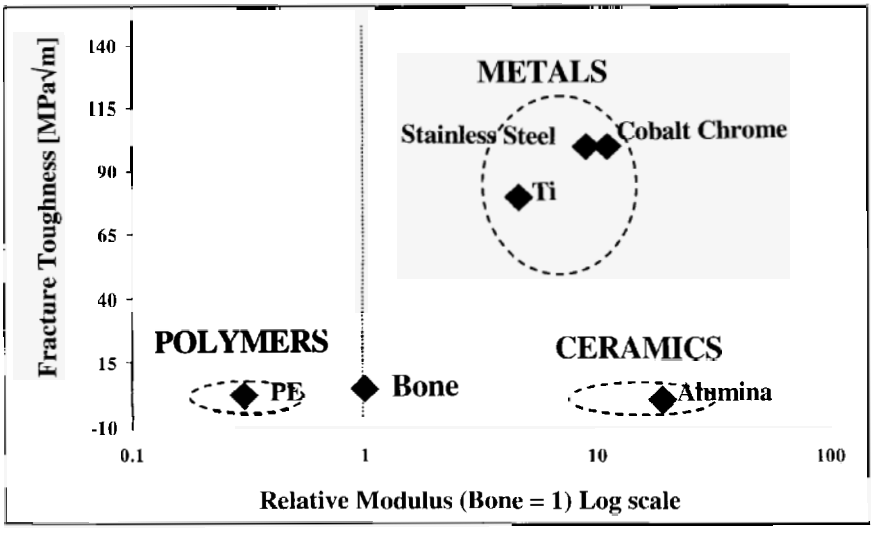

Figure 1–2(d) Comparison of fracture toughness of biomaterials relative to the log (Young's modulus) with bone as the reference. Note that the fracture toughness values of metals are generally several orders of magnitude higher than those of the other materials. The Young's modulus is also much higher than that of bone, giving rise to stress shielding.

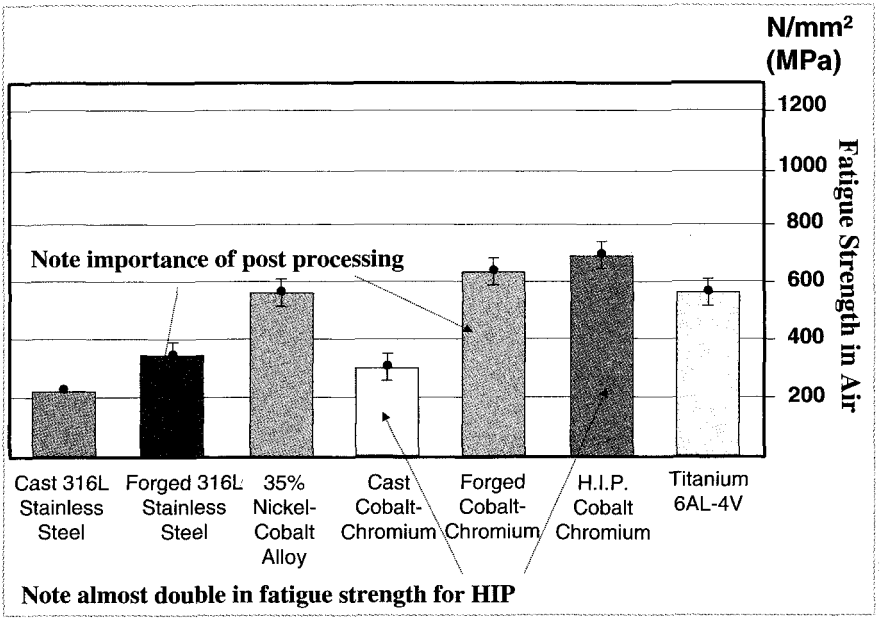

Figure 1–3 Fatigue strengths (in air) of common alloys used as implants. Note the effect of post processing conditions to improve fatigue strength (after Teoh [12]).

Fast fracture occurs when K becomes larger than the fracture toughness, K_{IC}. Fracture strength, σ_S, can then be given by:

$$\sigma_S = K_{IC}/\{Y\sigma\sqrt{a}\} \quad (3)$$

Composite processing by combining two or more phases is one route to produce enhanced properties of biomaterials. Another approach to obtain improved strength and reliability is to refine ceramic processing to produce homogeneous components with a defect size as small as possible. This can be done by refining powder processing to eliminate microstructural flaws. Ceramics such as alumina has been used for femoral heads in total hip replacements (THR) as an alternative to metal. This is because the wear rate in a ceramic-polyethylene combination was shown to be reduced significantly. However, reports of *in vivo* brittle fractures of ceramics due to delayed slow crack growth had brought about a new development in using composites of alumina and zirconia. The influence of processing conditions (such as those in colloidal processing) on the microstructures development of zirconia-toughened alumina composites, and the effect of these microstructures on the mechanical properties of alumina–zirconia composites, are discussed by De Aza *et al.* [11]. They have demonstrated that by using colloidal processing, microstructure refinement has brought about a significant improvement in the fracture toughness of ceramics (see Table 1–2).

Table 1–2 Fracture threshold, toughness and hardness of alumina, zirconia, and alumina–zirconia composites (after De Aza *et al.* [11]

Ceramic	Fracture Threshold, K_{I0} (MPa$\sqrt{m}$)	Fracture Toughness, K_{IC} (MPa$\sqrt{m}$)	Hardness (Vickers)
Alumina (Al_2O_3)	2.5±0.2	4.2±0.2	1600±50
Zirconia (ZrO_2)	3.1±0.2	5.5±0.2	1290±50
Al_2O_3–10vol% ZrO_2	4.0±0.2	5.9±0.2	1530±50

1.5.2 Effect of Molding Conditions and Irradiation on Polymeric Wear

Wear of polymeric materials used in implants is perhaps the most difficult to understand [7]. As a result, numerous reports on polymeric wear have emerged over the years [12,13]. In biomedical applications such as occluders in mechanical heart valves and joint prostheses, fatigue fracture and wear of the polymers have been considered to be an important factor in determining the durability of the prostheses. In the case of UHMWPE, many factors influence its wear properties. For example, when UHMWPE was molded between 190 and 200°C and some antioxidants were added during processing, its wear resistance appeared to improve. Molding at higher pressures and increasing the molecular weight, on the other hand, were reported to be detrimental. Nonetheless, there is a possibility that there could be an optimum processing condition and molecular weight distribution that could give the best wear characteristics. More recent work has shown that processing conditions play a vital role on the cyclic fatigue of UHMWPE. In particular, γ-radiation and oxidative aging are very detrimental to the fatigue threshold and crack propagation resistance (Table 1–3). Moreover, compression molding appears to render a better fatigue resistance when compared to extrusion.

1.5.3 Effect of Composite Lamination

Nanolaminates' layer of interpenetrating-networked composites such as those found in nature have unique fracture resistance. Examples are seashells which have been shown to yield improved fracture resistance with unique wear characteristics [15] (see Figure 1–4). The microstructure is made of nano brick-type arrangement of ceramic phase sandwiched by ultra-thin polymeric protein layers. Presumably, the small brick-like ceramic components (often biodegradable) allow easy removal/dissolution, a concept which needs to be mimicked in engineering a biomaterial that has wear debris which is eco-compatible. By using the laminate concept, fracture toughness reaching values as high as 16 MPa$\sqrt{m}$ can be achieved — as in the case of boron carbide/aluminum laminates. These laminates also have high flexural strength.

Microlaminates of interpenetrating-networked composites (Figure 1–5) can be produced by bi-axial stretching of one crystalline phase (UHMWPE) or by infiltrating with elastomeric polyurethane (PU) [16]. These microlaminates show significant improvement in strength and fracture toughness, and are used for elastomeric composite membrane (less than 40 μm) in biomedical application.

Table 1–3 Effect of processing conditions on the fatigue threshold (ΔK_{th}) of UHMWPE (after Pruiit and Bailey [14])

Condition	ΔK_{th}
Compression molded	1.8
Compression molded γ-air	1.2
Extruded 90°	1.7
Extruded 0° non-sterilized	1.3
Extruded 0° γ-air	1.0
Extruded 0° γ-peroxide	1.1

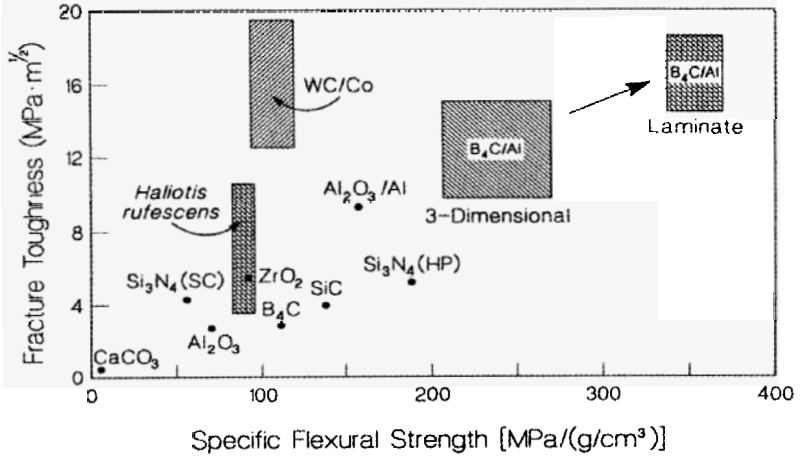

Figure 1–4 Fracture toughness versus specific flexural strength of some bioceramics and nanolaminates of metal matrix-ceramics composites. Note the effect of laminates in improving both fracture toughness and flexural strength (after Saikaya and Aksay [15]; reprinted with permission from Springer–Verlag, Berlin).

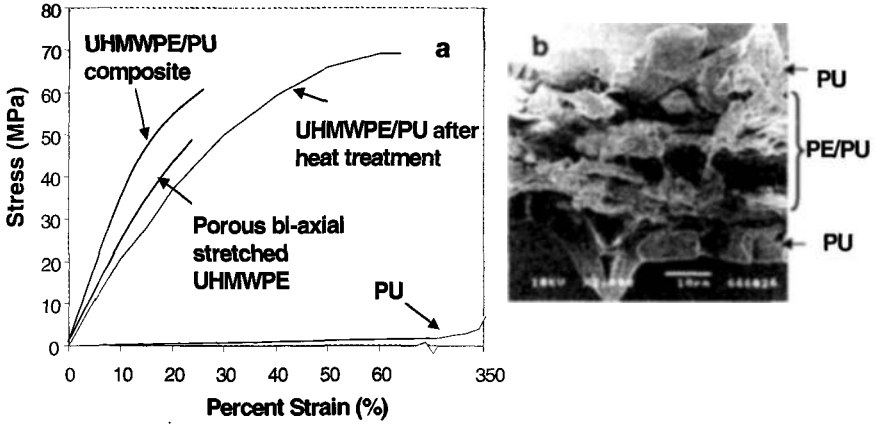

Figure 1–5 (a) Bi-axial stretching of UHMWPE and infiltrating with elastomeric polyurethane (PU) to produce microlaminates with significantly improved mechanical properties; (b) cross-sectional view of internal microstructure (after Teoh *et al.* [16])

1.6 Tissue Engineering — New Wave in Biomaterials Engineering

1.6.1 Need for Organ and Tissue Replacement

Loss of human tissues or organs is a devastating problem for the individual patient. Each year in United States alone, it is estimated that organs failure and tissue loss cost an estimated US$400b. Incidentally, patients waiting for organ transplants are also on the rise. Despite technological advances in biomaterials engineering, the figure significantly — for example from 27,883 in 1988 to 65,677 in 1995. Moreover, as life span increases in developed countries, coupled with rising number of calamities ranging from earthquakes to diseases outbreak and war tragedies, the need for organ and tissue replacement is expected to reach astronomical numbers by late 2010 [17].

1.6.2 Limitation of Current Technologies

Current technology for organ and tissue replacement has limitations. These include donor scarcity, adverse immunological response from the host tissue, biocompatibility, infection, pathogen transfer, and high cost to patient. Then, there is the perennial deficiency of synthetic material to provide the multifunctional requirement of organ. For example, bone is not just a structural element but also a "factory to produce bone marrow". These limitations prompt scientists worldwide to consider alternative technologies, amongst which tissue engineering has been heralded as the promising answer. As a result more than 20 companies were founded, according to an 1998 issue in Business Week

("The Era of Regenerative Medicine", July 27). However, recently, this hype soon met up with the reality of business enterprises when a number of them had to close, merge, or be bought up by large conglomerates. Nevertheless, new technologies and processes need to be discovered and invented.

1.6.3 Platform Technology Development in Tissue Engineering

The aim of tissue engineering (TE) is to restore tissue and organ functions with minimal host rejection. This arose from the need to develop an alternative method of treating patients suffering from tissue loss or organ failure. TE has been heralded as the new wave to revolutionize the healthcare-biotechnology industry. It is a multidisciplinary field and involves the integration of engineering principles, basic life sciences, and molecular cell biology.

The success of tissue engineering lies in five key technologies (Figure 1–6). They are namely: 1) Biomaterials; 2) Cells; 3) Scaffolds; 4) Bioreactors; and 5) Medical Imaging technology. It may seem simple to produce a one-off, tissue-engineered product in the laboratory, but it is a completely different matter to produce hundreds of products of consistent quality for clinical use.

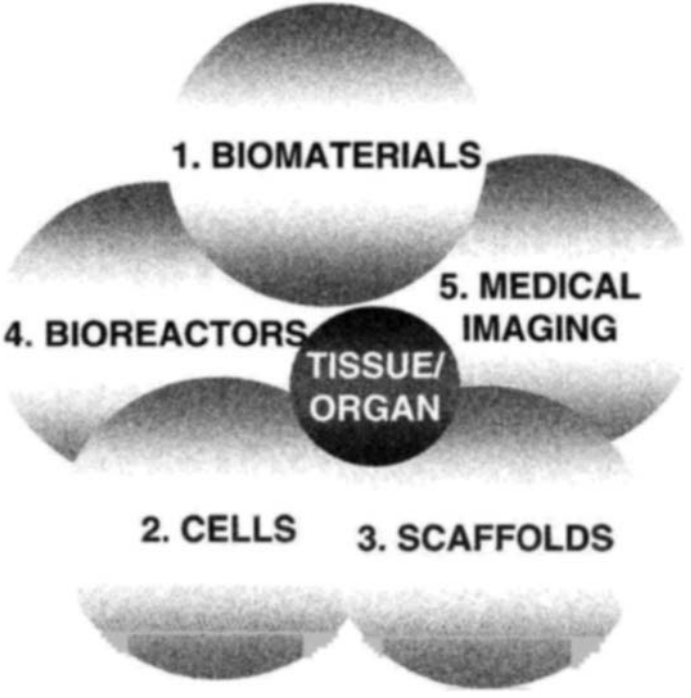

Figure 1–6 Five core technologies (biomaterials, cells, scaffolds, bioreactors, and medical imaging) required for tissue engineering

TE involves a scaffold which acts as a temporary extracellular matrix for the cells to adhere to, differentiate, and grow. Breakthrough has been made in the development of a platform technology which integrates medical imaging, computational mechanics, biomaterials, and advanced manufacturing to produce three-dimensional, porous load bearing scaffolds for tissue engineering of bone [18]. The technology makes use of polycaprolactone (PCL) bioresorbable polymer and Fused Deposition Modeling's (FDM) rapid prototyping advanced manufacturing fabrication process to produce the scaffolds without a mold [19] (Figure 1–7). Controlled three-dimensional architecture with interconnected pores enables good cells entrapment, facilitates easy flow path for nutrients and waste removal, and demonstrates long-term cell viability. Patient-specific scaffolds can now be made using this technology. Already more than 10 patients in Singapore have received scaffolds of this nature for cranioplastic surgery. This biomaterial processing technology has paved the way for patient-specific tissue engineering concepts not dreamed of a few years ago.

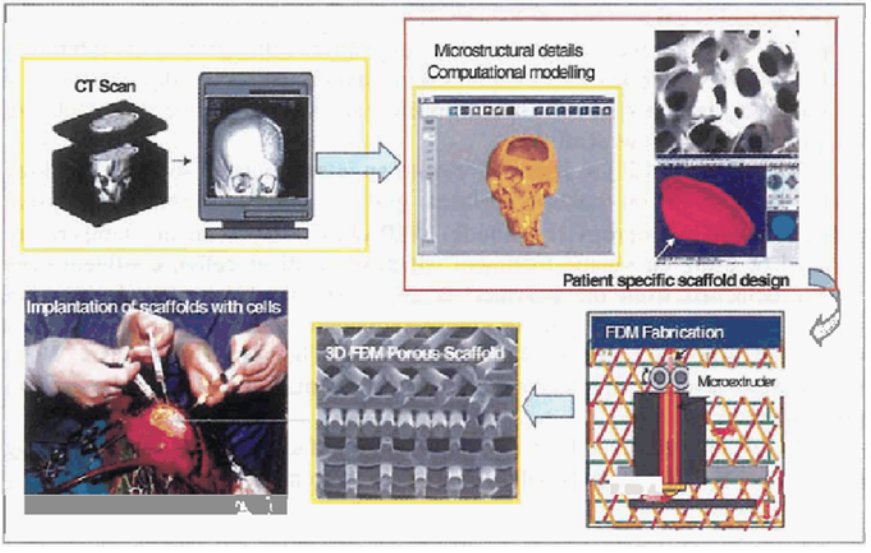

Figure 1–7 Platform technology for patient-specific scaffolds for bone tissue engineering

1.6.4 Tissue Engineering Issues and Challenges

In tissue engineering, there are certainly issues and challenges which are yet to be resolved. These issues range from cell-biomaterial interactions, stem cells technology to know-how in scaffolds manufacturing. For example, in the case of cell-biomaterial interactions, though we can grow single cell sheets such as

cartilage, we hardly understand how the cells in composite tissues (such as the heart valve leaflets) recognize their own territories and hence do not cross and violate each other. They seem to know how to live in harmony. Although we no longer need to focus on biochemical effects such as growth factors, we need to study the mechano-induction effects. This is because the manner in which cells differentiate, proliferate, and express their extracellular matrix (ECM) is also a function of the stress fields they experience.

Stem cells and scaffolds technologies also pose some challenges. Recently, some work on human blood vessels was done by Auger's group [20] in Canada. They showed that by growing the cells in sheets and then rolling them into a tube helps to eliminate immunological mismatch. This is because smooth muscles cells (SMCs) re-expressed desmin, a differentiation marker known to be lost under culture conditions. As a result, large amounts of ECM were produced and the structural integrity maintained. However, the handling of the sheets is delicate and it is not clear if the material would survive the viscoelastic compliance mismatch in long-term *in vivo* physiological environment. Other major obstacles exist. One of them is over SMCs proliferation. This could be related to the presence of endothelial progenitor cells (EPCs) in inhibiting SMCs, and EPCs are known to express nitric oxide. However, dipyridalmole is also a strong inhibitor of SMCs, and much work has been done to immobilize this chemical on porous scaffolds.

Okano's group [21] in Japan developed an interesting cell sheets technology where cells grew on culture surfaces grafted with temperature-responsive polymer, poly(N–isopropylacrylamide) (PIPAAm). By reducing temperature (instead of using enzymatic treatment which traumatizes cells), confluent cells simply detached from the polymer as a cell sheet. Layered cell sheets of cardiomyocytes then began to pulse simultaneously and morphological communication via connexin 43 was established between the sheets. When sheets were layered, engineered constructs were macroscopically observed to pulse spontaneously too.

The examples quoted above point to the fact that tissue engineering breakthroughs will further gravitate towards even greater challenges ahead.

1.7 Conclusions

For a material to be used as a biomaterial, it must possess the mandatory properties of biocompatibility and sterilizability. In addition, a biomaterial must be malleable. This is because the ability of a biomaterial to be pulled or pressed into shape often determines its success as a medical device in the long run. When it comes to the manufacturability of a biomaterial, processing techniques often affect the final property of the biomaterial — which means affecting the durability of the device. On this note, engineers need to examine the various

processing effects that stem from grain refinement of steel to molding conditions and irradiation on UHMWPE.

Future direction seems to lead us to nanolaminate composites, which give better properties such as fracture toughness and wear enhancement. The era of tissue engineering also paves the way for new biomaterial processes to be developed and invented. The integration of different modalities from cells, biomaterials to medical imaging has opened up new challenges in the healthcare industry.

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CHAPTER 2

DURABILITY OF METALLIC IMPLANT MATERIALS

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Metallic implant materials such as stainless steel, titanium, and cobalt-based alloys have found many applications as medical devices. This is due to their excellent mechanical properties such as fatigue strength and fracture toughness. Their durability however is dependent on their corrosion and wear resistance. The heat treatment and manufacturing method also affect these properties. The issues of adverse cellular response to wear debris from fretting fatigue and contact motion in artificial joints continue to present many challenges to the design of medical implants. The leaching of metallic ions such as nickel during the corrosion process has caused considerable concerns. This has paved way to development of new nickel-free alloys and amorphous metals that are more biocompatible.

2.1 Introduction

Metallic materials are often used to replace structural components of the human body because they surpass plastic or ceramic materials in terms of tensile strength, fatigue strength, and fracture toughness. As such, they are used in medical devices such as artificial joints, dental implants, artificial hearts, bone plates, staples, wires, and stents. They also possess better electro conductivity qualities, and hence are used for enclosing electronic devices such as pacemaker electrodes and artificial inner ears. Figure 2–1(a) shows typical applications of metallic implant devices, and Figure 2–1(b) shows a stainless steel stent used successfully in a coronary artery.