Review

Biomaterials and Their Biomechanical Compatibilities

by

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ABSTRACT

The European Society for Biomaterials has defined [1] that "BIOMATERIAL" is "a non-viable materials used in a medical device, intended to interact with biological systems". Biomaterials science is one of those areas of advanced technology and is considered inter-disciplinary within physical, chemical, and medical sciences. Even though a numerous efforts have been made to improve the biocompatibility and biofunctionality of biomaterials, still the reliabilities of medical devices are not always sufficient. The more careful biomechanical considerations and designs are required.

Key Words :Biomaterials, Biomechanical compatibility, Adaptational remodeling

1. INTRODUCTION

The variety of biomaterials are quite wide in their applications from the supplementary devices such as a syringe and antiseptic gauze (artificial skin) covering wound in short term treatments to the implants and artificial organs in long term utilizations. These biomaterials should be biocompatible so as to perform or function harmoniously and consistently in contact or within the environment of a living body without causing disease or harmful reaction. They must fundamentally be secure from cytotoxicity and allergenic actions, thrombogenicity, carcinogenicity, mutagenicity, and so on.

Though the conventional biomaterials that show the above mentioned "pathological biocompatibility" have been mainly selected as "bio-inert" materials, the new biomaterials have become of major interest lately as "bio-active" materials like Bioglass and hydroxy apatite which can bond with the living bone.

Furthermore, the "bio-degradable" materials like tricalcium phosphate (TCP) which gradually absorbed, metabolized and/or replaced by the new bone have been also developed and used. Thus the definition of "biocompatibility" varies from case to case in applications, and hereat it is difficult to determine a standard for evaluation of biocompatibility of biomaterials. The evaluation methods

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Table 1. Bioceramics

Bio-inert	Oxides	Alumina (Al_2O_3) Zirconia (ZrO_2) Calcium Aluminate ($\text{CaO-Al}_2\text{O}_3$) Alumino Silicate ($\text{Na}_2\text{O-Al}_2\text{O}_3\text{-SiO}_2$)
	Non-Oxides	Carbon (vitrous, pyrolic, Graphite) Nitride (Si_3N_4) Carbides (SiC)
Bio-active	Bio-glass	Bioglass ($\text{SiO}_2\text{-Na}_2\text{O-CaO-P}_2\text{O}_5$) Ceravital ($\text{SiO}_2\text{-CaO-Na}_2\text{O-K}_2\text{O-MgO}$)
	Glass-Ceramics	Mica type ($\text{SiO}_2\text{-B}_2\text{O}_3\text{-Al}_2\text{O}_3\text{-MgO-K}_2\text{O}$) A-W type ($\text{SiO}_2\text{-CaO-MgO-P}_2\text{O}_5$) β -Ca(PO_3) ₂ type ($\text{CaO-P}_2\text{O}_5$) Diopside type ($\text{CaO-2SiO}_2\text{-MgO}$)
	Calcium Phosphates	Hydroxy Apatite ($\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$)
	Calcium Phosphate	TCP ($\text{Ca}_3(\text{PO}_4)_2$) Low Crystalline HAP
Bio-degradable	Calcium Aluminate	Calcium Aluminate ($\text{CaO-Al}_2\text{O}_3$)

have been discussed in the new Technical Committee (ISO/TC194: Biological Testing of Medical and Dental Materials and Devices) in the International Organization for Standardization since 1989.

The "biomechanical compatibility" means the mechanical harmonization between living tissues and biomaterials/devices, and has direct effects upon the performance lifetime of implants/devices, and has direct effects upon the performance lifetime of implants/devices. In the ISO/TC150 not only the materials but also deveices for surgical implants have been under deliberation to evaluate the biomechanical biocompatibility affected by designs.

2. BIOMATERIALS

2.1 Inorganic Biomaterials

As seen in Table 1, there are many inorganic biomaterials called "bioceramics". For the dental implants and artificial joints which should resist heavy loads and wear, single- and poly-crystalline devices made of alumina with high strength and bio-inertness have been used. Some trials to use partially stabilized zirconia with much more toughness and wear resistance have started to minimize the implants and to extend their permanence.

For these implants to insert in the hard tissues of teeth and bones it is desirable to use the bio-active ceramics which can combine with tooth and bone. Synthetic hydroxy apatite (HAP) has been extensively used for dental implants and artificial bones, because HAP is the principal ingredient of the hard tissues and is able to unite with new bones directly.

However, the low bending strength of the sintered HAP and the gradual decrease of its fatigue

strength in the body fluids restrict implants designs and applications. Therefore, HAP is used as composites as coating layer on the tougher metals or as fillers in the light curing resins.

Recently several glass-ceramics with higher strength and better bone conductivity than HAP have been developed. The glass ceramics of A-W (Apatite-Wollastonite: CaSiO_3), $\text{CaO-P}_2\text{O}_5$, and diopside ($\text{CaO-2SiO}_2\text{-MgO}$) are tried in dental and orthopaedic clinics. Especially diopside glass ceramic material is interested in its good press-formability at 850°C with 400 MPa in bending strength and $2.7 \text{ MPa m}^{1/2}$ in fracture toughness [2]. This is also machinable for CAD/CAM (Computer Aided Design/Computer Aided Manufacturing). The diopside's easiness of forming to the optimum shape for each specific implant is in the improvement stage for practical application by pressing, casting or machining.

2.2.2 Metallic biomaterials

The clinical history of metallic biomaterials is quite long. The representative biomedical alloys are shown in Table 2. Titanium has lately attracted attention in medical applications because of its better corrosion resistance with formation of more stable passive film than stainless steel and Co-Cr alloys (Fig. 1) [3]. Titanium alloys (Ti-6Al-4V, β alloy, etc.) are applied to artificial joints due to their excellent biocompatibility and high specific strength.

The shape memory effect and super elasticity of Ti-Ni alloy are utilized in treatments of the spine deformities (scoliosis), orthodontics, and dental implants.

2.3 Polymeric Biomaterials

Biomedical polymers have expansively been applied for replacements not only of the soft tissues such as skin and blood vessel, but of the hard tissues (Table 3).

The new practical application of polymeric biomaterials is the drug delivery system (DDS) that

Table 2. Chemical requirements for biomedical alloys by ASTM

		C	Cr	Ni	Mo	W	Co	Fe	(mass%)
Stainless steel	SUS316L	<0.03	16.0	12.0	2.0			Bal.	
			~18.0	~15.0	~3.0				
	COP-1	<0.03	19.0	19.0	3.50		19.0	Bal.	
			~21.0	~21.0	~4.50		~21.0		
Co-Cr alloy (Vitallium)	Cast (HS21)	<0.35	27.0	<1.0	5.0	<0.75		Bal.	
			~30.0		~7.0				
	Wrought (HS25)	0.05	19.0	9.0		14.0	Bal.	<3.00	
		~0.15	~21.0	~11.0		~16.0			
Stellite		1.5	30.0			9.0	Bal.		
		N	C	O	H	Fe	Al	V	Ti
Ti and its alloys	Pure Ti	<0.05		<0.15	<0.013	<0.2			Bal.
	Ti-6Al-4V	0.05	0.08	0.13	0.0125	0.25	5.5	3.5	Bal.
							~6.5	~4.5

Fig.1. Anodic polarization curves in a rat body and Ringer solution [3].

Table 3. Polymeric biomaterials for implants

Polymers	Examples
Polyethyl Methacrylate (PMMA)	Contact and intraocular lenses, Dental resin, Bone cement
Polydimethylsiloxanes (Silicones)	Soft-tissue augmentation, Artificial finger joints
Polytetrafluoroethylene (PTFE)	Ligament prostheses, Vascular prostheses, Sutures
Polyethylene terephthalate (PET)	Vascular prostheses
Polypropylene (PP)	Sutures, Ligament prostheses
Polyethylene (HMWHDPE)	Artificial articular surfaces

enables (1) controlled release formulations which are designed to optimize the rate of drug appearance in the target tissue and optimize per dose the duration of drug activity; and (2) drug-targeted formulations which are designed to deliver drug uniquely to the target organ or disease (e.g. bacterial infection) such that active drug is only liberated at that site within the body. Soluble polymers (polylactic acid (PLA), polyglycolic acid (PGA), polyethylene glycol etc.) have found use in both types of application.

3. BIOMECHANICAL COMPATIBILITY

Most of Biomaterials can not avoid deterioration of their strength in the body by biological reactions (Phagocytosis, calcification and protein adsorption/absorption), by chemical degradations (corrosion and resorption), and by physical damages (wear, fatigue, change of crystallinity). Even the very stable ceramic materials like alumina decrease the surface free energy γ by water and increase the brittleness. As shown in Figure 2 bending strength of sintered HAP specimens in water at 37°C was lower than that measured in air [4]. The reason of this difference may be caused by higher rate of sub-critical crack growth activated in water. In this fatigue fracture mechanical point of view it is required to design carefully the lifetime of implants immersed in the human body liquid (Figure 3) [4].

The fractures and failures of implants were not caused simply by weakness of biomaterials or living tissues, but rather by mismatch of both mechanical behaviors at the interfaces or contact points. Those were mainly caused by the difference of strains or flexibilities. In this reason it is advisable to coincide the mechanical properties of biomaterials with those of the surrounding living tissues. Especially the elastic moduli are desirable to be similar, but it is not easy to obtain the biomaterial which has the low elastic modulus with high strength the same as the general living tissues have. The

Fig.2. Weibull plots of bending strength of sintered HAP in air and H₂O [4]

Fig.3. SPT diagram for sintered HAP [4]

stronger in the biomaterials are to be designed, the higher the elastic moduli of them increase. Moreover, biomaterials are much less in toughness, i.e. with low endurance than the living tissues in general (Table 4).

If the distribution pattern of strains, stresses or strain energy densities are different from the natural histological pattern after the implantation of devices, the living tissues would try to change their morphological shape and structures. It is so-called "adaptational remodeling". As Wolff hypothesized in his bone remodeling theory [5] in 1892, the bone seems mechanically optimum in its inner architecture and outer shape as well. And, it seems to change its structure in response to changes of

Table 4. Fracture toughness of biomaterials

Materials	Fracture toughness (MPa $m^{1/2}$)		
Hydroxy apatite (HAP)	0.69	~	1.16
Tricalcium phosphate (TCP)	1.14	~	1.30
Silica glass	0.7	~	0.8
Diopside glass ceramic	2.7		
Alumina	3.1	~	5.5
Silicon nitride	3.4	~	8.0
Silicon carbide	3.8	~	5.5
Partially stabilized zirconia	5.7	~	9.6
Mar-aged steel	56.4	~	93.0
Titanium alloy (Ti-6Al-4V)	37.8		
Compact bone	2.2	~	4.6
Tooth (Enamel)	0.61	~	0.86

loading conditions. Since this biomechanical adaptation of living tissues are limited in a certain range of mechanical stimulations, the design of implants should be done neither to induce excessive stresses nor too low strain energies ("stress shielding"). For this purpose we have been studying on computer designing method for implants with biomechanical compatibility based on our numerical simulation of remodeling by using the finite element method [6,7].

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