

# **Biomaterials**

Biomaterials are used to make devices to replace a part or a function of the body in safe, reliably economically, and physiologically acceptable manner. A variety of devices and materials are used in the treatment of disease or injury. Commonplace examples include suture needles, plates, teeth fillings, etc.

## **Term Definitions**

**Biomaterial:** A synthetic material used to make devices to replace part of a living system or to function in intimate contact with living tissue.

**Biological Material:** A material that is produced by a biological system.

**Bio-compatibility:** Acceptance of an artificial implant by the surrounding tissues and by the body as a whole.

## **Fields of Knowledge to Develop Biomaterials**

- 1- Science and engineering: (Materials Science) structure-property relationships of synthetic and biological materials including metals, ceramics, polymers, composites, tissues (blood and connective tissues), etc.
- 2- Biology and Physiology: Cell and molecular biology, anatomy, animal and human physiology, histopathology, experimental surgery, immunology, etc.
- 3- Clinical Sciences: (All the clinical Specialties) dentistry, maxillofacial, neurosurgery, obstetrics and gynecology, ophthalmology, orthopedics, plastic and reconstructive surgery, thoracic and cardiovascular surgery, veterinary medicine and surgery, etc.

**Uses of Biomaterials**

Uses of Biomaterials	Example
Replacement of diseased and damaged part	Artificial hip joint, kidney dialysis machine
Assist in healing	Sutures, bone plates and screws
Improve function	Cardiac pacemaker, intra-ocular lens
Correct functional abnormalities	Cardiac pacemaker
Correct cosmetic problem	Mastectomy augmentation, chin augmentation
Aid to diagnosis	Probes and catheters
Aid to treatment	Catheters, drains

**Biomaterials in Organs**

Organ	Example
Heart	Cardiac pacemaker, artificial heart valve, Totally artificial heart
Lung	Oxy-generator machine
Eye	Contact lens, intraocular lens
Ear	Artificial stapes, cochlea implant
Bone	Bone plate, intra-medullary rod
Kidney	Kidney dialysis machine
Bladder	Catheter and stent

## Materials for Use in the Body

Materials	Advantages	Disadvantages	Examples
<b>Polymers (nylon, silicon Rubber, polyester, PTFE, etc)</b>	<b>Resilient Easy to Fabricate</b>	<b>Not strong Deforms with time May degrade</b>	<b>Blood vessels, Sutures, ear, nose, Soft tissues</b>
<b>Metals (Ti and its alloys Co-Cr alloys, stainless Steels)</b>	<b>Strong Tough ductile</b>	<b>May corrode, dense, Difficult to make</b>	<b>Joint replacement, Bone plates and Screws, dental root Implant, pacemaker, and suture</b>
<b>Ceramics (Aluminum Oxide, calcium phosphates, including hydroxyapatite carbon)</b>	<b>Very biocompatible Inert strong in compression</b>	<b>Difficult to make Brittle Not resilient</b>	<b>Dental coating Orthopedic implants Femoral head of hip</b>
<b>Composites (Carbon-carbon, wire Or fiber reinforced Bone cement)</b>	<b>Compression strong</b>	<b>Difficult to make</b>	<b>Joint implants Heart valves</b>

The science of biomedical materials involves a study of the composition and properties of materials and the way in which they interact with the environment in which they are placed.

The number of medical devices used each year is very large. The chart below estimates usage for common devices.

Device	Usage Estimate
Contact lens	75,000,000
Hip and knee prostheses	1,000,000
Catheter	300,000,000
Heart valve	200,000
Vascular graft	400,000
Breast implant	300,000
Dental implant	500,000
Pace maker	200,000
Renal dialyzer	25,000,000
Cardiovascular	2,000,000
Intraocular lens	7,000,000
Left ventricular assist devices	100,000

**Selection of Biomedical Materials**

The process of material selection should ideally be for a logical sequence involving:

- 1- Analysis of the problem;
- 2- Consideration of requirement;
- 3- Consideration of available material and their properties leading to:
- 4- Choice of material.

The choice of a specific biomedical material is now determined by consideration of the following:

- 1- A proper specification of the desired function for the material;
- 2- An accurate characterization of the environment in which it must function, and the effects that environment will have on the properties of the material;
- 3- A delineation of the length of time the material must function;
- 4- A clear understanding of what is meant by safe for human use.

As the number of available materials increases, it becomes more and more important to be protected from unsuitable products or materials, which haven't been thoroughly evaluated.

Most manufacturers of materials operate an extensive quality assurance program and materials are thoroughly tested before being released to the general practitioner.

- 1- Standard Specifications: Many standard specification tests of both national and international standards organizations (ISO) are now available, which effectively maintain quality levels. Such specifications normally give details for:
  - (a) the testing of certain products,
  - (b) the method of calculating the results
  - (c) the minimum permissible result, which is acceptable.
- 2- Laboratory Evaluation: Laboratory tests, some of which are used in standard specification, can be used to indicate the suitability of certain materials. It is important that methods used to evaluate materials in laboratory give results, which can be correlated with clinical experience.
- 3- Clinical Trials: Although laboratory tests can provide many important and useful data on materials, the ultimate test is the controlled clinical trial and verdict of practitioners after a period of use in general practice. Many materials produce good results in the laboratory, only to be found lacking when subjected to clinical use. The majority of manufacturers carry out extensive clinical trials of new materials, normally in cooperation with a university or hospital department, prior to releasing a product for use by general practitioners.

The most common classes of materials used as biomedical materials are polymers, metals, and ceramics. These three classes are used singly and in combination to form most of the implantation devices available today.

## 1- Polymers

There are a large number of polymeric materials that have been used as implants or part of implant systems. The polymeric systems include acrylics, polyamides, polyesters, polyethylene, polysiloxanes, polyurethane, and a number of reprocessed biological materials.

Some of the applications include the use of membranes of ethylene-vinyl-acetate (EVA) copolymer for controlled release and the use of poly-glycolic acid for use as a resorbable suture material. Some other typical biomedical polymeric materials applications include: artificial heart, kidney, liver, pancreas, bladder, bone cement, catheters, contact lenses, cornea and eye-lens replacements, external and internal ear repairs, heart valves, cardiac assist devices, implantable pumps, joint replacements, pacemaker, encapsulations, soft-tissue replacement, artificial blood vessels, artificial skin, and sutures.

As bioengineers search for designs of ever increasing capabilities to meet the needs of medical practice, polymeric materials alone and in combination with metals and ceramics are becoming increasingly incorporated into devices used in the body.

## 2- Metals

The metallic systems most frequently used in the body are:

- (a) Iron-base alloys of the 316L stainless steel
- (b) Titanium and titanium-base alloys, such as
  - (i) Ti-6% Al-4% V, and commercially pure <sup>3</sup> 98.9%
  - (ii) Ti-Ni (55% Ni and 45% Ti)
- (c) Cobalt base alloys of four types
  - (i) Cr (27-30%), Mo (5-7%), Ni (2-5%)
  - (ii) Cr (19-21%), Ni (9-11%), W (14-16%)
  - (iii) Cr (18-22%), Fe (4-6%), Ni (15-25%), W (3-4%)
  - (iv) Cr (19-20%), Mo (9-10%), Ni (33-37%)

## Chapter One

## Introduction

The most commonly used implant metals are the 316L stainless steels, Ti-6%-4% V, and Cobalt base alloys of type "i" and "ii". Other metal systems being investigated include Cobalt-base alloys of type "iii" and "iv", and Niobium and shape memory alloys, of which (Ti 45% - 55%Ni) is receiving most attention. Further details of metallic biomedical materials will be given later.

### 3- Composite Materials

Composite materials have been extensively used in dentistry and prosthesis designers are now incorporating these materials into other applications. Typically, a matrix of ultrahigh-molecular-weight polyethylene (UHMWPE) is reinforced with carbon fibers. These carbon fibers are made by pyrolyzing acrylic fibers to obtain oriented graphitic structure of high tensile strength and high modulus of elasticity. The carbon fibers are 6-15 $\mu$ m in diameter, and they are randomly oriented in the matrix. In order for the high modulus property of the reinforcing fibers to strengthen the matrix, a sufficient interfacial bond between the fiber and matrix must be achieved during the manufacturing process. This fiber reinforced composite can then be used to make a variety of implants such as intra-medullary rods and artificial joints. Since the mechanical properties of these composites with the proportion of carbon fibers in the composites, it is possible to modify the material design flexibility to suit the ultimate design of prostheses.

Composites have unique properties and are usually stronger than any of the single materials from which they are made. Workers in this field have taken advantages of this fact and applied it to some difficult problems where tissue in-growth is necessary.

Examples:

Deposited Al<sub>2</sub>O<sub>3</sub> onto carbon;

Carbon / PTFE;

Al<sub>2</sub>O<sub>3</sub> / PTFE;

PLA-coated Carbon fibers.

### 4 – Ceramics

The most frequently used ceramic implant materials include aluminum oxides, calcium phosphates, and apatites and graphite. Glasses have also been developed for medical applications. The use of ceramics was motivated by:

- (i) their inertness in the body,
- (ii) their formability into a variety of shapes and porosities,
- (iii) their high compressive strength, and
- (iv) some cases their excellent wear characteristics.

Selected applications of ceramics include:

- (a) hip prostheses,
- (b) artificial knees,
- (c) bone grafts,
- (d) a variety of tissues in growth related applications in
  - (d.1) orthopedics
  - (d.2) dentistry, and
  - (d.3) heart valves.

Applications of ceramics are in some cases **limited** by their generally poor mechanical properties: (a) in tension; (b) load bearing, implant devices that are to be subjected to significant tensile stresses must be designed and manufactured with great care if ceramics are to be safely used.

### 5 – Biodegradable Materials

Another class of materials that is receiving increased attention is biodegradable materials. Generally, when a material degrades in the body its properties change from their original values leading to altered and less desirable performance. It is possible, however, to design into an implant's performance the controlled degradation of a material, such that natural tissue replaces the prosthesis and its function.



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Examples include: Suture material that hold a wound together but resorb in the body as the wound heals and gains strength. Another application of these materials occurs when they are used to encourage natural tissue to grow. Certain wound dressings and ceramic bone augmentation materials encourage tissue to grow into them by providing a "scaffold". The scaffold material may or may not resorb over a period of time but in each case, natural tissue has grown into the space, then by restoring natural function. One final application of biodegradable materials is in drug therapy, where it is possible to chemically bond certain drugs to the biodegradable material, when these materials are placed within the body the drug is released as the material degrades, thereby providing a localized, sustained release of drugs over a predictable period of time.

### **Success and Failure are seen with Biomaterials and Medical Devices**

Most biomaterials and medical devices perform satisfactorily, improving the quality of life for the recipient or saving lives. Still, man-made constructs are never perfect. Manufactured devices have a failure rate. Also, all humans differ in genetics, gender, body chemistries, living environment, and physical activity. Furthermore, physicians also differ in their "talent" for implanting devices.

The other side to the medical device success story is that there are problems, compromises and complications that occur with medical devices.

Central issues for the biomaterials scientist, manufacturer, patient, physician, and attorney are:

- 1- what represents good design;
- 2- Who should be responsible when devices perform with an inappropriate host response;
- 3- What is the cost/risk or cost/benefit ratio for the implant or therapy?

These five characteristics of biomaterial science-multidisciplinary, multi-material, need driven, substantial market, and risk-benefit, color the field of biomaterials.

### **What Subjects are Important to Biomaterials Science?**

#### **1- Toxicology**

A biomaterial should not be toxic, unless it is specifically engineered for such requirements (for example a "smart" bomb" drug delivery system that targets cancer cells and destroy them). Toxicology for biomaterials deals with the substances that migrate out of the biomaterials. It is reasonable to say that a biomaterial should not give off anything from its mass unless it is specifically designed to do so.

#### **2- Biocompatibility**

It is the ability of a material to perform with an appropriate host response in a specific application. "Appropriate host response" includes lack of blood clotting, resistance of bacterial colonization and normal healing. The operational definition of biocompatible "the patient is alive so it must be biocompatible".

#### **3-Functional Tissue Structure and Pathobiology**

Biomaterials incorporated into medical devices are implanted into tissues and organs. Therefore, the key principles governing the structure of normal and abnormal cells, tissues or organs, the technique by which the structure and function of normal and abnormal tissues are studied, and the fundamental mechanisms of disease processes are critical considerations to workers in the field.

#### **4- Healing**

Special processes are invoked when a material or device heals in the body. Injury to tissue will stimulate the well-defined inflammatory reaction sequence that leads to healing. When a foreign body is present in the wound site, the reaction sequence is referred to as the "foreign body reaction". This reaction will differ in intensity and duration depending upon the anatomical site involved.

**5- Dependence on Specific Anatomical Sites of Implantation**

An intraocular lens may go into the lens capsule or the anterior chamber of the eye. A hip-joint will be implanted in bone across an articulating joint space. A heart valve will be sutured into cardiac muscle and will contact both soft tissues and blood. A catheter may be placed in an artery. Each of these sites challenges the biomedical device designer with special requirements for geometry, size, mechanical properties, and bio-responses.

**6- Mechanical and Performance Requirements**

Biomaterials and devices have mechanical and performance requirements that originate from the physical properties of the materials. The following are three categories of such requirements:

- i. Mechanical Performance
- ii. Mechanical durability
- iii. Physical Properties

**(A) Mechanical performance.**

Device	Properties
A hip prosthesis	Must be strong and rigid
A tendon material	Must be strong and flexible
A heart valve leaflet	Must be flexible and tough
An articular cartilage substitute	Must be soft and elastomeric
A dialysis membrane	Must be strong and flexible but not elastomer

**(B) Mechanical durability**

A catheter may only have to perform for 3 days. A bone plate may fulfill its function in 6 months or longer. A leaflet in a heart valve must flex 60 times per minute without tearing for the lifetime of the patient (for 10 years). A hip joint must not fail under heavy loads for more than 10 years.

### **(C) The physical properties**

The dialysis membrane has a specified permeability. The articular cup of the hip joint has high lubricity. The intraocular lens has clarity and refraction requirements.

### **7- Industrial Involvement**

A significant basic research effort is now under way to understand how biomaterials function and how to optimize them. At the same time, companies are producing implants for use in humans and appropriate to the mission of the company, earning profits on the sale of medical devices.

Industry deals well with technologies, such as packaging, sterilization, storage, distribution and quality control, and analysis. These subjects are specialized technologies, often ignored by academic researchers.

### **8- Ethics**

A wide range of ethical considerations impact biomaterials. Like most ethical questions, an absolute answer may be difficult to come by. Some articles have addressed ethical questions in biomaterials and debated the important points.

### **9- Regulation**

The patient demands safe medical devices. To prevent inadequately tested devices and materials from coming on the market, and to screen out individuals clearly unqualified to produce biomaterials. The International Standards Organization (ISO) has introduced international standards for world community.

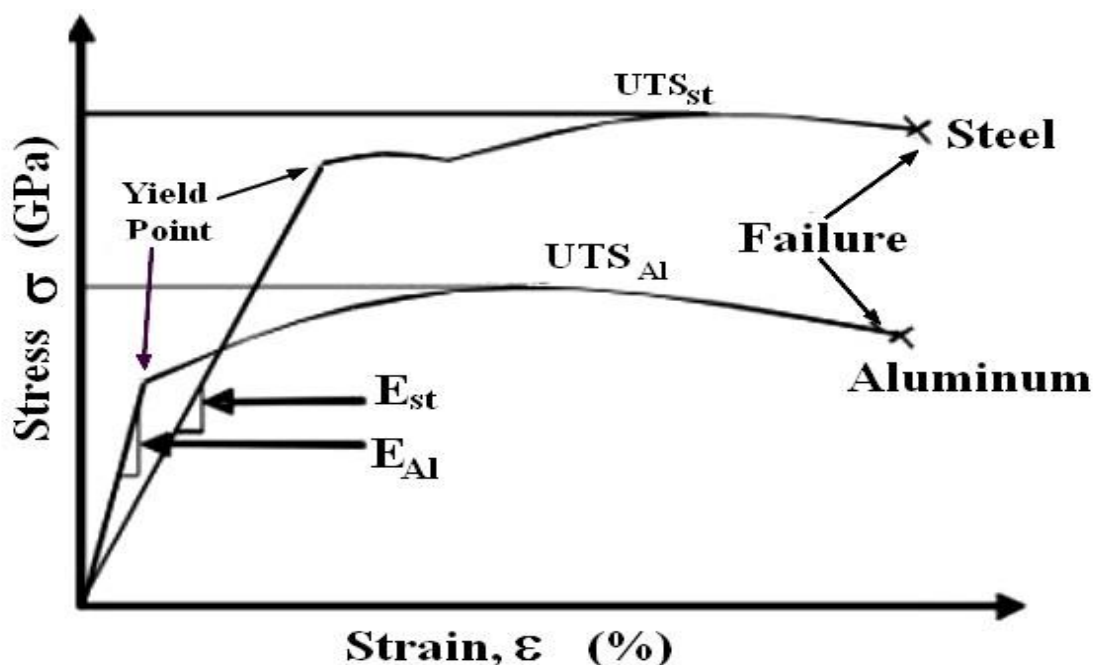
## 1- Physical Properties

### (i) Mechanical Properties of Biomaterials

The tensile test is a common testing procedure used to provide data for characterization of biomaterials. The discussion below focuses on special considerations needed for tensile testing biological soft tissue (e.g. ligament and tendon) compared to traditional engineering materials (e.g. aluminum and steel).

#### (a) Traditional Engineering Materials

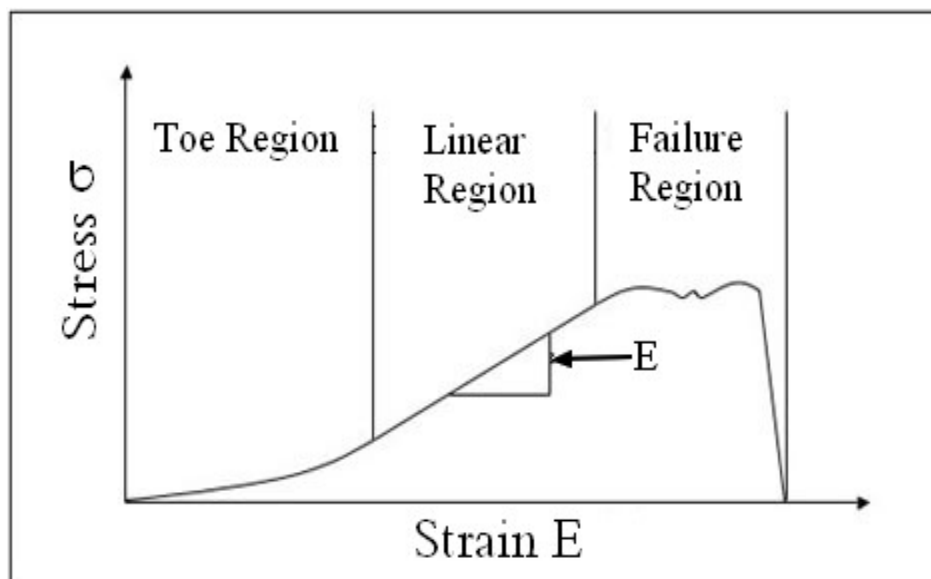
Common assumptions used for testing and analysis of traditional materials are that they are homogeneous, exhibit small deformations and are linearly elastic. Young's modulus ( $E$ ), the slope of the elastic portion of stress-strain curve, is a quantity often used to assess a material stiffness. The linear elastic assumption makes the determination of " $E$ " relatively straight-forward as it can be assessed anywhere along the initial linear portion of the curve.



Stress-strain curve of traditional engineering materials

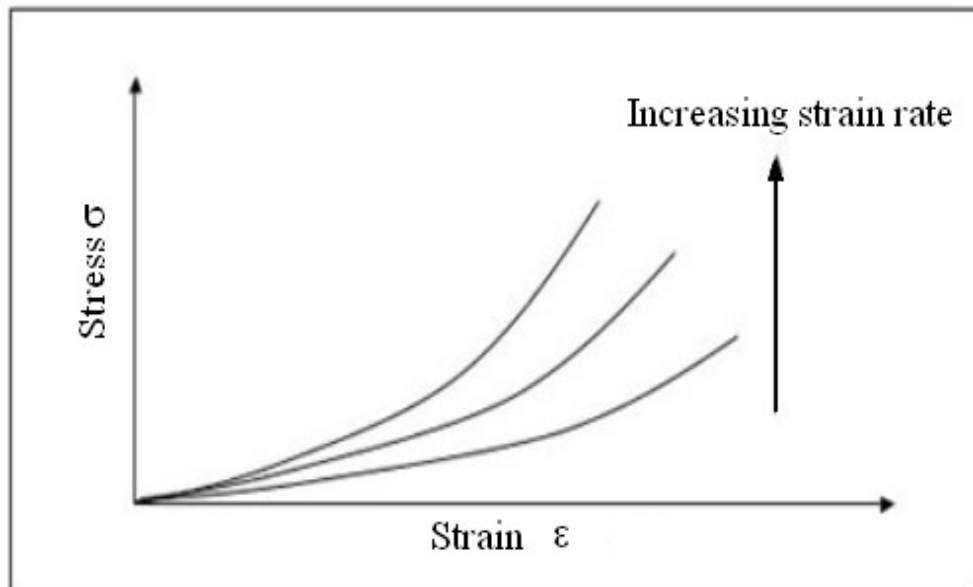
**Biological Soft Tissue Materials**

The assumptions made for the traditional materials are not valid when testing biological soft tissue samples. These materials are, in general, non-homogeneous due to the orientation of their collagen and elastin fibers. Hence, care must be taken when collecting samples and positioning them in testing system to ensure the directions are consistent with the intended analysis. Biological tissues exhibit large deformation before failure, therefore, any transducer used to measure strain will need to accommodate the large movement. Due to the un-crimping of collagen fibers and elasticity of elastin, the initial portion of a biological sample stress-strain curve has a high deformation/low force characteristics known as the toe region. In short, unlike traditional materials, this region is non-linear. A linear region is typically identified after the toe region and is used for the determination of  $E$ .



Stress-Strain Curve of Biological Soft Tissue Material

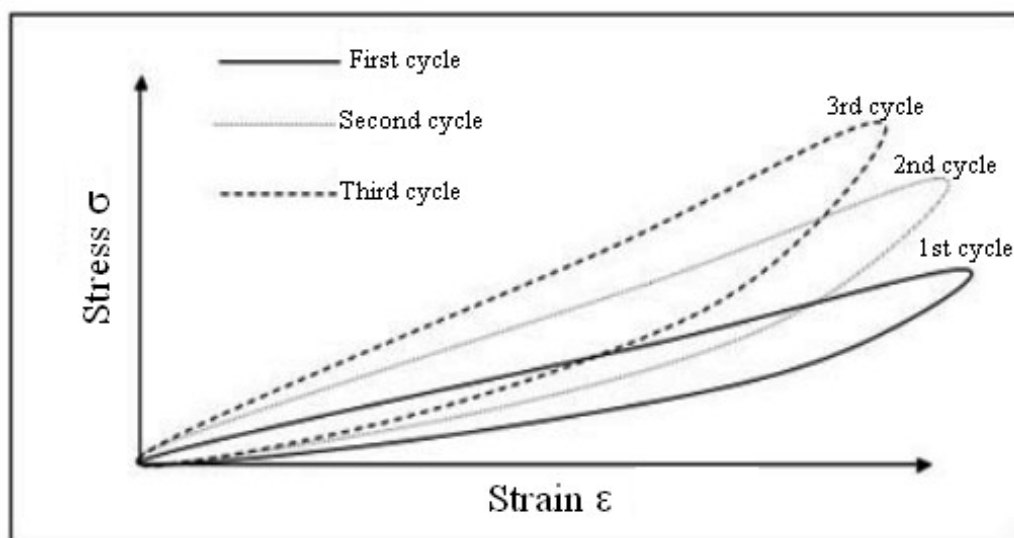
The mechanical properties of biological tissues are strain or loading rate dependent due to these tissues, visco-elastic nature. For example, biological tissues typically become stiffer with increasing strain rate (see figure below).



Strain rate Dependence

As such, predetermined and tightly controlled strain or loading rates must be maintained during testing. Furthermore, many biological tissues in their normal state are preconditioned (e.g. the anterior cruciate ligament) while many are not (e.g. brain).

For a tissue that has not been preconditioned, its response to load or displacement from one cycle to the next will not be similar; hence results will not be consistent (See figure below).



Preconditioning

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Depending on the type of tissue being tested or response of interest (e.g. sudden impact or fatigue failure), preconditioning as part of the testing protocol may or may not be necessary.

### (ii) Thermal Properties

Wide temperature fluctuations occur in the oral cavity due to the ingestion of hot or cold food and drink. Thermal Conductivity is the rate of heat flow per unit temperature gradient. Thus, good conductors have high values of conductivity.

Material	Thermal Conductivity
Enamel	$0.92 \text{ W.m}^{-1}.\text{°C}^{-1}$
Dentine	$0.63 \text{ W.m}^{-1}.\text{°C}^{-1}$
Acrylic Resin	$0.21 \text{ W.m}^{-1}.\text{°C}^{-1}$
Dental Amalgam	$23.02 \text{ W.m}^{-1}.\text{°C}^{-1}$
Zinc Phosphate Cement	$1.17 \text{ W.m}^{-1}.\text{°C}^{-1}$
Zinc Oxide Cement	$0.46 \text{ W.m}^{-1}.\text{°C}^{-1}$
Silicate Materials	$0.75 \text{ W.m}^{-1}.\text{°C}^{-1}$
Porcelain	$1.05 \text{ W.m}^{-1}.\text{°C}^{-1}$
Gold	$291.70 \text{ W.m}^{-1}.\text{°C}^{-1}$

(a) **Thermal Diffusivity** ( $D$ ) is defined by the equation:  $D = \frac{K}{C_p \rho}$ ,

Where,  $K$  is thermal conductivity;

$C_p$  is heat capacity, and

$\rho$  is density.



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Measurements of thermal diffusivity are often made by embedding a thermocouple in a specimen of material and plunging the specimen into hot or cold liquid. If the temperature, recorded by the thermocouple, rapidly reaches that of the liquid, this indicates a high value of diffusivity. A slow response indicates a lower value of diffusivity is preferred. In many circumstances, a low value of diffusivity is preferred. There are occasions on which a high value is beneficial. For example, a denture base material, ideally, should have a high value of thermal diffusivity in order that the patient retains a satisfactory response to hot and cold stimuli in the mouth.

**(b) Coefficient of Thermal Expansion** is defined as the fractional increase in length of a body for each degree centigrade increase in temperature.

$$\alpha = \frac{\Delta L / L_0}{\Delta T} \text{ } ^\circ\text{C}^{-1}$$

Where  $\Delta L$  is the change in length;

$L_0$  is the original length;

$\Delta T$  is the temperature change.

Because the values of  $\alpha$  very small numbers. For example for amalgam  $\alpha = 0.0000025 \text{ } ^\circ\text{C}^{-1} = 25 \text{ } ^\circ\text{C}^{-1} \text{ p.p.m}$  ( part per million).

Material	Coefficient of thermal expansion(p.p.m. $^\circ\text{C}^{-1}$ )
Enamel	11.4
Dentine	8.0
Acrylic Resin	90.0
Porcelain	4.0
Amalgam	25.0
Composite resins	25 – 60
Silicate Cements	10.0

This property is particularly important for filling materials. For filling materials, the most ideal combination of properties would be low value of diffusivity combined with ( $\alpha$ ) similar to that for tooth substance.

## **(2) Chemical Properties**

One of the main factors, which determine the durability of a material, is its chemical stability. Material should not dissolve, erode or corrode, nor should they leach important constituents into oral fluids.

### **(i) Solubility and Erosion**

The solubility of a material is a measurement of the extent to which it will dissolve in a given fluid, for example, water or saliva. Erosion is a process which combines the chemical process of dissolution with a mild mechanical action.

These properties are particularly important for all restorative materials since a high solubility or poor resistance to erosion will severely limit the effective lifetime of the restoration.

The pH of oral fluids may vary from pH4 to pH8.5, representing a range from mildly acidic to mildly alkaline. Highly acidic soft drinks and the use of chalk-containing tooth-pastes extend this range from a lower end of pH2 up to pH11. It is possible for a material to be stable at near neutral pH7 values but to erode rapidly at extremes of either acidity or alkalinity.

Standard tests of solubility often involve the storage of disc specimens of materials in water for a period of time, the results being quoted as the percentage weight loss of the disc. Such methods, however, often give misleading results.

When comparing silicate and phosphate cements, for example, silicate materials appear more soluble in simple laboratory test, but in practice they are more durable than the phosphates.

**(ii) Leaching of Constituents**

Many materials, when placed in an aqueous environment, absorb water by a diffusion process. Constituents of the material may be lost into the oral fluids by a diffusion process commonly referred to as leaching.

Some soft acrylic polymers, used for cushioning, the fitting surfaces of dentures rely on the absence of relatively large quantities of plasticizer in the acrylic resin for their softness. The slow leaching of plasticizer causes the resin to become hard and, therefore, ineffective as a cushion.

Occasionally, leaching is used to the benefit of the patient. For example, in some cements containing calcium hydroxide, slow leaching causes an alkaline environment in the base of deep cavities. This has the dual benefit of being antibacterial and of encouraging secondary dentine formation.

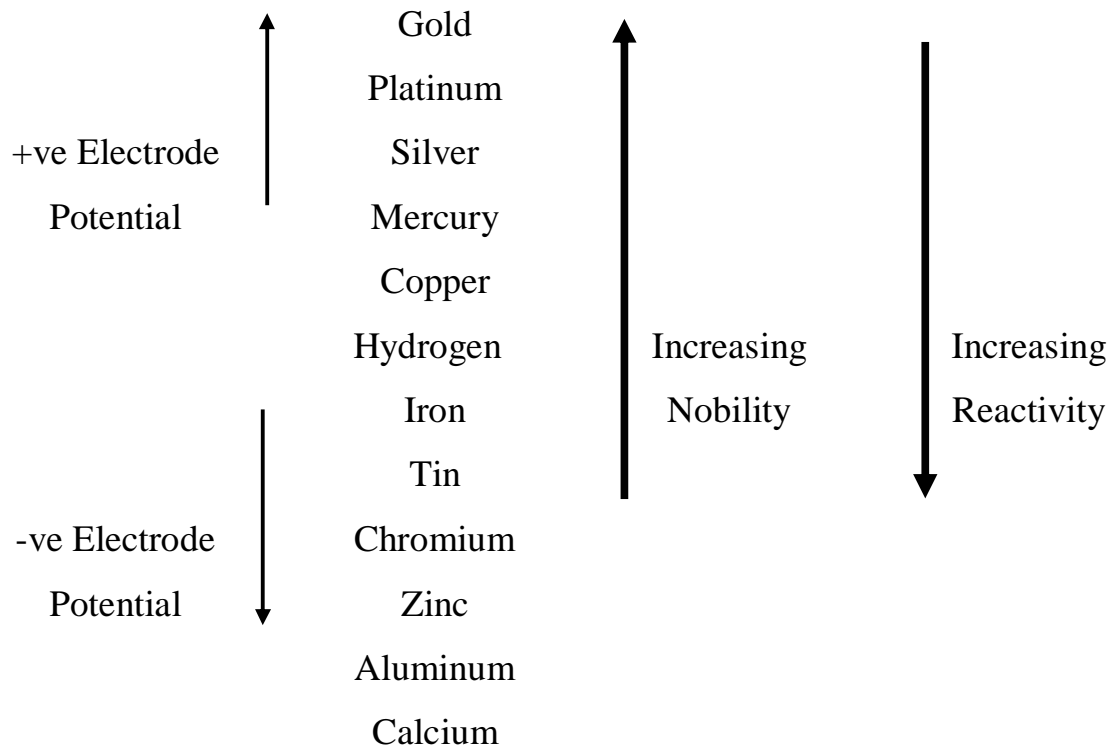
**(iii) Corrosion**

It is a term which specifically characterizes the chemical reactivity of metals and alloys. Metals and alloys are good electrical conductors and many corrosion processes involve the setting up of an electrolytic cell as a first stage in the process.

The tendency of a metal to corrode can be predicted from its electrode potential. It can be seen from the figure below, that materials with large negative electrode potential values are more reactive whilst those with large positive values are far less reactive and are often referred to as noble metals.

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It can be seen that chromium has a negative value of electrolytic potential and is at the reactive end of the series of metals shown. It is, therefore, surprising to learn that chromium is included as a component of many alloys in order to improve corrosion resistance. The apparent contradiction can be explained by the passivating effect. Although chromium is electrochemically active it reacts readily forming a layer of chromic oxide, which protects the metal or alloy from further decomposition.

Other factors, which can affect the corrosion of metals and alloys, are stress and surface roughness. Stress in metal components of appliances produces, for example, by excessive or continued bending can accelerate the rate of corrosion and may lead to failure by *stress corrosion cracking*.

Pits in rough surfaces can lead to the setting up of small corrosion cells in which the material at the bottom of the pit acts as the anode and that at the surface acts as the cathode. The mechanism of this type of corrosion sometimes referred to as *concentration cell corrosion*, is complicated but is caused by the fact that pits tend to become filled with debris, which reduces the oxygen

concentration in the base of the pit compared with the surface. In order to reduce corrosion by this new mechanism, metals and alloys used in the mouth should be polished to remove surface irregularities.

Ideally, a material placed into a patient's mouth should be non-toxic, non-irritant, have no carcinogenic or allergic potential and if used as a filling material, should be harmless to the pulp.

**(I) Bio-ceramics**

Ceramics are used for the repair and restoration of diseased or damaged parts of the musculo-skeletal system.

Bio-ceramics may be:

- 1- Bioinert like Alumina ( $\text{Al}_2\text{O}_3$ ), Zirconia ( $\text{ZrO}_2$ );
- 2- Resorbable like tri-calcium phosphate (TCP);
- 3- Bioactive like Hydroxyapatite, bioactive glasses, and glass-ceramics;
- 4- Porous for tissue in-growth (hydroxyapatite-coated metals, alumina) of the jaw bone.

Applications include: Replacement for hips, knees, teeth, tendons and ligaments, and repair for periodontal disease, maxillofacial reconstruction, augmentation and stabilization, spinal fusion and bone fillers after tumor surgery. Carbon coatings are thrombo-resistant and are used for prosthetic heart valves.

**(II) Types of Bio-ceramics – Tissue Attachment**

The mechanism of tissue attachment is directly related to the type of tissue response at the implant interface. No material implanted in living tissues is inert; all materials elicit a response from living tissues.

Four types of response allow different means of achieving attachment of prostheses to the musculo-skeletal system.

The types of implant-tissue response are:

- a- If the material is toxic, the surrounding tissue dies;
- b- the material is nontoxic and biologically inactive (nearly inert), a fibrous tissue of variable thickness forms;
- c- If the material is nontoxic and biologically active (bioactive), an interfacial bond forms;
- d- If the material is nontoxic and dissolves, the surrounding tissue replaces it.

The attachment mechanisms with examples are summarized below:

Type of Bioceramic	Type of Attachment	Example
1	Dense, nonporous, nearly inert ceramics attach to bone-growth into surface irregularities by cementing the device into the tissues, or by pressing fitting into a defect (termed <b>Morphology Fixation</b> ).	$\text{Al}_2\text{O}_3$ (single crystal and polycrystalline)
2	For porous inert implants bone ingrowth occurs, which mechanically attaches the bone to the material (termed <b>Biological Fixation</b> )	$\text{Al}_2\text{O}_3$ (porous polycrystalline) hydroxyapatite-coated porous metals
3	Dense, nonporous, surface-reactive ceramics and glass-ceramics attach directly by chemical bonding with the bone (termed <b>Bioactive Fixation</b> )	Bioactive glasses Bioactive glass-ceramics Hydroxyapatite
4	Dense, nonporous (or porous), resorbable ceramics are designed to be slowly replaced by bone.	Calcium sulphate (Plaster of Paris) Tricalcium phosphate, Calcium phosphate salts

### (III) Nearly Inert Crystalline Bioceramics

**Inert** refers to materials that are essentially stable with little or no tissue reactivity when implanted within the living organism.

When a biomaterial is nearly inert (type1) and the interface is not chemically or biologically bonded, there is relative movement and progressive development of a non-adherent fibrous capsule in both soft and hard tissues. Movement at the biomaterial-tissue interface eventually leads to deterioration in function of the implant or the tissue at the interface or both.

Bone at an interface with type1, nearly inert, implant is very often structurally weak because of disease, localized death of bone, or stress shielding when higher elastic modules of the implant prevents the bone from being loaded properly. Most notable among the nearly inert ceramics are alumina and special forms of carbon and silicon.

High density high purity (>99.5%) alumina ( $\alpha\text{-Al}_2\text{O}_3$ ) was the first bioceramic widely used clinically. It is used in load-bearing hip prostheses and dental implants, because of its combination of excellent corrosion resistance, good biocompatibility, and high wear resistance, and high strength.

Although some dental implants are single-crystal sapphire, most alumina devices are very-fine-grained polycrystalline  $\alpha\text{-Al}_2\text{O}_3$ . A very small amount of magnesia (<0.5%) is used as an aid to sintering and to limit grain growth during sintering.

Strength, fatigue resistance, and fracture toughness of polycrystalline  $\alpha\text{-Al}_2\text{O}_3$  are a function of grain size and percentage of sintering aid, i.e. purity. Alumina with an average grain size of <4 $\mu\text{m}$  and >99.7% purity exhibits good flexural strength and excellent compressive strength.



Low wear rates have led to wide-spread use of alumina non-cemented cups, press fitted into the acetabulum (socket) of the hip. The cups are stabilized by bone growth into grooves or round pegs. The mating femoral ball surface is also of alumina, which is bonded to a metallic stem. Though long-term results in general have been excellent, it is essential that the age of the patient, nature of the disease of the joint, and bioceramics of the repair be considered carefully before any prosthesis is used.

The primary use of alumina is for the ball of the hip joint, with the socket component being made of ultrahigh molecular weight polyethylene (PE). Other clinical applications of alumina implants include knee prostheses, bone screws, jaw bone reconstruction, segmental bone replacement, and blade, screws or post-type dental implants.

#### **(IV) Porous Ceramics**

The concept behind nearly inert, micro-porous bioceramics (type2) is the ingrowths of tissue into pores on the surface or throughout the implant. The increased interfacial area between the implant and the tissues result in an increased inertial resistance to movement of the device in the tissue. The interface is established by the living tissue in the pores. This method of attachment is often termed biological fixation. It is capable of withstanding more complex stress states than type1 implants, which achieve only morphological fixation.

The limitation associated with type2 porous implants is that, for tissue to remain viable and healthy, it is necessary for the pores to be greater than 100 to 150 $\mu$ m in diameter. The large interfacial area required for the porosity is due to the need to provide a blood supply to the ingrown connective tissue. Vascular tissue does not appear in pores, which measure less than 100 $\mu$ m. If micro-movement occurs at the interface of a porous implant, tissue is damaged, the blood supply may be cut off, tissue dies, inflammation ensues and the interfacial stability can be destroyed.

The potential advantage offered by a porous ceramic is the inertness combined with the mechanical stability of the highly convoluted interface developed when bone grows into the pores of the ceramic. Mechanical requirements of prostheses, however, severely restrict the use of low strength porous ceramics to low-load or non-load bearing applications. Studies show that, when load bearing is not a primary requirement, nearly inert porous ceramics can provide a functional implant.

When pore sizes exceed 100μm, bone will grow within the interconnecting pore channels near the surface and maintain its blood supply and long-term health. In this manner, the implant serves as a structural bridge and model or scaffold for bone formation. The microstructures of certain marine corals make an almost ideal casting material for obtaining structures with highly controlled pore sizes.

Several types of coral are promising, with pore-size ranges of 40-160μm and 200-1000μm. After the coral shape is machined, it is fired to drive off CO<sub>2</sub> from the limestone, forming a porous structure of calcia, or transformed directly into hydroxyapatite ceramic.

Porous ceramic surfaces can also be prepared by mixing soluble metal or salt particles into the surface. The pore size and structure are determined by the size and shape of the soluble particles that are subsequently removed with a suitable etchant. The porous surface layer produced by this technique is an integral part of the underlying dense ceramic phase. Materials, such as alumina, may also be made porous by using a suitable foaming agent that evolves gases during heating.

Porous materials are weaker than the equivalent bulk form. As the porosity increases, the strength of the material decreases rapidly. Much surface area is also exposed, so that the effects of the environment on decreasing the strength become much more important than for dense nonporous materials.

$$S = S_0 e^{-cr}$$

Where  $\sigma$  is strength;

$\sigma_0$  is strength at zero porosity (Nonporous);

$c$  is a constant;

and  $\rho$  is porosity.

### (V) Bioactive Glasses and Glass-Ceramics

Another approach to the solution of the problems of interfacial attachment is the use of bioactive materials (type3). The concept of bioactive materials is intermediate between resorbable and bioinert.

Certain compositions of glasses, ceramics, glass-ceramics, and composites have been shown to bond to bone. These materials are also called bioactive ceramics. Some, even more specialized compositions of bioactive glasses, will bond to soft tissues as well as bone. A common characteristic of such bioactive materials is a modification of the surface that occurs upon implantation. The surface forms a biologically active hydroxycarbonate apatite (HCA) layer, which provides the bonding interface with tissues. The HCA phase that forms on bioactive implants has the same chemical structure as the mineral phase in bone, and is therefore responsible for interfacial bonding.

The bonding results in an interface that resists substantial mechanical forces. Bonding to bone was first demonstrated for a range of bioactive glasses, which contained specific amounts of  $\text{SiO}_2$ ,  $\text{CaO}$ , and  $\text{P}_2\text{O}_5$ . These glasses contained less than 60 mol%  $\text{SiO}_2$ , high contents of  $\text{Na}_2\text{O}$ , and  $\text{CaO}$ , and had a high  $\text{CaO}/\text{P}_2\text{O}_5$  ratio. Such a composition produced a surface that was highly reactive when exposed to an aqueous medium.

Many bioactive silica glasses are based upon the formula (called 45S5), which signifies 45wt%  $\text{SiO}_2$ , S as the network former, and a 5 to 1 molar ratio of Ca to P (in form of  $\text{CaO}$  and  $\text{P}_2\text{O}_5$  do not bond to bone. 45S5 glass implants have been used successfully for replacement of ear bones and maintenance of the jaw bone for denture wearers for up to eight years, with nearly 90% retention ratio.

This glass is also used for the restoration of the bone next to teeth that might otherwise be lost because of gum disease. Several other compositions have developed that are bioactive, as tabulated below:

Component	45S5 Bioglass	KGC Ceravital	A/W Glass-ceramic
SiO <sub>2</sub>	45	46.2	34.2
P <sub>2</sub> O <sub>5</sub>	6	-	16.3
CaO	24.5	20.2	44.9
Ca(PO <sub>3</sub> ) <sub>2</sub>	-	25.5	-
CaF <sub>2</sub>	-	-	0.5
MgO	-	2.9	4.6
Na <sub>2</sub> O	24.5	4.8	-
Structure	Glass and glass-ceramic	Glass-Ceramic	Glass-Ceramic

Bioactive glass ceramics is biocompatible, osteoconductive, and bonds to bone without an intervening fibrous connective tissue interface. This material has been widely used for filling bone defects. When granules of bioactive glass are inserted into bone defects, ions are released in body fluids and precipitate into a bone-like apatite on the surface, promoting the adhesion and proliferation of osteogenic cells. After long-term implantation, this biological apatite layer is partially replaced by bone. Bioactive glass with macro-porous structure has the properties of layer surface areas, which are favorable for bone integration. The porosity provides a scaffold on which newly-formed bone can be deposited after vascular ingrowth and osteoblast differentiation. The porosity of bioglass is also beneficial for resorption and bioactivity.

#### (VI) Resorbable Ceramics (type4)

They are designed to degrade gradually over a period of time and be replaced by the natural host tissue. This leads to a very thin or nonexistent interfacial thickness. This is the optimal solution to the problem of biomaterials if the requirements of strength and short-term performance can be met. Natural tissues can repair themselves and are gradually replaced throughout life by a continual turnover of cell population. As we grow older, the replacement of cells and tissues is slower and less efficient, which is why parts "wear out", unfortunately sum faster than others. Thus resorbable biomaterials are based on the same principles of repair which have evolved over millions of years.

One of the unique advantages of the resorbable ceramic is that its initial pore-size can be small, thereby possessing high mechanical strength compared to the strength of more porous substances. As the ceramic dissolves, it becomes more and more porous allowing the ingrowth of more supporting tissue to occur. As a result, mechanical integrity is maintained and stress concentrations minimized.

Complications in development of resorbable bio-ceramics are:

- (1) Maintenance of strength and the stability of the interface during the degradation period and replacement by the natural host tissue.
- (2) Matching resorption rates to the repair to the repair rate of body tissues which themselves vary enormously. Some dissolve too rapidly and some too slowly. Because large quantities of material may be replaced, it is also essential that a resorbable biomaterial consist only of metabolically acceptable substances. This criterion imposes considerable limitations on the compositional design of resorbable biomaterials.

Resorbable bioceramics have been used too treat maxillofacial defects, for obliterating periodontal pockets, as artificial tendons and as composite bone plates.

### Calcium Phosphate Ceramics

Different phases of calcium phosphate ceramics are used depending upon whether a resorbable or bioactive material is desired. These include dicalcium phosphate ( $\text{CaHPO}_4$ ) and hydroxyapatite  $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$  [HA].

**Applications** include dental implants, skin treatments, gum treatment, jawbone reconstruction, orthopedics, facial surgery, ear, nose and throat repair, and spinal surgery.

The mechanical behavior of calcium phosphate ceramics strongly influences their application as implants. Tensile and compressive strength and fatigue resistance depend on the total volume of porosity. Because HA implant have low reliability under tensile load, such calcium phosphate bioceramics can only be used as powders, or as small, unloaded implants with reinforcing metal posts, coatings on metal implants, low-bonded porous implants where bone growth acts as a reinforcing phase and as the bioactive phase in a composite.

Calcium phosphate (CaP) biomaterials are available in various physical forms (particles or blocks; dense or porous). One of their main characteristics is their porosity. The ideal pore size for bioceramic is similar to that of spongy bone. Macroprosity (pore size  $>50\mu\text{m}$ ) is intentionally introduced into the material by adding volatile substances or porogens (naphthalene, sugar, hydrogen peroxide, polymer beads, fibers, etc) before sintering at high temperatures.

Microporosity is formed when the volatile materials are released. Microporosity is related to pore size  $<10\mu\text{m}$ . Microporosity is the result of the sintering process, where the sintering temperature and time are critical parameters. It has been demonstrated that microporosity allows body fluid circulation whereas

macroporosity provides a scaffold for bone colonization. Average pore size diameter of 560 $\mu\text{m}$  is reported as the ideal macropore size for bone ingrowth compared to a smaller size (300 $\mu\text{m}$ ). The main difference between the different commercially available BCP (biophasic calcium phosphate) are the microporosities, which are dependent on sintering process.

### **Composites and Coatings**

One of the primary restrictions on clinical use of bioceramics is the uncertain lifetime under the complex stress states, slow crack growth, and cyclic fatigue that arise in many clinical applications. Two solutions to these limitations are the use of bioactive ceramics as coatings or in composites. Much of the rapid growth in the field of bioactive ceramics is due to development of various composite and coating systems.

Composites have been composed of plastic, carbon, glass, or ceramic matrices reinforced with various types of fibers, including carbon, SiC, stainless steel, HA, phosphate glass, and ZrO<sub>2</sub>. In most cases the goal is to increase flexural strength and strain to failure and decrease elastic modulus. The strongest composite achieved to date is A/W glass-ceramic containing a dispersion of tetragonal Zirconia, which has a bend strength of 700MPa, and fracture toughness of 4MPa $\text{m}^{1/2}$ .

The table below shows the characteristics of those composites:

Matrix	Reinforcing Phase
	Type1: Nearly inert Composites
Polyethylene	Carbon fiber
Poly(methyl methacrylate)	Carbon fiber
Carbon	SiC
Epoxy resin	Alumina/ stainless steel
	Type 2: Porous ingrowth composites
Coral HA yoniopora	DL polylactic acid
	Type3: Bioactive Composites
Bioglass	Stainless steel fibers
Bioglass	Titanium fibers
Collagen	HA
Polyethylene	HA
Poly(methyl methacrylate)	Phosphate-silicate-apatite glass fiber
A/W glass-ceramic	Transformation-toughened ZrO <sub>2</sub>
	Type4: Resorbable composite
Polyhydroxybuturate	HA
PLA/PGA	HA
PLA/PGA	PLA/PGA fibers
PLA is poly(lactic acid)	
PGA is poly(glycalic acid)	

Implant materials with similar mechanical properties should be the goal when bone is to be replaced. Because of the anisotropic deformation and fracture characteristics of cortical bone, which is itself a composite of compliant collagen fibrils and brittle HCA crystals, the Young's modulus (E) varies between about 7 to 25GPa. The critical strain intensity increases from as low as  $600\text{Jm}^{-2}$  to as much as  $5000\text{J m}^{-2}$  depending on orientation, age, and test conditions.

Most bioceramics are much stiffer than bone, many exhibit poor fracture toughness. Consequently, one approach to achieve properties analogous to bone is to stiffen a compliant biocompatible synthetic polymer, such as PE with a higher modulus ceramic second phase, such as HA powders. The effect is to increase Young's modulus from 1 to 8GPa and to decrease the strain to failure from >90% to 3% as the volume fraction of HA increases to 0.5.

Thus, the mechanical properties of the PE-HA composite are close to or superior to those of bone.



Another promising approach toward achieving high toughness, ductility and Young's modulus matching that of bone was developed. This composite uses sintered 316 stainless steel of 50-, 100-, 200- $\mu\text{m}$  or Titanium fibers, which provide an interconnected fibrous matrix which then impregnated with molten 45S5 bioglass. After the composite is cooled and annealed, very strong and tough material results, with metal to glass volume ratio between  $\frac{4}{6}$  to  $\frac{6}{4}$ .

Stress enhancement of up to 340MPa is obtained in bending with substantial ductility of up to 10% elongation, which bends  $90^\circ$  without fracturing.

### Coatings

A biometric coating, which has reached a significant level of clinical application, is the use of HA as a coating on porous metal surfaces for fixation of orthopedic prostheses. This approach combines biological and bioactive fixation. Though a wide range of methods have been used to apply the coating, plasma spray coating is usually preferred. The table below lists the bioceramic coatings:

Substrate	Coating
316L stainless steel	Pyrolytic carbon
316L stainless steel	45S5 bioglass
316L stainless steel	$\alpha\text{Al}_2\text{O}_3$ -HA-TiN
316L stainless steel	HA
Co-Cr alloy	45S5 bioglass
Co-Cr alloy	HA
Ti-6Al-4V alloy	45S5 bioglass
Ti-6Al-4V alloy	HA
Ti-6Al-4V alloy	$\text{Al}_2\text{O}_3$
Ti-6Al-4V alloy	HA/ABS glass[ABS is alkali borosilicate glass]

### 1- Carbon

The medical use of pyrolytic carbon coatings on metal substrates were used in heart surgery. The first time the low-temperature isotropic (LTI) carbon coatings were used in humans was a prosthetic heart valve.

Almost all commonly used prosthetic heart valves today have LTI carbon coatings for the orifice and/or occluder because of their excellent resistance to blood clot formation and long fatigue life. More than 600,000 lives have been prolonged through the use of these bioceramic-in-heart valves.

Three types of Carbon are used in biomedical devices:

- 1- Low temperature Isotropic (LTI);
- 2- Ultra low Temperature Isotropic (ULTI);
- 3- Glassy Carbons.

The LIT, ULTI and glassy carbon are sub-crystalline forms and represent a lower degree of crystal perfection. There is no order between the layers such as there is in graphite; therefore the crystal structure of these carbons is two-dimensional. Such a structure, called turbostratic, has densities between  $1400\text{--}2100\text{ kg.m}^{-3}$ .

High density LTI carbons are the strongest bulk forms of carbon and their strength can further be increased by adding silicon.

ULTI carbon can also be produced with high densities and strength, but it is available only as a thin coating (0.1 to  $1\mu\text{m}$ ) of pure carbon.

Glassy carbon is inherently a low density material and, as such, is weak. Its strength cannot be increased through processing.

The turbostratic carbon materials have extremely good wear resistance, some of which can be attributed to their toughness, i.e. their capacity to sustain large local elastic strains under concentrated or point loading without galling or incurring surface damage.

Another unique characteristic of the turbostratic carbons is that they do not fatigue. The ultimate strength of turbostratic carbon, as opposed to metals, does not degrade with cyclical loading.

Carbon surfaces are not only thromboresistant, but also appear to be compatible with the cellular elements of blood; they do not influence plasma proteins or alter the activity of plasma enzymes. One of the proposed explanations for the blood compatibility of these materials is that they absorb blood proteins on their surface without altering them.

## 2- Hydroxyapatite (HA)

A second bioceramic coating which has reached a significant level of clinical applications is the use of HA as a coating on porous metal surfaces for fixation of orthopedic prostheses.

Resorption or biodegradation of calcium phosphate ceramic is caused by:

- (i) Physiochemical dissolution, which depends on the solubility product of the material and local pH of its environment;
- (ii) Physical disintegration into small particles due to preferential chemical attack of grain boundaries;
- (iii) Biological factors, such as phagocytosis, which causes a decrease in local pH.

The rate of biodegradation increases as:

- (a) Surface area increases;
- (b) Crystallinity increases;
- (c) Crystal perfection decreases;
- (d) Crystal and grain size decrease;
- (e) Ionic substitutions of  $\text{CO}_3^{2-}$ ,  $\text{Mg}^{2+}$ ,  $\text{Sr}^{2+}$  in HA take place.

Factors which result in a decreasing rate of biodegradation include:

- (1) F-substitution in HA;
- (2)  $\text{Mg}^{2+}$  substitution in  $\beta$ -TCP [ $\beta$ - $\text{Ca}_3(\text{PO}_4)_2$ ,  $\beta$ -tricalcium phosphate];
- (3) Decreasing  $\beta$ -TCP/HA ratios in biphasic calcium phosphate.

Because of these variables, it is necessary to control the microstructure and phase state of resorbable calcium phosphate bioceramic in addition to achieving precise compositional control to produce a given rate of resorption in the body.

### Natural Composites

Natural occurring composites are within us all. On the macroscale, soft and hard tissues are formed from a complex structural array of organic fibers and matrix.

Soft tissues are formed from elastic (elastin) and non-elastic fibers (collagen) with a cellular matrix between the fibers. Biological structures, such as tendon, linking muscles to bone, are low in elastin, thus allowing muscle movement to be translated to the bone. However, ligaments linking bone to bone are high in elastin allowing movement between bones but retaining sufficient support to stop joints dislocating.

Tissue	Tensile Strength (MPa)	Ultimate Elongation %
Tendon (Low elastin content)	53	9.4
Skin (High elastin content)	7.6	78.0
Elastin	1	100
Collagen	50-100	10

### Hard Tissues

The two most important naturally occurring forms of bone required for structural stability are termed cancellous (spongy bone) and cortical. Spongy bone is a sponge-like structure, which approximates to an isotropic material. Cortical bone is highly anisotropic with reinforcing structures along its loading axis and a highly organized blood supply called Haversian system.

All hard tissues are formed from the four basic phases, shown below. The relative fractions of each phase vary between bone types and conditions. The relative percentages of mass for a typical cortical bone are included.

Organic- Collagen Fiber	16%
Mineral – Hydroxyapatite (HA) $[\text{Ca}_{10}(\text{PO}_4)_2(\text{OH})_2]$	60%
Ground substance	2%
Water	23%

The collagen fibers provide the framework and architecture of bone, with the HA particles located between the fibers. The ground substance is formed from proteins, polysaccharides, and musco-polysaccharides, which acts as a cement, filling the spaces between collagen fibers and HA mineral.

The microstructural level has two possible forms:

1- Woven bone is an immature version of the more mature lamellar form.

Woven bone is formed very rapidly and has no distinct structure.

- 2- Lamellar bone is formed into concentric rings called Osteons with central blood supply or Haversian systems. Each osteon is formed from 4-20 rings, with each ring being 4-7 mm thick and having a different fiber orientation. The arrangement of different fiber orientations in each layer gives the osteon the appearance of successive light and dark layers. In the centre of the rings, there is a Haversian canal which contains the blood supply. Whilst the outer layer is a cement layer formed from ground substance, it is less mineralized than the rest of the bone and has no collagen fibers. Consequently, the cement line is a site of weakness.

### **Synthetic Bone Grafting Materials**

These materials must be:

- 1- Biocompatible with host tissues, i.e.
  - a- non-toxic;
  - b- non-allergic;
  - c- non-carcinogenic;
  - d- non-inflammatory
- 2- Able to stimulate bone induction;
- 3- Resorbable following replacement by bone;
- 4- Radio-opaque;
- 5- Capable of withstanding sterilization
- 6- Inexpensive and stable to variation of temperature and humidity;
- 7- It has sufficient porosity to allow bone conduction and growth.

### Polymer as Biomaterial

Polymers have assumed an important role in medical applications. In most of these applications, polymers have little or no competition from other types of materials. Their unique properties are:

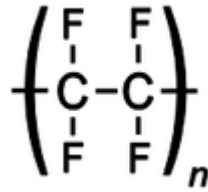
- 1- Flexibility;
- 2- Resistance to biochemical attack;
- 3- Good biocompatibility;
- 4- Light weight;
- 5- Available in a wide variety of compositions with adequate physical and mechanical properties;
- 6- Can be easily manufactured into products with the desired shape.

#### **Applications in biomedical field as:**

- 1- Tissue engineering;
- 2- Implantation of medical devices and artificial organs due to its inert nature;
- 3- Prostheses;
- 4- Dentistry;
- 5- Bone repair;
- 6- Drug delivery and targeting into sites of inflammation or tumors;
- 7- Plastic tubing for intra-venous infusion;
- 8- Bags for the transport of blood plasma;
- 9- Catheter.

#### **A few of the major classes of polymer are listed below:**

(1) (PTFE) Polytetrafluoroethylene is a fluorocarbon-based polymer. Commercially, the material is best known as Teflon. It is made by free-radical polymerization of tetrafluoroethylene and has a carbon backbone chain, where each carbon has two fluorine atoms attached to it.



## Properties of PTFE

- 1-Hydrophobic (Water hating)
- 2- Biologically inert\*
- 3- Non-biodegradable
- 4- Has low friction characteristics
- 5- Excellent "Slipperiness"
- 6- Relatively lower wear resistance.
- 7- Highly crystalline (94%)
- 8- Very high density (2.2 kg.m<sup>-3</sup>)
- 9- Low modulus of elasticity (0.5MPa)
- 10- Low tensile strength (14MPa)

\* The chemical inertness (stability) of PTFE is related to the strength of the fluorine-carbon bond. This is why nothing sticks to this polymer

## PTFE has many medical uses, including:

- 1- Arterial grafts (artificial vascular graft);
- 2- Catheters;
- 3- Sutures;
- 4- Uses in reconstructive and cosmetic facial surgery.

## PTFE can be fabricated in many forms, such as:

- 1- Can be woven into a porous fabric like mesh. When implanted in the body, this mesh allows tissue to grow into its pores, making it ideal for medical devices, such as vascular grafts;
- 2- Pastes;
- 3- Tubes;
- 4- Strands;
- 5- Sheets.

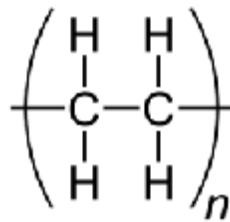


### Disadvantages of PTFE

PTFE has relatively low wear resistance. Under compression or in solutions where rubbing or abrasion can occur, it can produce wear particles. These can result in a chronic inflammatory reaction, an undesirable outcome.

### 2- Polyethylene, (PE)

It is chemically the simplest of all polymers and as a homochain polymer.



It is essentially:

- 1- Stable and suitable for long-time implantation under many circumstances;
- 2- Relatively inexpensive;
- 3- Has good general mechanical properties.

So that it has become a versatile biomedical polymer with applications ranging from catheters to joint-replacement.

### 3- Polypropylene, (PP)

Polypropylene is widely used in medical devices ranging from sutures to finger joints and oxygenerators.

### 4- Poly (methyl methacrylate), PMMA

It is a hard brittle polymer that appears to be unsuitable for most clinical applications, but it does have several important characteristics.

- (a) It can be prepared under ambient conditions so that it can be manipulated in the operating theater or dental clinic, explaining its use in dentures and bone cement.
- (b) The relative success of many joint prostheses is dependent on the performance of the PMMA cement, which is prepared intra-operatively by mixing powdered polymer with monomeric methylmethacrylate, which forms a dough that can be placed in the bone, where it then sets.

### **The disadvantages of PMMA**

- (a) The exotherm of polymerization;
- (b) The toxicity of the volatile methylmethacrylate;
- (c) The poor fracture toughness.

*(But no better material has been developed to date)*

### **5- Polyesters**

### **6-Polyurathanes**

### **Denture Base Resins**

Although individual denture bases may be formed from metals or metal alloys, most denture bases are fabricated using common polymers. Such polymers are chosen based on:

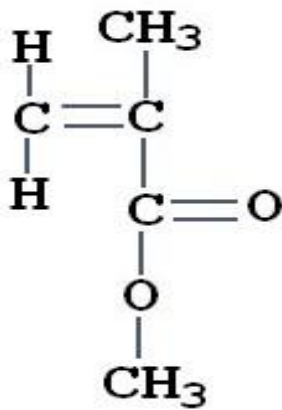
- (a) Availability;
- (b) Dimensional stability;
- (c) Handling characteristics;
- (d) Color;
- (e) Compatibility with oral tissues.

**General Techniques**

Several processing techniques are available for the fabrication of denture bases. Each technique is available for the fabrication of an accurate impression of the edentulous arch. Using this impression, a dental cast is generated. In turn, a resin recorded base is fabricated on the cast. Wax is added to the record base and the teeth are positioned in the wax.

**Acrylic Resins**

Most denture bases have been fabricated using Poly (methyl methacrylate) resins. Such resins are resilient plastics formed by joining multiple methylmethacrylate molecules (PMMA).



Pure PMMA is a colorless transparent solid. To facilitate its use in dental applications, the polymer may be tinted to provide almost any shade and degree of transparency. Its color and optical properties remain stable under normal intraoral conditions, and its physical properties have proved adequate for dental applications.

One decided advantage of PMMA as a denture base material is the relative ease with which it may be processed.

PMMA denture base material usually is supplied as a powder-liquid system. The liquid contains unpolymerized MMA, and the powder contains propolymerized PMMA resin in the form of small beads. When the liquid and powder are mixed in the correct proportions, a workable mass is formed. Subsequently, the material is introduced into a mold cavity of the desired shape and polymerized.

**Properties of Denture Base Resin**

When, methyl methacrylate monomer is polymerized, to form Poly (methyl methacrylate), the density of the mass changes from 0.94 to 1.19gm/cm<sup>3</sup>. This change in density results in a volumetric shrinkage of 7%. Based on projected volumetric shrinkage of 7%, an acrylic resin denture base should exhibit a linear shrinkage of approximately 2%.

PMMA absorbs relatively small amounts of water when placed in an aqueous environment. Nevertheless, this water exerts significant effect on the mechanical and dimensional properties of the polymer.

PMMA exhibits a water sorption value of 0.69mg/cm<sup>2</sup>. Although this amount of water may seem inconsequential, it exerts significant effect on the dimensions of polymerized denture base. Laboratory trials indicate a linear expansion caused by water absorption is approximately equal to the thermal shrinkage encountered as a result of the polymerization process. Hence these processes almost offset one another.

Although denture base resins are soluble in a variety of solvents and a small amount of monomer may be leached, they are virtually insoluble in the fluids commonly encountered in the oral cavity.

The strength of an individual denture base resin is dependent on several factors. These factors include:

- (a) Composition of the resin;
- (b) Processing technique;
- (c) Conditions presented by the oral environment.

Because of the resilient nature of denture base resins, some elastic deformation that is recoverable deformation also occurs. Clinically, this means that load application produces stresses within a resin and a change in the overall shape of the denture base. When the load is released, stresses within the resin are relaxed and the denture base returns to its original shape. Nevertheless, the existence of plastic deformation prevents complete recovery. Therefore, some permanent deformation remains.

Perhaps the most important determinant of overall resin strength is the degree of polymerization exhibited by the material. As the degree of polymerization increases the strength of the resin also increases.

### **Resin Teeth for Prosthodontic Applications**

PMMA resins used in the fabrication of prosthetic teeth are similar to those used in denture base construction. Nevertheless, the degree of cross-linking within prosthetic teeth is somewhat greater than that within polymerized denture bases. This increase is achieved by elevating the amount of cross-linking agent in the denture base liquid, that is, the monomer. The resultant polymer displays enhanced stability and improved clinical properties.

Despite the current emphasis on resin teeth, prosthetic teeth also may be fabricated using dental porcelain. Hence a comparison of resin and porcelain teeth is provided that:

- (a) Resin teeth display greater fracture toughness than porcelain teeth. As a result, resin teeth are less likely to chip or fracture on impact, such as when a denture is dropped;

- (b) Resin teeth are easier to adjust and display greater resistance to thermal shock;
- (c) Porcelain teeth display better dimensional stability and increasing wear resistance;
- (d) Porcelain teeth, especially when contacting surfaces have been roughened often cause significant wear of opposing enamel and gold surfaces. As a result, porcelain teeth should not oppose such surfaces, and if they are used, they should be polished periodically to reduce such abrasive damage;
- (e) As a final note, resin teeth are capable of chemical bonding with commonly used denture base resins. Porcelain teeth do not form chemical bonds with denture resins and must be retained by other means, such as mechanical undercuts and silanization.

### Materials in Maxillofacial Prosthetic

Despite improvements in surgical and restorative techniques, the materials used in maxillofacial prosthetics are far from ideal. An ideal material should be inexpensive, biocompatible, strong, and stable. In addition, the material should be skin-like in color and texture. Maxillofacial materials must exhibit resistance to tearing and should be able to withstand moderate thermal and chemical challenges. Currently, no material fulfills all of these requirements. A brief description of maxillofacial materials is included in the following paragraphs:

#### Latexes

Latexes are soft, inexpensive materials that may be used to create lifelike prostheses. Unfortunately, these materials are weak, degenerate rapidly, exhibit color instability and can cause allergic reactions.

A recently developed synthetic latex is a tripolymer of butylacrylate, methyl methacrylate, and methyl methacrylamide. This material is nearly transparent, but has limited applications.

### **Vinyl Plastisols**

They are plasticized vinyl resin sometimes are used in maxillofacial applications. Plastsols are thick liquids comprising small vinyl particles dispersed in a plasticizer. Colorants are added to these materials to match individual skin tones. Unfortunately, vinyl plastisols harden with age because plasticizer loss. Ultraviolet light also has an adverse effect on these materials. For these reasons, the use of vinyl is limited.

### **Silicone Rubbers**

Both heat-vulcanizing and room temperature vulcanizing silicones are in use today and both exhibit advantages and disadvantages.

Room temperature vulcanizing silicones are supplied as single- paste systems. These silicones are not as strong as the heat-vulcanized silicones and generally are monochromatic.

Heat-vulcanizing silicone is supplied as a semi-solid material that requires milling, packing under pressure, and 30-minute heat treatment application cycle at 180°C. Heat vulcanizing silicone displays better strength and color than room temperature vulcanizing silicone.

### **Polyurethane polymers**

Polyurethane is the most recent of the materials used in maxillofacial prosthetics. Fabrication of a polyurethane prosthesis requires accurate proportioning of three materials. The material is placed in a stone or metal mold and allowed to polymerize at room temperature. Although a polyurethane

prosthesis has a natural feel and appearance, it is susceptible to rapid deterioration.

The loss of natural teeth, through disease or trauma, has for many years been compensated by the provision of artificial teeth in the form of bridges and dentures. These essentially provide an aesthetic replacement of crown of the tooth but do nothing to replace the root and its attachment to the bone of the jaw.

### Natural Polymers

Natural polymers, or polymers, derived from living creatures, are of great interest in the biomaterials field. In the area of tissue-engineering, for example, scientists and engineers look for scaffold on which one may successfully grow cells to replace damaged tissue.

Typically, it is desirable for these scaffolds to be:

- (1) Biodegradable;
- (2) Non-toxic/ non-inflammatory;
- (3) Mechanically similar to the tissue to be replaced;
- (4) Highly porous;
- (5) Encouraging of cell attachments and growth;
- (6) Easy and cheap to manufacture;
- (7) Capable of attachment with other molecules ( to potentially increase scaffold interaction with normal tissue)

Normal polymers often easily fulfill these expectations, as they are naturally engineered to work well within the living beings from which they come. Three examples of natural polymers that have been previously studied for use as biomaterials are: collagen, chitosan, and alginate.



**Collagen** is the most widely found protein in mammals (25% of our protein mass) and is the major provider of strength to tissue. A typical collagen molecule consists of three intertwined protein chains that form a helical structure similar to a typical staircase). These molecules polymerize together to form collagen fibers of varying length, thickness and interweaving pattern (some collagen molecules will form ropelike structures, while others will form meshes or networks). There are actually at least 15 different types of collagen, differing in their structure, function, location, and other characteristics. The predominant form used in biomedical applications, however, is type I collagen, which is a "rope-forming" collagen and can be found almost everywhere in the body, including skin and bone.

Collagen can be resorbed into the body, is non-toxic produces only a minimal immune response, and is excellent for attachment and biological interaction with cell. Collagen may also be processed into a variety of formats, including porous sponges, gels and sheets, and can be cross-linked with chemicals to make it stronger or to alter its degradation rate. The number of biomedical applications in which collagen has been utilized is too high to count here, it not only explored for use in various types of surgery, cosmetics, and drug delivery, but in bio-prosthetic implants and tissue-engineering of multiple organs as well. Cells grown in collagen often come close to behaving as they do within the body, which is why collagen is so promising when one is trying to duplicate natural tissue function and healing.

However, some disadvantages to using collagen as a cell substrate do exist. Depending on how it is processed, collagen can potentially cause alteration of cell behavior (e.g. changes in growth or movement), have inappropriate mechanical properties, or undergo contraction (shrinkage). Because cells interact so easily with collagen, cells can actually pull and reorganize collagen fibers, causing scaffolds to lose their shape if they are not

properly stabilized by cross-linking or mixing with another less "vulnerable material".

Fortunately, collagen can be easily combined with other biological or synthetic materials, to improve its mechanical properties or change the way cells behave when grown upon it.

### **Chitosan**

It is derived from chitin, a type of polysaccharide (sugar) that is present in the hard exoskeletons of shellfish like shrimp and crab. Chitin has sparked interest in the tissue-engineering field due to several desirable properties:

- 1- Minimal foreign body reaction;
- 2- Mild processing conditions (synthetic polymers often need to be dissolved in harsh chemicals; chitosan will dissolve in water based on pH);
- 3- Controllable mechanical/biodegradation properties (such as scaffold porosity);
- 4- Availability of chemical side groups for attachment to other molecules.

Chitosan has already been investigated for use in the engineering of cartilage, nerve and liver tissues. Chitosan has also been studied for use in wound healing and drug delivery. Current difficulties with using chitosan as a polymer scaffold in tissue-engineering, however, include low strength and inconsistent behavior with seeded cells. Fortunately, chitosan may be easily combined with other materials in order to increase its strength and cell-attachment potential. Mixtures with synthetic polymers such as poly (vinyl alcohol) and poly (ethylene glycol) or natural polymers such as collagen have already been produced.

**Alginate**

It is a polysaccharide derived from brown seaweed. Like chitosan, alginate can be processed easily in water and has been found to be fairly non-toxic and non-inflammatory enough, so that it has been approved in some countries for wound dressing and for use in food products. Alginate is biodegradable, has controllable porosity, and may be linked to other biologically active molecules. Interestingly, encapsulation of certain cell types into alginate beads may actually enhance cell survival and growth. In addition, alginate has been explored for use in liver, nerve, heart, and cartilage tissue-engineering. Unfortunately, some drawbacks of alginate include mechanical weakness and poor cell adhesion. Again, to overcome these limitations, the strength and cell behavior of alginate have been enhanced by mixing with other materials, including the natural polymers agarose and chitosan.

### Metals and Alloys

Metals are used as biomaterial due to their excellent electrical and thermal conductivity and mechanical properties. Since some electrons are independent in metals, they can quickly transfer an electric charge and thermal energy. The mobile free electrons as the binding force to hold the positive metal ions together. This attraction is strong, as evidenced by the closely-packed atomic arrangement resulting in high specific gravity and high melting points of most metals. Since the metallic bond is essentially non-directional, the position of the metal ions can be altered without destroying the crystal structure, resulting in a plastically deformable solid.

Some metals are used as passive substitutes for hard tissue replacement such as:

- 1- Total hip;
- 2- Knee joints;
- 3- For fracture healing aids as bone plates and screws;
- 4- Spinal fixation devices;
- 5- Dental implants, because of their excellent mechanical properties, and corrosion resistance;
- 6- Vascular stents;
- 7- Catheter guide wires.

### Stainless Steels

Stainless steel was first used successfully as an important material in the surgical field.

- I- Type 302 stainless steel was introduced, which is stronger and more resistant to corrosion than the vanadium steel;

- II- Type 316 stainless steel was introduced, which contains a small percentage of molybdenum (18-8sMo) to improve the corrosion resistance in chloride solution (salt water);
- III- Type 316L stainless steel. The carbon content was reduced from 0.08 to a maximum amount of 0.03% for better corrosion resistance to chloride solution.

The inclusion of molybdenum enhances resistance to pitting corrosion in salt water. Even the 316L stainless steels may corrode in the body under certain circumstances in highly stressed and oxygen depleted region, such as the contacts under the screws of the bone fracture plate. Thus, these stainless steels are suitable to use only in temporary implant devices, such as fracture plates, screws, and hip nails.

### CoCr Alloys

There are basically two types of cobalt-chromium alloys:

- 1- The CoCrMo alloy [ Cr (27-30%), Mo (5-7%), Ni (2.5%)] has been used for many decades in dentistry, and in making artificial joints;
- 2- The CoNiCrMo alloy [Cr (19-21%), Ni (33-37%), and Mo (9-11%)] has been used for making the stems of prostheses for heavily loaded joints, such as knee and hip.

The ASTM lists four types of CoCr alloys, which are recommended for surgical implant applications:

- 1) CoCrMo alloy [Cr (29-30%), Mo (5-7%), Ni (2.5%)];
- 2) CoCrWNi alloy [Cr (19-21%), W (14-16%), Ni (9-11%)];
- 3) CoNiCrMo alloy [Ni (33-37%), Cr (19-21%), Mo (9-11%)];
- 4) CoNiCrMoWFe alloy [Ni (15-25%), Cr (18-22%), Mo (3-4%), W (3-4%), Fe (4-6%)].

The two basic elements of the CoCr alloys form a solid solution of up to 65% Co. The molybdenum is added to produce finer grains, which results in higher strengths after casting. The chromium enhances corrosion resistance, as well as solid solution strengthening of the alloy.

The CoNiCrMo alloy contains approximately 35% Co and Ni each. The alloy is highly corrosion resistant to seawater (containing chloride ions) under stress.

### **Titanium and its Alloys**

Titanium and its alloys are getting great attention in both medical and dental fields because of:

- (a) Excellent biocompatibility;
- (b) Light weight;
- (c) Excellent balance of mechanical properties;
- (d) Excellent corrosion resistance.

They are commonly used for implant devices replacing failed hard tissue, for example, (1) artificial hip joints, (2) artificial knee joint, (3) bone plate, (4) dental implants, (5) dental products, such as crowns, bridges and dentures, and (6) used to fix soft tissue, such as blood vessels.

In the elemental form, titanium has a high melting point (1668°C) and possesses a hexagonal closely packed structure (hcp)  $\alpha$  up to a temperature of 882.5°C. Titanium transforms into a body centered cubic structure (bcc)  $\beta$  above this temperature.

One titanium alloy (Ti6Al4V) is widely used to manufacture implants. The main alloying elements of the alloy are Aluminum (5.5-6.5%) and Vanadium (3.5-4.5%). The addition of alloying elements to titanium enables it to have a wide range of properties:

- 1- Aluminum tends to stabilize the  $\alpha$ -phase; it increases the transformation temperature from  $\alpha$ - to  $\beta$ -phase.
- 2- Vanadium stabilizes the  $\beta$ -phase by lowering the temperature of transformation from  $\alpha$  to  $\beta$ .

The titanium-nickel alloys show unusual properties, that is, after it is deformed the material can snap back to its previous shape following heating of the material. This phenomenon is called (shape memory effect) SME. The equi-atomic TiNi or NiTi alloy (Nitinol) exhibits an exceptional SME near room temperature: if it is plastically deformed below the transformation temperature it reverts back to its original shape as the temperature is raised.

Another unusual property is super-elasticity, which is shown schematically below in Figure.1. As can be seen the stress does not increase with increased strain after the initial elastic stress or strain, the metal springs back to its original shape in contrast to other metals, such as stainless steel.

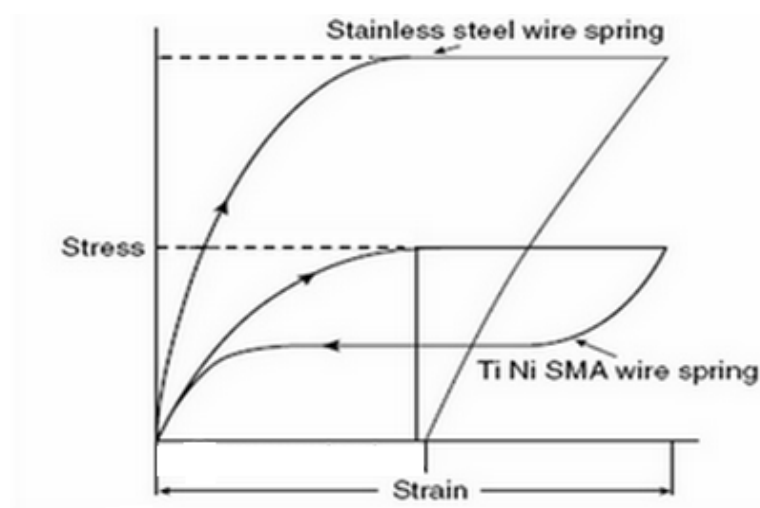


Fig.1 Schematic illustration of the stainless steel wire and TiNi SMR wire springs for orthodontics arch-wire behavior

## Biomedical Applications

The applications of titanium and its alloys can be classified according to their biomedical functionalities:

### 1- Hard Tissue Replacement

Hard tissues are often damaged due to accidents, aging, and other causes. Titanium and titanium alloys are widely used as hard tissue replacements in artificial bones, joints, and dental implants. As a hard tissue replacement, the low elastic modulus of titanium and its alloys is generally viewed as a biomechanical advantage because the smaller elastic modulus can result in smaller stress shielding.

One of the most common applications of titanium and its alloys is artificial hip joint that consists of an articulating bearing (femoral head and cup) and stem as in Fig.2.

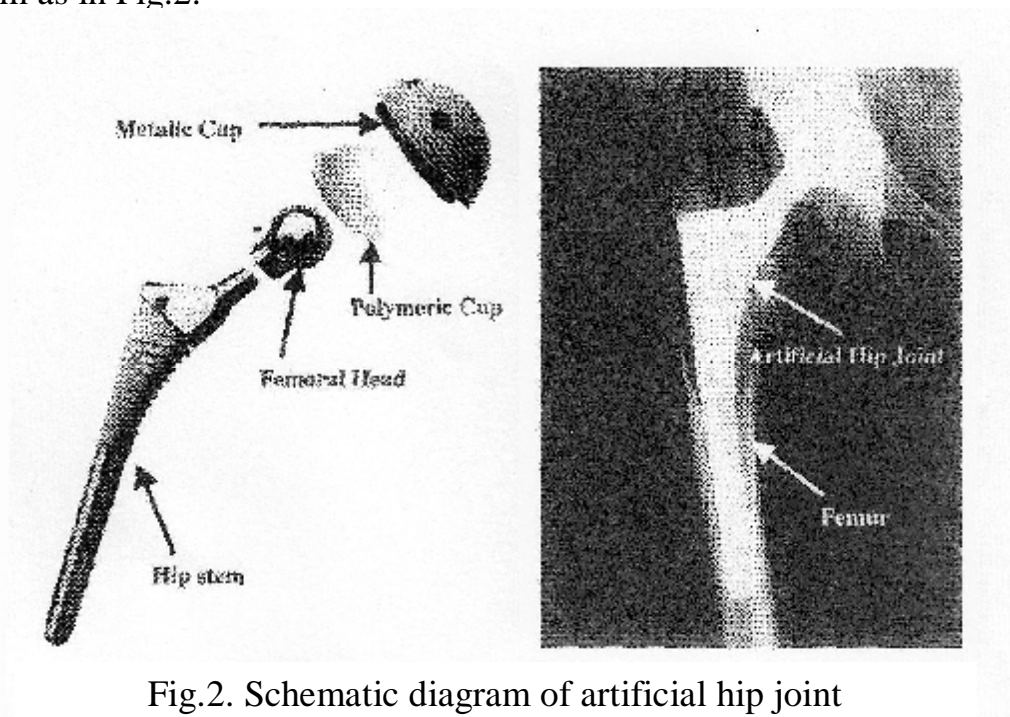


Fig.2. Schematic diagram of artificial hip joint

Titanium and titanium alloys are also often used in knee joint replacement, which consists of a femoral component, tibial component, and patella.



Titanium and titanium alloys are common in dental implants, the most commonly used implants are root-forming analogs. Fig.3 displays some of the popular designs, such as screw-shaped devices and cylinders.

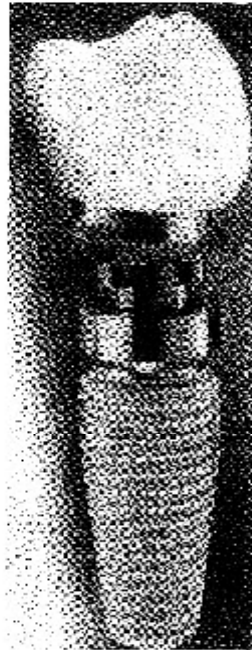


Fig.3. Schematic diagram of the screw-shaped artificial tooth

## **2- Cardiac and Cardiovascular Applications**

Titanium and titanium alloys are common in cardiovascular implants, because of their unique properties. Early applications examples were prosthetic heart valves, protective cases in pacemakers, artificial hearts and circulatory devices. Recently, the use of shape memory Nickel-Titanium alloy (Ni-Ti) in intravascular devices, such as stents and occlusion coils has received considerable attention.

The advantages of titanium in cardiovascular applications are that it is strong, inert and non-magnetic. A disadvantage is that it is not sufficiently radio-opaque in finer structures. Many types of prosthetic heart valves have been used clinically. The common designs as shown in Fig.4.

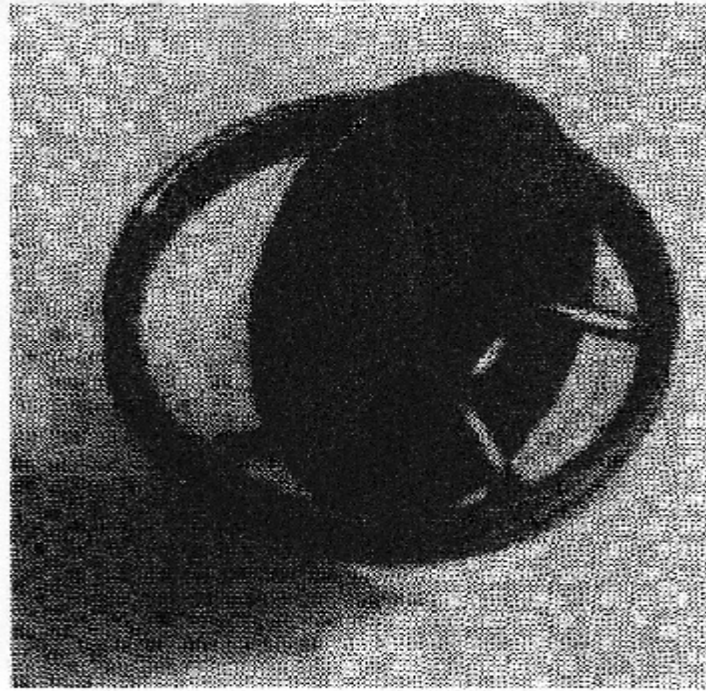


Fig.4. Artificial Heart Valve

At present stents (Fig.5) are commonly used in the treatment of cardiovascular disease. They dilate and keep narrowed blood vessels open. Stents are usually mounted on balloon catheters or folded inside special delivery catheters. Nickel-Titanium alloy is one of the most common materials used in vascular stents due to its special shape memory effects.

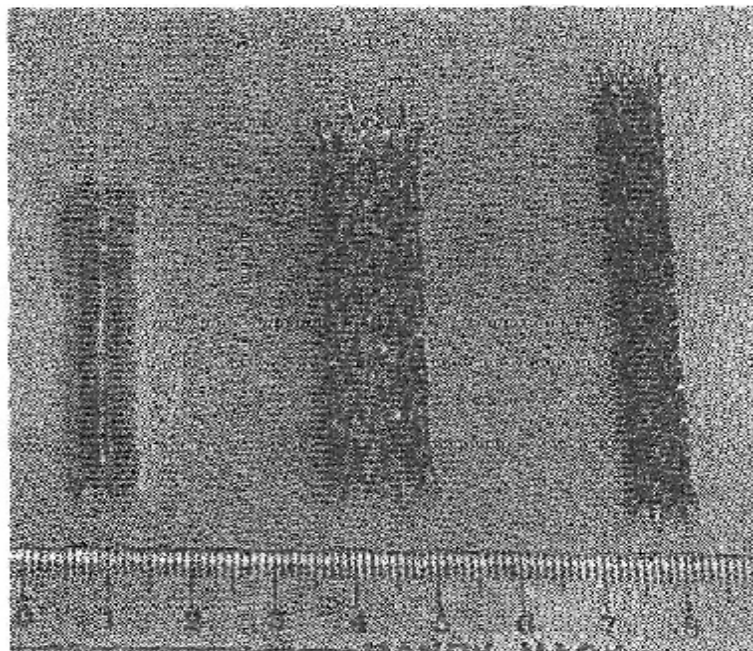


Fig.5. Artificial Vascular Stents

### 3- Other Applications

Titanium and titanium alloys are attractive materials in osteo-synthesis implant in view of its special properties that fulfill the requirements of osteo-synthesis applications. Typical implants for osteo-synthesis include bone screws, bone plates (Fig.6), maxillofacial implants, etc.

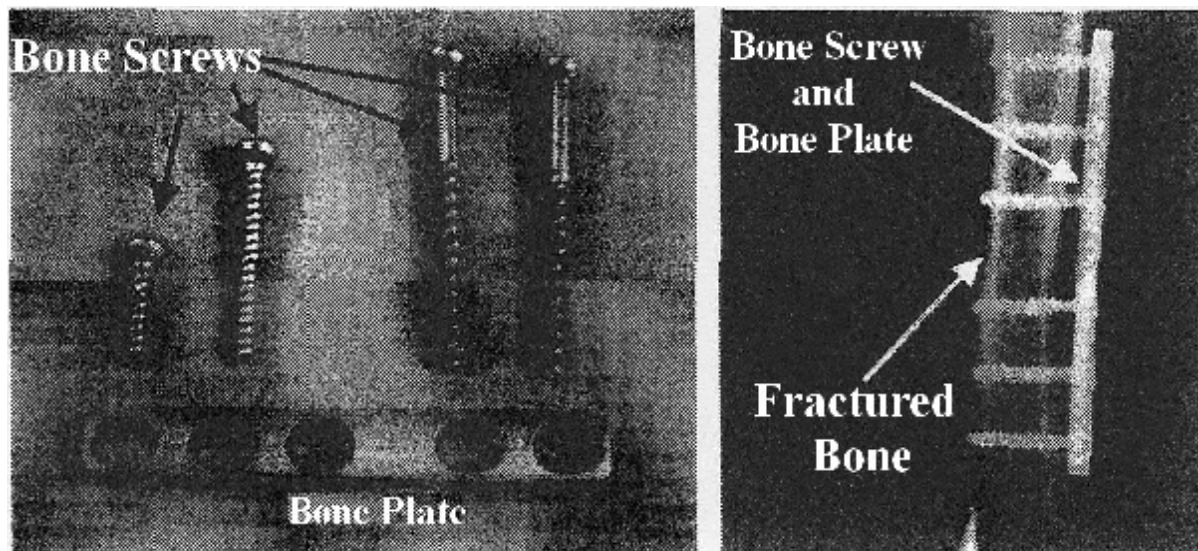


Fig.6: Bone screws and bone plate.

### Surface Structure and Properties

There has been a considerable amount of scientific and technical knowledge published on the structure, composition, and preparation of titanium and titanium alloys, and many of the favorable properties arising from the presence of the surface oxide. It is well-known that a native oxide film grows spontaneously on the surface upon exposure to air. The excellent chemical inertness, corrosion resistance, repassivation ability, and even biocompatibility of titanium and most other titanium alloys are thought to result from the chemical stability and structure of titanium oxide film that is typically only few nanometers thick.

The characteristics of films grown at room temperature on pure titanium are summarized as follows in Fig.7.

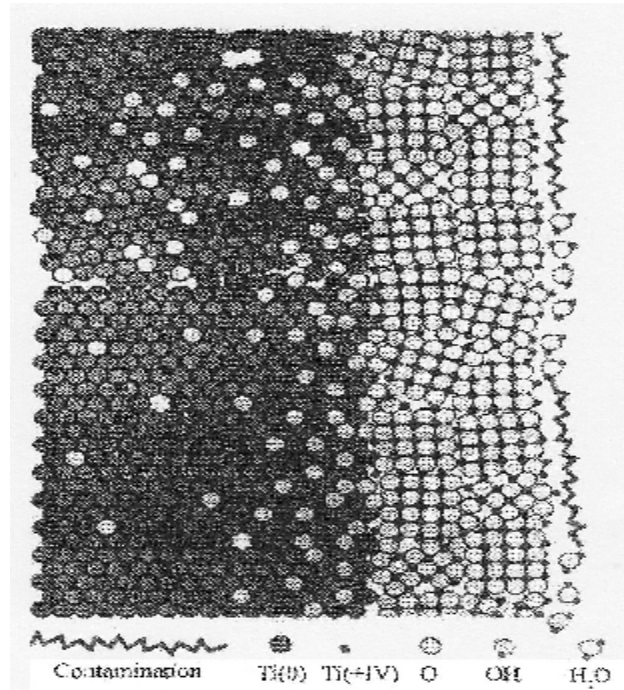


Fig.7 Schematic View of the oxide film on pure titanium

- 1- The amorphous or nano-crystalline oxide film is typically 3-7nm thick and mainly composed of the stable oxide  $\text{TiO}_2$ ;
- 2- The  $\text{TiO}_2/\text{Ti}$  interface has an O to Ti concentration ratio that varies gradually from 2 to 1 from the  $\text{TiO}_2$  film to a much lower ratio in the bulk;
- 3- Hydroxide and chemisorbed water bond with Ti cations leads to weakly bound physisorbed water on the surface. In addition, some organic species like hydrocarbons adsorb and metal-organic species, such as alkoxides or carboxylates of titanium also exist on the outmost surface layer whose concentrations depend on not only the surface conditions, such as cleanliness but also the exposure time to air as well as the quality of the atmosphere during storage.

## Mechanical Properties

Titanium is very promising in orthopedics due to its high specific strength and low elastic modulus. However, titanium has low wear and abrasion resistance because of its hardness.

## Biological Properties

Biocompatibility is the ability of the materials to perform in the presence of an appropriate host for a specific application. Titanium and titanium alloys are generally regarded to have good biocompatibility. They are relatively inert and have good corrosion resistance because of the thin surface oxide. They typically do not suffer from significant corrosion in a biological environment. Titanium readily absorbs proteins from biological fluids.

Titanium and bones are generally separated by a thin non-mineral layer and true adhesion of titanium to bones has not been observed. Instead, the bond associated with osteo-integration is attributed to mechanical interlocking of titanium surface asperities and pores in the bones. In order to make titanium biologically bond to bones, surface modification methods have been proposed to improve the bone conductivity or bioactivity of titanium.

Table 9.1 Biomaterials Applications in Internal Fixation

Materials	Properties	Application
<b>Stainless Steel</b>	<b>Low cost, easy fabrication</b>	<b>Surgical wire (annealed)</b>
		<b>Pin, plate, screw</b>
		<b>IM nail</b>
<b>Ti alloy</b>	<b>High cost</b>	<b>Surgical wire</b>
	<b>Low density and modulus</b>	<b>Plate, screws, IM nails</b>
	<b>Excellent bony contact</b>	
<b>Co-Cr (wrought)</b>	<b>High cost</b>	<b>Surgical wire</b>
	<b>High density and modulus</b>	<b>IM nail</b>
	<b>Difficult fabrication</b>	
<b>Polylactic acid</b>	<b>Resorbable</b>	<b>Pin screw</b>
<b>Polyglycolic acid</b>	<b>Weak strength</b>	
<b>Nylon</b>	<b>Non-resorbable plastic</b>	<b>Cerclage band</b>

Table 9.3 Biomaterials fir Total Joint Replacements

Materials	Properties	Application
<b>Co-Cr alloy</b>	<b>Stem, head (ball)</b>	<b>Heavy, hard, stiff</b>
<b>(casted or wrought)</b>	<b>Cup, porous coating</b>	<b>High wear resistance</b>
	<b>Metal backing</b>	
<b>Ti alloy</b>	<b>Stem porous coating</b>	<b>Low stiffness</b>
	<b>Metal backing</b>	<b>Low wear resistance</b>
<b>Pure titanium</b>	<b>Porous coating</b>	<b>Excellent osseousintegration</b>
<b>Tantulum</b>	<b>Porous structure</b>	<b>Excellent osseousintegration</b>
	<b>Good mechanical strength</b>	
<b>Alumina</b>	<b>Ball, cup</b>	<b>Hard, brittle</b>
		<b>High wear resistance</b>
<b>Zirconia</b>	<b>Ball</b>	<b>Heavy and high toughness</b>
		<b>High wear resistance</b>
<b>UHMWPE</b>	<b>Cup</b>	<b>Low friction, wear debris</b>
		<b>Low creep resistance</b>
<b>PMMA</b>	<b>Bone cement fixation</b>	<b>Brittle, weak in tension</b>
		<b>Low fatigue strength</b>

Table 9.4 Types of Total Joint Replacements

Joint	Types
<b>Hip</b>	<b>Bull and Socket</b>
<b>Knee</b>	<b>Hinged, semi-constrained, surface replacement</b>
	<b>Uni-compartment or bio-compartment</b>
<b>Shoulder</b>	<b>Bull and Socket</b>
<b>Ankle</b>	<b>Surface replacement</b>
<b>Elbow</b>	<b>Hinged, unconstrained, surface replacement</b>
<b>Wrist</b>	<b>Ball and socket, space filter</b>
<b>Finger</b>	<b>Hinged, space filter</b>

## Dental Materials

Dental amalgam is an alloy made of liquid mercury and other solid materials particulate alloys made of silver, tin, copper, etc. The solid alloy is mixed with (liquid) mercury in a mechanical vibrating mixer and the resulting material is packed into the prepared cavity. One of the solid alloys is composed of at least 65% silver, and not more than 29% tin, 6% copper, 2% zinc, and 3% mercury. The final composition of dental amalgams typically contains 45% to 55% mercury, 35% to 45% silver, and about 15% tin after fully set in about one day.

Gold and gold alloys are useful metals in dentistry as a result of their durability, stability, and corrosion resistance. Gold alloys are introduced by two methods: casting and malleling. Gold alloys are used for cast restorations, since they have mechanical properties which are superior to those of pure gold. The pure gold is relatively soft, so this type of restoration is limited to areas not subjected to much stress.

### Other Metals

Tantalum has been subjected to animal implant studies and has been shown very biocompatible. Due to its poor mechanical properties and its high density ( $16.6 \text{ gm/cm}^3$ ) it is restricted to few applications such as wire sutures for plastic surgeons and neurosurgeons, and a radioisotope for bladder tumors.

Surface modifications of metal alloys such as coatings by plasma spray, physical or chemical vapor deposition, ion implantation, and fluidized bed deposition have been used in industry. Coating implants with tissue compatible material such as hydroxyapatite, oxide ceramics, bio-glass, and pyrolytic carbon are typical applications in implants. Such efforts have been largely ineffective if the implants are subjected to a large loading. The main problem is in the delaminating of the coating or eventual wear of the coating. The added cost of coating or ion implanting hinders the use of such techniques unless the technique shows unequivocal superiority compared to the non-treated implants.

### Defining Terms

**In vitro:** In glass, as in a test tube. An in vitro test is one done in the laboratory, usually involving isolated tissues, organs, or cells.

**In vivo:** A test performed in a living body or organism.

**Passivation:** Production of corrosion resistance by a surface layer of reaction products (normally oxide layer which is impervious to gas and water)

**Passivity:** Resistance to corrosion by a surface layer of reaction products.

**Pitting:** A form of localized corrosion, in which, pits form on the metal surface.

## **Hard Tissue Replacements**

### **Bone Repair and Joint Implants**

A large number of devices are available for the repair of the bone tissue.

#### **1- Bone Repair**

The principal functions of the skeleton are to provide a frame to support the organ-systems, and to determine the direction and range of body movements. Bone provides an anchoring point for the most of skeletal muscles and ligaments.

Bone is the only tissue able to undergo spontaneous regeneration and to remodel its micro- and macro-structure. This is accomplished through a delicate balance between an osteogenic (bone forming) and osteoclastic (bone removing) process.

Nature provides different types of mechanisms to repair fracture in order to be able to cope with different mechanical environments about a fracture. With external fracture fixation, the bone fragments are held in alignment by pins placed through the skin onto the skeleton, structurally supported by external bars. With internal fracture fixation, the bone fragments are held by wires, screws, plates, and/or intra-medullary devices.

All the internal fixation devices should meet the general requirements of biomaterials, that is, biocompatibility, sufficient strength, corrosion resistance, and a suitable mechanical environment for fracture healing. From this perspective, stainless steel, cobalt-chrome alloys, and titanium alloys are most suitable for internal fixation. Most internal fixation devices persist in the body after the fracture has healed, often causing discomfort and requiring removal. Recently, biodegradable polymers, for example, polylactic acid (PLA) and polyglycolic acid (PGA) have been used to treat minimally loaded fractures, thereby eliminating the need for a second surgery for implant removal.



**Wires**

Surgical wires are used to reattach fragments of bone, like the greater trochanter, which is often detached during total hip replacement. They are also used to provide additional stability in long-oblique or spiral fractures of long bones which have already been stabilized by other means.

Twisting and knotting is unavoidable when fastening wires to bone, however, by doing so, the strength of the wire can be reduced by 25% or more due to stress concentration. This can be overcome by using a thicker wire, since its strength increases directly proportional to its diameter (Fig 9.1).

**Pins**

Pins are widely used primarily to hold fragments of bones together provisionally or permanently and to guide large screws during insertion. To facilitate implantation, the pins have different tip designs which have been optimized for different types of bone. The trochar tip is the most efficient in cutting hence; it is often used for cortical bone.

The holding power of the pin comes from elastic deformation surrounding bone. In order to increase the holding power to bone, threaded pins are used. Most pins are made of 316L stainless steel; however, recently, biodegradable pins made of polylactic or polyglycolic acid have been employed for the treatment of minimally loaded fractures. (Fig.9.2)

**Screws**

Screws are the most widely used devices for fixation of bone fragments. There are two types of bone screws:

- 1- Cortical bone screws, which have small threads, and
- 2- Cancellous screws which have large threads to get more thread-to-bone contact. They may have either V or buttress threads.

The holding power of screws can be affected by the size of the pilot drill-hole, the depth of screw engagement, the outside diameter of the screw, and quality of the bone. (Fig.9.3)

### **Plates**

Plates are available in a wide variety of shapes and are intended to facilitate fixation of bone fragments. They range from the very rigid, intended to produce primary bone healing, to the relatively flexible, intended to facilitate physiological loading of bone.

The rigidity and strength of a plate in bending depend on the cross-sectional shape and material of which it is made. The effect of the material on the rigidity of the plate is defined by the elastic modulus of the material for bending and by the shear modulus for twisting. Thus, given the same dimensions, a titanium alloy plate will be less rigid than a stainless steel plate, since the elastic modulus of each alloy is 110 and 200GPa respectively. (Fig.9.5)

### **Joint Replacement**

The design of an implant for joint replacement should be based on the kinematics and dynamic load transfer characteristics of the joint. The material properties shape, and methods used for fixation of the implant to the patient determines the load transfer characteristics. This is one of the most important elements that determine long-term survival of the implant, since bone responds to changes in load transfer with a remodeling process. Overloading the implant-bone interface or shielding it from load transfer may result in bone resorption and subsequent loosening of the implant. The articulating surfaces of the joint should function with minimum friction and produce the least amount of wear products. The implant should be securely fixed to the body as early as possible (ideally immediately after implantation); however, removal of the implant should not require destruction of a large amount of surrounding tissues.

**Implant Fixation Method**

Fixation of implants with polymethyl-methacrylate (PMMA, bone cement) provides immediate stability, allowing patients to bear all of their weight on the extremity at once. In contrast, implants which depend on bone ingrowth require the patient to wait about 12 weeks to bear full weight. Being a viscoelastic polymer, it has the ability to function as a shock absorber. It allows loads to be transmitted uniformly between the implant and bone, reducing localized high-content stress.

The problems with bone-cement interface may arise from intrinsic factors, such as the properties of the PMMA and bone, as well as extrinsic factors such as the cementing techniques.

**Porous Ingrowth Fixation**

Bone ingrowth can occur with inert implants which provide pores larger than 25 $\mu$ m in diameter, which is the size required to accommodate an osteon. For the best ingrowth in clinical practice, pore size range should be 100 to 350  $\mu$ m and pores should be interconnected with each other with similar size of opening.

Commercially, pure titanium, titanium alloys, tantalum, and calcium hydroxyapatite (HA) are currently used in porous coating materials. With pure titanium, three different types of porosity can be achieved:

- 1- Plasma spray coating;
- 2- Sintering of wire mesh;
- 3- Sintering of beads on an implant surface.

Thermal processing of the porous coating may weaken the underlying metal (implant). Additional problems may result from flaking of the porous coating materials, since loosened metal particles may cause severe wear when they migrate into the articulation.

Recently, a cellular, structural biomaterial comprised of 15 to 25% tantalum has been developed. The average pore size is about 550 $\mu$ m, and the pores are fully interconnected.

## **Total Joint Replacement**

### **1- Hip Joint Replacement**

The prosthesis for total hip replacement consists of a femoral component and an acetabular component. (Fig. ) The femoral stem is divided into head, neck, and shaft. The femoral stem is made of Ti alloy or CoCr alloy and is fixed into a reamed medullary canal by cementation or press fitting. The femoral head is made of CoCr alloy, alumina or zirconia. The acetabular component is generally made of ultra-high molecular-weight polyethylene (UHMWPE). The hip joint is a ball-and-socket joint which derives its stability from **cony ity** of the implants, pelvic, and capsule.

### **2- Knee Joint Replacements**

The prosthesis for total knee joint replacement consists of femoral, tibial, and patellar components. Compared to the hip joint, the knee has a more complicated geometry and movement biomechanics, and it is not intrinsically stable. In a normal knee, the center of movement is controlled by the geometry of the ligaments.

Total knee replacement can be implanted with or without cement, the latter relying on porous coating for fixation. The femoral components are typically made of CoCr alloy and the monolithic tibial components are made of UHMWPE.

In modular component, the tibial polyethylene component is assembled onto a titanium alloy tibial **tra** . The patellar component is made of UHMWPE, and titanium alloy back is added to components designed for uncemented use.

### **3- Ankle Joint Replacement**

Total ankle replacements have not met with as much success as total hip and knee replacements, and typically loosen within a few years of service. This is mainly due to the high load transfer demand over the relatively small ankle surface area and need to replace three articulating surfaces (tibial, talar, and fibular). The materials used to construct ankle joints are usually CoCr alloy and UHMWPE.

### **4- Shoulder Joint Replacements**

The prostheses for total shoulder replacement consist of humeral and glenoid components. Like the femoral stem, the humeral component can be divided into head, neck, and shaft. The shoulder has the largest range of motion in the body, which results from a shallow ball and socket joint, which allows a combination of rotation and sliding motions between the joint surfaces.

### **5- Elbow Joint Replacements**

The elbow joint is a hinge-type joint allowing mostly flexion and extension, but having a polycentric motion. The elbow joint implants are hinged, semi-constrained, or unconstrained. These implants, like those of the ankle, have a high failure rate and are not used commonly. The high loosening rate is the result of high rotational movements, limited bone stock for fixation, and minimal ligamentous support.

### **6- Finger Joint Replacements**

Finger joint replacements are divided into three types:

- 1- Hinge
- 2- Polycentric
- 3- Space-filler

The most widely used are the space-filler type. These are of high performance silicone rubber (poly dimethylsiloxane) and are stabilized with a passive fixation method.



## **Composite Biomaterials**

Biomaterials are solids which contain two or more distinct constituent materials or phases, on a scale larger than the atomic. The term "composite" is usually reserved for those materials in which the distinct phases are separated on a scale larger than the atomic, and in which properties such as the elastic modulus are significantly altered in comparison with those of a homogeneous material. Accordingly, reinforced plastics such as fiberglass as well as natural materials, such as bone are viewed as composite materials. Natural composites often exhibit hierarchical structures in which particulate, porous, and fibrous structural features are seen in different micro-scales.

Composite materials offer a variety of advantages in comparison with homogeneous materials. Those include the ability for the scientist or engineer to exercise considerable control over material properties. This is the potential for stiff, strong, light-weight materials as well as for highly resilient and compliant materials. Some applications of composites in biomaterial applications are:

- (1) Dental filling composites;
- (2) Reinforced methyl methacrylate bone cement and ultra-high molecular weight polyethylene;
- (3) Orthopedic implants with porous surfaces.

### **Structure**

The properties of composite materials depend very much upon structure. Composites differ from homogeneous materials in that considerable control can be exerted over the larger scale structure, and hence over the desired properties. In particular, the properties of a composite material depend upon the shape of the heterogeneities, upon the volume fraction occupied by them, and upon the interface among the constituents. The shape of the heterogeneities in a composite material is classified as follows:

- a- The particle, with no long dimension;
- b- The fiber, with one long dimension;
- c- The platelet or lamina, with two long dimensions.

**Bonds on Properties**

Mechanical properties in many composite materials depend on structure in a complex way, however for some structures; the prediction of properties is relatively simple. The simplest composite structures are the idealized Voigt and Reuss models, shown in Fig.2. The dark and light areas in these diagrams represent the two constituent materials in the composite. In contrast to most composite structures, it is easy to calculate the stiffness of materials with the Voigt and Reuss structures, since in the Voigt structure the strain is the same in both constituents, in the Reuss structure the stress is the same. The Young's modulus,  $E$ , of the Voigt composite is given by:

$$E = E_i V_i + E_m [1 - V_i]$$

Where  $E_i$  is the Voigt modulus of the inclusions,

$V_i$  is the volume fraction of the inclusions,

$E_m$  is the Young's modulus of the matrix.

The Reuss stiffness  $R$ , is less than that of the Voigt model

$$E = \frac{V_i}{\frac{1}{E_i}} + \frac{1 - V_i}{\frac{1}{E_m}}$$

The Voigt and Reuss models provide upper and lower bounds respectively upon the stiffness of a composite of arbitrary phase geometry. For composite materials which are isotropic, the more complex relations of Hashin and Shtrikman provide tighter bounds upon the moduli both the Young's and shear moduli must be known for each constituent to calculate these bounds.



An isotropic material has the same material properties in any direction. Anisotropic composites offer superior strength and stiffness in comparison with isotropic ones.

### Particulate Composites

It is often convenient to stiffen or harden a material, commonly a polymer, by the incorporation of particulate inclusions. The shape of the particles is important. In isotropic systems, stiff composite, followed by fibers and the last effective geometry for stiff inclusions is the spherical particles.

Particle reinforcement has been used to improve the properties of bone cement. For example, inclusion of bone particles in PMMA cement somewhat improves the stiffness and improves the fatigue life considerably. Moreover, the bone particles at the interface with the patient's bone are ultimately resorbed and are replaced by ingrown new bone tissue.

Rubber, used in catheters, rubber gloves, etc is usually reinforced with very fine particles of silica ( $\text{SiO}_2$ ) to make the rubber stronger and tougher.

Teeth with decayed regions have traditionally been restored with metals such as silver amalgam. Metallic restoration is not considered desirable for interior teeth for cosmetic reasons. Acrylic resins and silicate cements had been used for anterior teeth, but their poor material properties led to short service life and clinical failures. Dental composite resins have virtually replaced these materials and are very commonly used to restore posterior teeth as well as anterior teeth.

The dental composite resins consist of a polymer matrix and stiff inorganic inclusions. The inorganic inclusions confer a relatively high stiffness and high wear resistance on the material. Available dental composite resins use quartz, barium glass and colloidal silica as fillers. Fillers have particle size from 0.04 to 13 $\mu$ m, and concentrations from 33 to 78% by weight.

In restoring a cavity, the dentist mixes several constituents, then places them in the prepared cavity to polymerize. For this procedure to be successful the viscosity of the mixed paste must be sufficiently low and the polymerization must be controllable.

Dental composites have a Young's modulus in the range 10 to 16GPa, and the compressive strength from 170 to 260 MPa. These composites are still considerably less stiff than dental enamel, which contains about 99% mineral.

The thermal expansion of dental composites, as with other dental materials exceeds that of tooth structure. Moreover, there is a contraction during polymerization to 1.2 to 1.6%. These effects are thought to contribute to leakage saliva, bacteria, etc. at the interface margins. Such leakage in some cases can cause further decay of the tooth. All the dental composites exhibit creep.

### **Fibrous Composites**

Fibers incorporated in a polymer matrix increase the stiffness, fatigue life, and other properties. Fibers are mechanically more effective in achieving a stiff, strong composite than particles. Materials can be prepared in fiber form with very few defects which concentrate stress. Fibers such as graphite are stiff (Young's modulus is 200–800GPa) and strong (the tensile strength is 2.7–5.5GPa). Composites made from them can be as strong as steel but much lighter.