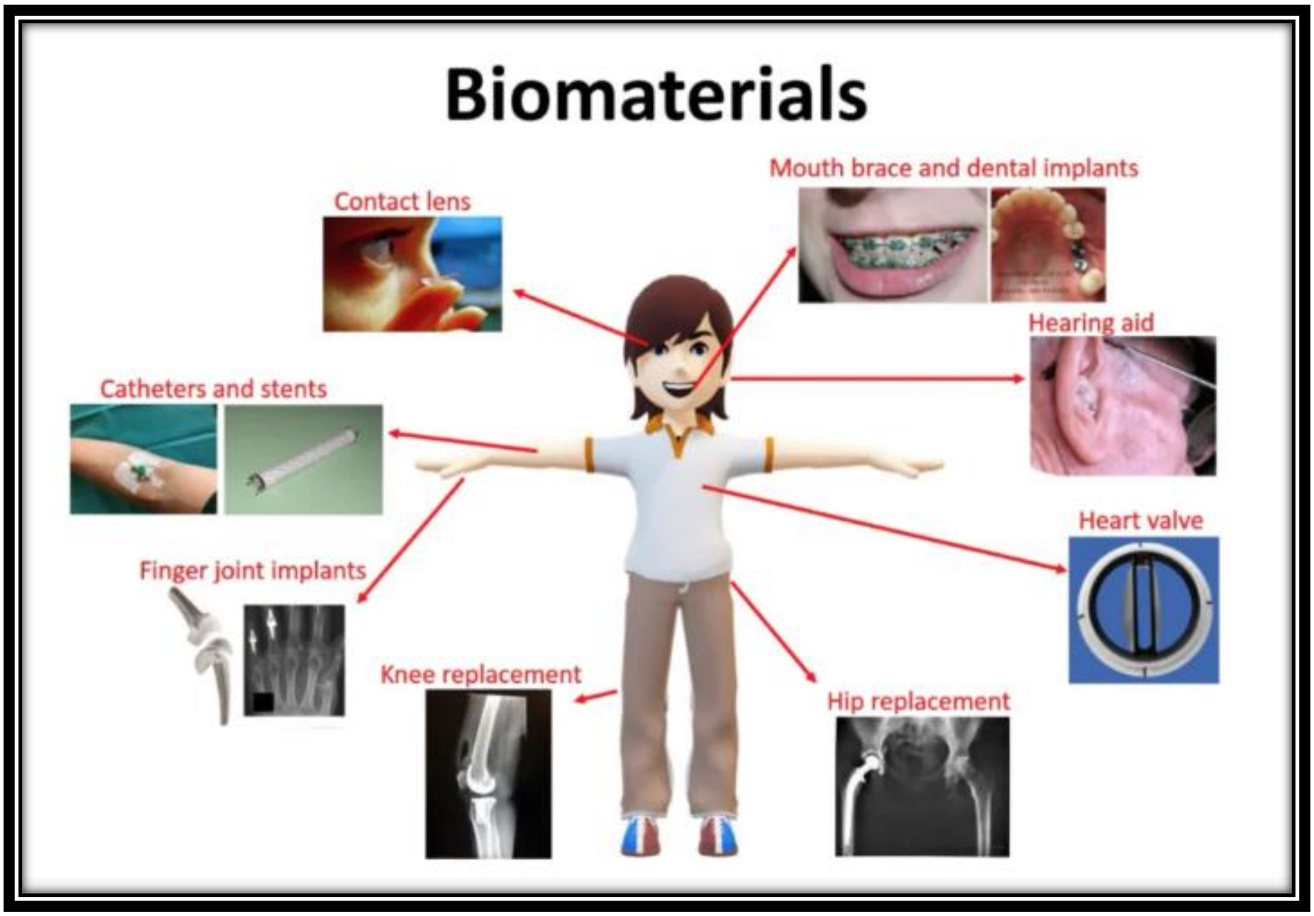
Biomaterial

A biomaterial is a material, synthetic or natural, that can be used in medical applications to perform a body function or replace a body part or tissue. A biomaterial is intended to interact at the interface of biological systems. Biomaterials are designed based on application needs. A biomaterial must be biocompatible, i.e., it should be friendly to biological system and not do any harm to the system, whether at the cellular level or at the system level.



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).

2- Biology and Physiology: Cell and molecular biology, anatomy, animal and human physiology, histopathology, experimental surgery etc.

3- Clinical Sciences: (All the clinical Specialties) maxillofacial, neurosurgery, and 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

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:

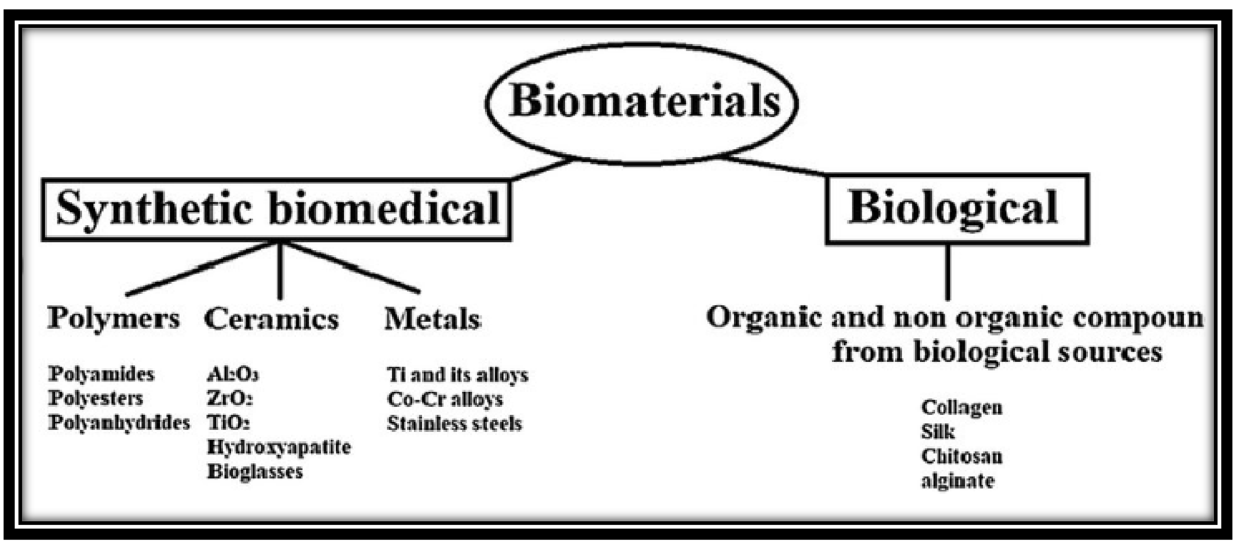
4- Choice of material.

Recent practice in medicine often times uses tissue reconstruction using autograft, where tissue graft or organ transplant from one point to another of the same individual takes place.

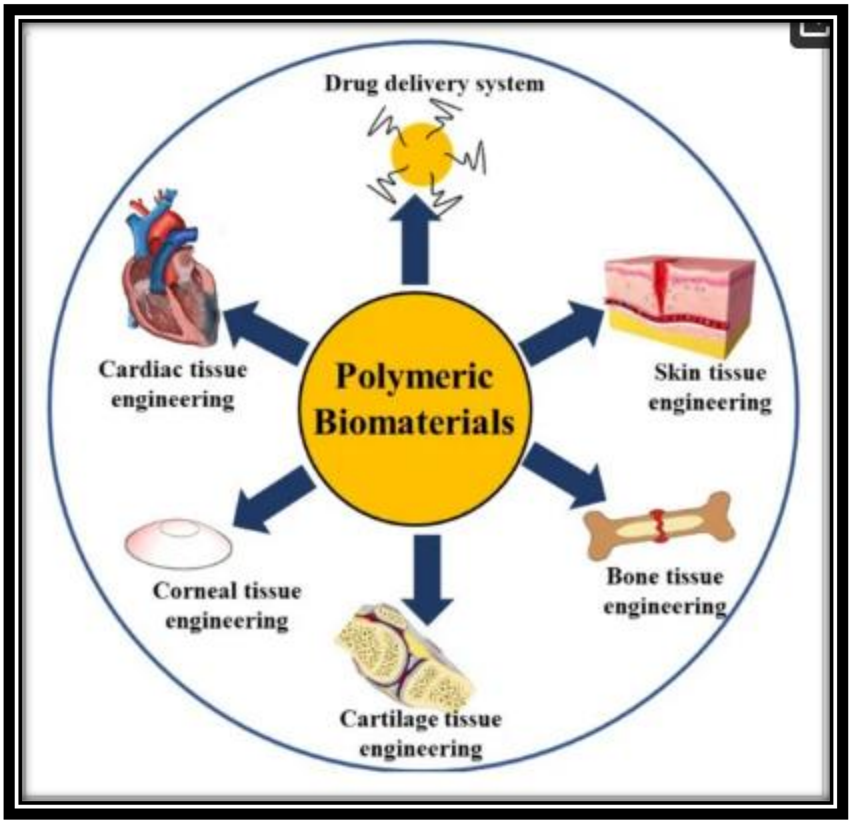
However, limited availability, donor site morbidity and above all, the need for a second surgery restrict their application. On the other hand, potential alternative is the use of allograft, i.e. tissue graft or organ transplant from a donor of the same species as the recipient. The other alternative could be xenograft, which is tissue graft or organ transplant from a donor of a different species from the recipient. Both allograft and xenograft use are somewhat restricted due to the immunogenic response and they may impose adverse biocompatibility in patients' body. These reasons draw our attention to the biomaterials that are available from other sources, which could be synthetic or natural.

Types of Biomaterials

Like any other materials, biomaterials can be grouped into four major categories: (1) polymers, (2) metals, (3) ceramics, and (4) composites.



1- **Polymers** can be used in both soft and hard tissue applications, and comprise the largest class of biomaterials. Polymers could be natural (examples: collagen, sodium alginate, and cellulose) or synthetic (examples: silicone rubber, PMMA, poly(vinyl chloride), and PCL).



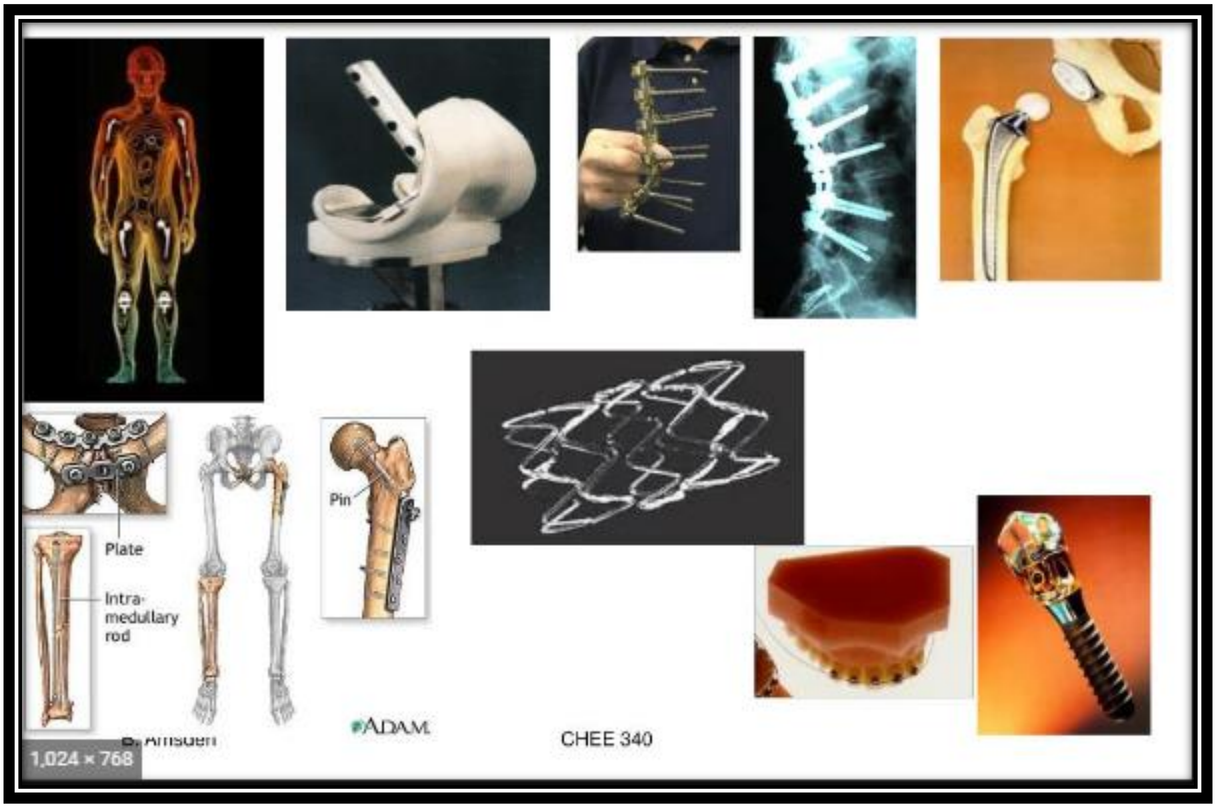
2-**Metals** are mostly used for dental and orthopedic applications. Most commonly used metals are Ti and its alloy, stainless steels and Co–Cr alloy. The metallic systems most frequently used in the body are:

(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 ^{3} 98.9%

(ii) Ti-Ni (55% Ni and 45% Ti).



3-Ceramics are mainly used in hard tissue repair, regeneration and augmentation, especially in nonload-bearing applications or as coatings on metal implants. Most widely used ceramic biomaterials are calcium phosphates (CaP), alumina (Al_2O_3), and bioglass.

The use of ceramics was motivated by:

(i) their inertness in the body,

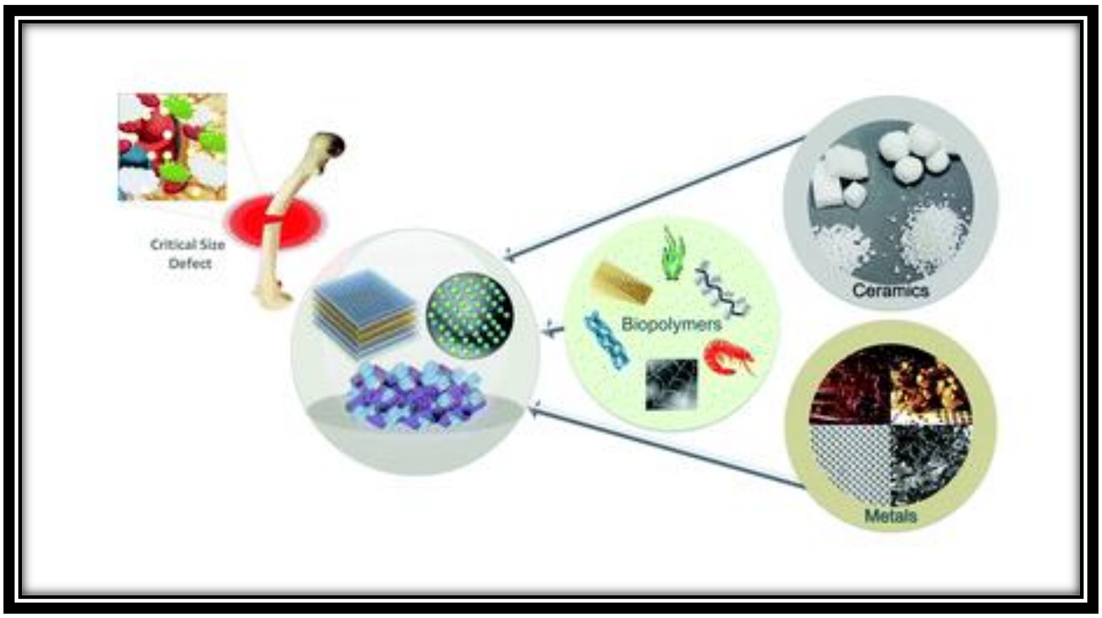
(ii) their formability into a variety of shapes and porosities,

(iii) their high compressive strength, and

(iv) some cases their excellent wear characteristics.

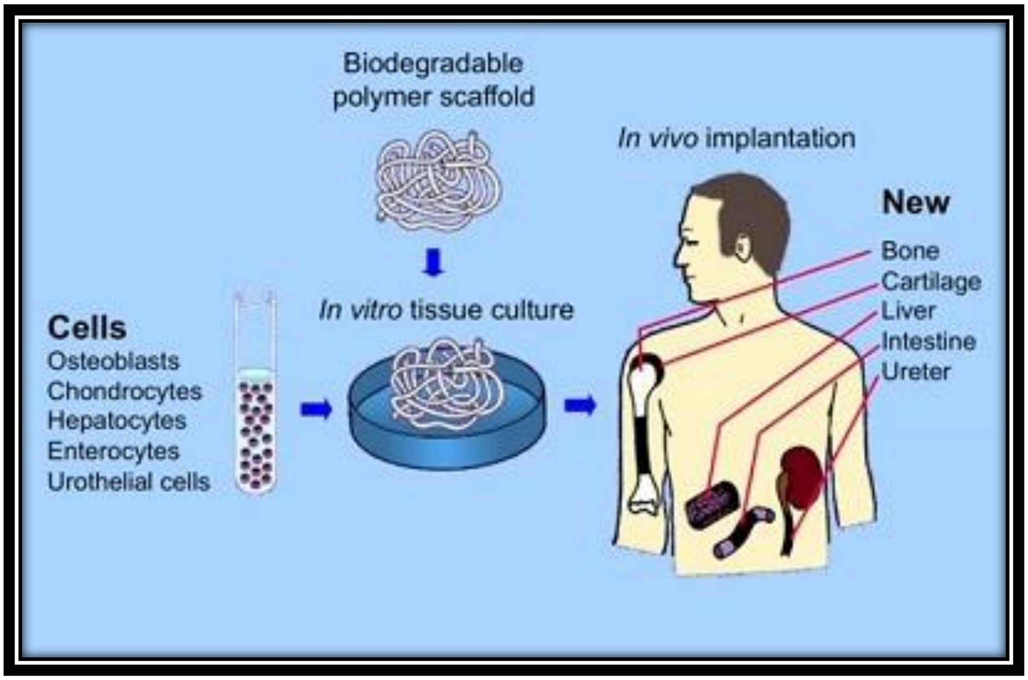
Polymer–ceramic composite represents the major part of composite biomaterials.

4-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.



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.



<u>Biomaterials–tissue responses can be divided into four different types.</u>

(1) Toxic: toxic materials cause death to surrounding tissue.

(2) Bioinert: this type of response is caused by nontoxic but biologically inactive materials.

(3) Bioactive: this type of response is seen if the material is nontoxic and biologically active. The term biologically active means that an interfacial bond forms between the material and host tissue.

(4) Bioresorbable: this type of response is seen when a nontoxic material dissolves in vivo such as calcium sulfate (plaster of paris), tricalcium

phosphate, bioactive glasses and PLGA. As a result, the surrounding host tissue can replace the synthetic material.

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.

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?

What Subjects are Important to Biomaterials Science?

1- Toxicology

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 heating.

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.

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

i.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

ii. 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.

iii.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

Industry deals well with technologies, such as packaging, sterilization, storage, distribution and quality control, and analysis.

8- Ethics

A wide range of ethical considerations impact biomaterials. Like most ethical questions, an absolute answer may be difficult to come by.

1.2. Properties of Biomaterials

Among various materials properties, the most important ones related to biomaterials are chemical, physical, mechanical, and biological in relation to their surface and bulk properties. Chemical properties deal with the chemistry of the materials such as composition, bonding and atomic structures. Physical properties deal with microstructures, phases, density and different types of porosity. Mechanical properties deal with strength and toughness of the materials along with hardness and different failure mechanisms. Biological properties deal with how materials behave in a biological environment. If the biological environment is created in a Petri dish and properties are measured, then they are called in vitro properties; if the properties are measured inside an animal or a human body, then they are called in vivo properties. Surface properties deal with properties of materials at the outer layer where all bonds are not satisfied. Due to dangling bonds, surface properties are often quite different from the bulk properties of materials.

Selection of materials for different biomedical devices is a complicated process, which depends on many factors including but not limited to mechanical loading requirements, chemical and structural properties, and biological properties. Biomaterials are also used in tissue engineering and drug delivery.

Biological requirements should be met for each application, and materials should be characterized to fulfill the needs. Human biology is very complex and we are just beginning to understand the intricate processes and interactions between synthetic materials and our body. Figure shows generic applications of different types of biomaterials.

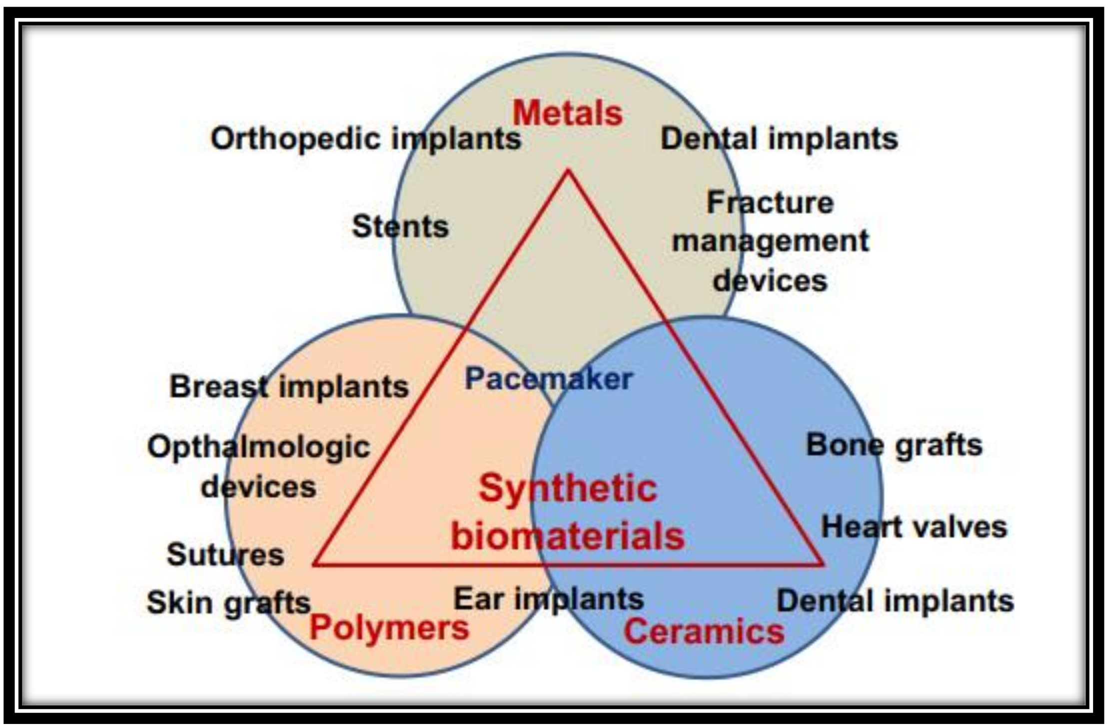


Figure 1.1 Applications of biomaterials in different devices.