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SCHOOL OF BIO AND CHEMICAL ENGINEERING

DEPARTMENT OF BIOMEDICAL ENGINEERING

UNIT – I - Biomaterials – SBM1304

INTRODUCTION AND METAL ALLOY

Biomaterials is defined as the synthetic material that is used to replace or restore function to a body tissue and is continuously or intermittently in contact with body fluids.

Characteristics of Biomaterials

i) Biocompatable
ii) Nontoxic
iii) Noncarcinogen
iv) Good physical mechanical properties
v) Low cost
vi) It must be readily available
vii) Moulded into different shape
viii) Resistant to degradation
ix) Acceptable strength
x) Resistant to wear

Application of Biomaterials

1. Orthopedic – prosthetics used to replace joint affected by arthritis. Eg. Fixation devices.
2. Cardiovascular application – artificial heart valve, stunt, etc.
3. Ophthalmology – intraocular lens and contact lens
4. Dental braces, filling, dental cap.
5. Wound healing – sutures and graft.
6. Drug delivery system – controlled and targeted delivery of drugs (doctor delivers drug to patient in remote areas).

History of Biomaterials

- Earliest operation were performed by surgeons for restoration of missing parts.
- Susbruta in 600 B.C. he repaired injured nose with a patch of living flesh taken off from the region of the cheek.
- Sicilian Laymen in 1430, nose construction was done by using skin flap taken from arms.
- In 19^{th} Century, modern implant development was seen by repairing long bone and joints.
- In 1893 – 1912 plate using steel was designed for fracture.
- In 1930 use of polymers was designed.
- In 1950, heart valve implantation was possible only after the development of open heart surgery.
- In 1944 dialysis of human beings was discovered.

Classification of biomaterials

Biomaterials have been classified into 4 different types.

i) Metals
ii) Polymers
iii) Ceramics
iv) Composites – stainless

Metals.

- Widely used for load bearing implants
- Wire, screw, plates, artificial joint for hip, knee, shoulder etc.
- Metal used as stainless steel, titanium and its alloy and cobalt based alloy.

Polymers

- Polymers resembles soft tissues and their application range from facial prosthesis to tracheal tubes, bladder, lens, tendons, etc.
- It can be used as sutures, catheters.

Ceramics

- Ceramics have been widely used in restorative materials in dentistry. The includes materials for crown (baby), cement, dentures (adult).

Composites

- The most successful composite are used in the field of dentistry as restorative material or dental cement.
- Carbon – carbon and carbon – reinforce polymer composites are used for bone repair and joint replacement because of the low elasticity modulus level.

Impact of biomaterials

- In the early days, relatively few engineering materials such as stainless steel, chromium, etc. were used to make artificial hearts with simple design.
- Today field of biomaterials has evoked more than 50 different materials in various types of complex prosthetic devices.
- The development of biomaterials used in medical devices as occur in response to growing number of patient afflicted in traumatic and non traumatic conditions.

Examples

- Arthritis – leading to joint disorder which needs correction.
- Total knee and hip replacement are achieved by using implants that are composites of metal polymer and ceramics
- Implants which are regularly used in ophthalmology includes lens implants, corneal transplant and protective corneal shields.
- Facial implants – purely cosmetic surgery
- Oral implants is of two types: i) artificial teeth or dentures, ii) implants is totally implanted in oral cavity.
- Vascular graft are made of synthetic polymer which are routinely used to replace aorta.
- Cancer a large number of implants are used for reconstructive surgery of the breast.

Strength of the (biological tissue) biomaterials

- Strength of the biological tissue can be determined by static and compression tension, torsional and b ending, dynamic impact load (or) fatigue oscillative.

Interfacial phenomenon

- There are 4 types of biomaterials in term of interfacial response of tissue.
- Type 1 – hearty inert, smooth surfaces
- Type 2 – nearly porous surfaces inert
- Type 3 – controller reactive surfaces
- Type 4 – Reasonable

Type 1: These materials achieve suitable combination of physical properties with a minimal of physical properties with a minimal toxic response in the host. The physical response of the implant always produce some response in the adjacent tissue which yield thin fibrous capsules (0.1 – 10 μm(surrounding the implant. In these cases, the lack of adherence of the capsule to implant results in motion of the tissue implant interface and under stress are flow and its responsible for the lifetime limitations of many devices.

Type 2 & 3: Improving interfacial stability, when the rate of surface reaction are correctly controlled where repairing tissues are incorporated structurally within the reactive layers on the implant surface, rendering stability to the implant.

Type 4: Biomaterial designed to the ultimately replaced by regenerating tissue, eliminating the original interface altogether and there is no discernible difference between implant site and host tissue after resorption is complete.

CELLULAR IMMUNE RESPONSE

- The body reaction to foreign material is to reject them.
- The foreign material may be walled of if it cannot be removed from the body
- If the material is particular of fluid, then it is ingested by the giant cell macrophage and removed.
- A typical tissue response is appearance of polymorphonuclear leucocytes near the implant followed by macrophages.
- If the implant is inert to the tissue, then the macrophages may not be present near the implant, only a thick collagenous layer encapsulates the implant.
- If the implant is chemically or physically irritating to the surrounding tissue then the inflammation occurs at the implant site.
- Porous implants are fixed by in growth of surrounding tissue.
- Some implants may cause necrosis of tissue by chemical, mechanical and thermal trauma.

Various mechanism involved in Tissue response to implants

- Inflammation (normal wound healing process)
- Cellular response to implants
- Systemic effect of implants
- Blood compatibility
- Carcinogenicity

Inflammation

Tissues are injured or destroyed.
↓
Adjacent cell repair them soon after injury
↓
Construction of capillary occurs
↓
Dilation of blood vessel occurs

↓

Followed by increased activity in the endothelial cells lining the capillaries

↓

Capillaries become covered by leucocytes, erythrocytes and platelets Leakage

↓

of fluid of plasma from capillary occurs

↓

Migrating leucocytes and dead tissue combined with leaked fluid form exudates Local

↓

lymphatics are also damaged

↓

Capillary damage will provide fibrinogen

↓

Elements of the blood which will quickly plug the damaged lymphatic

↓

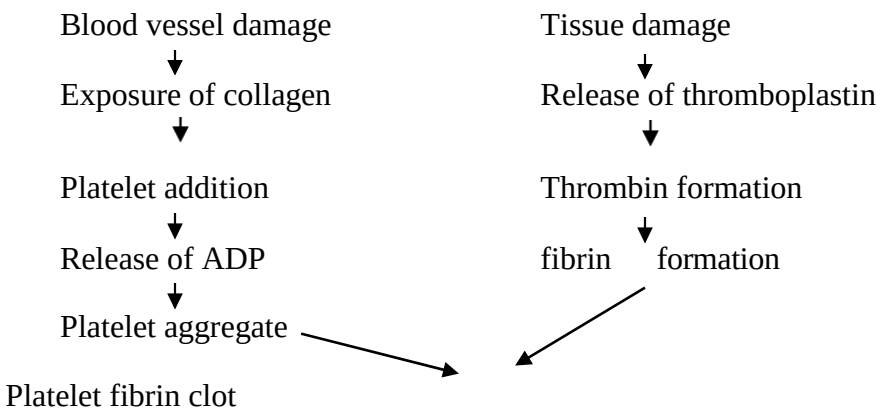
Localising the inflammatory reaction.

Chronic inflammation occurs after 3 – 5 days, this is marked by the presence of multinucleated giant cell. The macrophages and phagocyte remove foreign materials, sometimes the mononuclear cell evolved into histocyte skin macromphage which regenerate collagen. This regenerated collagen is used to unit the wound or remove foreign materials by encapsulation.

- Cellular response to implants
- Systemic effect of implants
- The polymethylmethacrylate (PMMA) bone cement is applied in femoral shafts in douth state is known to lower the blood pressure.
- Biodegenerable implants such as adsorable sutures surgical adhesives and corrosion particles released by metallic implant reduces systemic immune response.
- Corrosion resistant metal alloys are not completely stable some ion concentration in the elements are released into t he body which interferes with the normal physiological activity.
- The divalent metal ions may also inhibit various immune enzyme activity.
- Polymeric materials which contains additives induces cellular and systemic reaction.

Blood compatibility

- Blood coagulation is the most important factor for the blood compatibility
- The implant should not damage proteins, enzymes, RBC, WBC and platelets.
- If the blood is coagulated it is called as clot.
- Sometimes the clot formed inside blood vessel is referred to as thrombus or embolus depending whether the clot is fixed or floating



- The surface roughness is an important factor since roughness the surface, the more area is exposed to blood.
- Rough surface promotes faster blood coagulation than the highly polished surface of glass PMMA, polyethylene stainless steel.

Carcinogenicity

- A variety of chemical substance are known to induce the onset of cancerous disease in human beings are known as carcinogens. Eg: Sheets or film of many polymers produce cancer when implanted in animals especially rats.
- It was later found that the physical form of the implant was important and fibre and fabrics produce less tumour then sheets of same material
- But powder produce almost no tumours.

Metal and alloys for orthopedics implants

STAINLESS STEEL (SS)

- The first stainless steel used for implant material was 18 – 8 (type 302) which is stronger than vanadium steel and more resistant to corrosion.
- Vanadium steel is no longer in use in plants since it is corrosion resistant.
- Later 18 – 8s MO (molybdenum) SS was introduced which contains MO to improve the corrosion resistant in salt water.
- This alloy is known as type 316 SS. In 1950 the carbon content of 316 SS was reduced from 0.08 wt% - 0.03 wt%.
- This is better for corrosion resistance in chloride solution. This alloy is known as 316L.
- Chromium is the major component of corrosion resistant SS. The minimum effective conc. of Cr is 11 wt%
- Cr and its alloy gives an excellent corrosion resistant. The SS especially type 316 and

316LL are most widely used for implants. This group of SS is non-magnetic and possess better corrosion resistance than any other.

- American society for testing a material recommends type 316 L rather than 316 for implant fabrication.

Properties of SS

- A wide variety of properties can be obtained depending on the heat treatment – to get soft materials.
- Cold working of implant is done to get greater strength and hardness.
- The designer must be careful when selecting materials even the type 316L stainless steel may corrode inside the body due to high stress and oxygen depletion.
- So it can be used as a temporary devices such as facture plates, screws and hip nails.

Manufacture of implant

SS cannot be cold work with intermediate heat treatment

↓

Heat treatment should not induce Cr carbide which may cause corrosion

↓

It can be overcome by controlling the uniformity of heating

↓

Another undesirable effect of heat treatment is the formation of surface oxide scales

↓

↓

Which can be removed either chemically by acids

↓

After scales are removed

↓

Surface components is polished to a mirror or map finished

↓

Surface is then cleaned degreased with nitric acid

↓

Component is washed and cleaned again before packaging and sterilizing

Biomedical application

- Orthopedic implants
- Major uses include fracture, fixation and joint replacement
- It is used in hip joint, ankle joint, knee joint, intramedullary pins bone plates and screws.
- Cobalt based alloys
- These materials are usually referred to as Co-Cr alloys
- There are basically 2 types

- (a) Co Cr Mo alloys which is usually a cast product (b) Co Cr Ni Mo alloy which is usually wrought by hot togging
- The castable Co Cr Mo has been widely used in dentistry and recently in making artificial joints
- The wrought or forged alloy – Co Ni Cr Mo alloy is used for making the stems of prosthesis for heavily loaded joints such as knee and hip
- Types of cobalt based alloy
- ASTM listed 4 types of cobased alloy that are applicable for surgical implant application.

i) Co Cr Me alloy (F76)
ii) Wrought Co Cr W Ni alloy (F90)
iii) Wrought Co Ni Cr Mo alloy (F562)
iv) Wrought Co Ni Cr Mo W Fe alloy (F563) are widely used alloy at present

Properties of cobalt based alloys

The two basic elements of a cobalt based alloy form a solid solution upto 65% wt cobalt (Co) and the remainder is Cr.

- The molybdenum is added to produce fine grains which results in higher strength after casting or forging.
- Wrought cobalt based alloys is the Co ni Cr Mo alloys which has high degree of corrosion resistance to sea water.
- Cold forging can increase the strength of the alloy
- Hot forging can be used to fabricate and implant with an alloy (hip joint stem)
- Cast and wrought alloys have excellent corrosion resistance.

Manufacture of co based alloys.

- Cobased alloy can be used in one of three forms

i) Cast
ii) Wrought
iii) Forging

Casting

- The orthopedic implant of Co – Cr alloy are made by casting process
- Wax model of the implant is made
- Ceramic shell is built around the wax model
- Ceramic shell is pot fired to obtain the required mold strength
- Match metal alloy is then cold into the shell after cooling the shell is removed to obtain metal implant.

Wrought

- It possesses a uniform structure with fine grains
- Wrought Co Cr Mo alloy can be further strengthened by cold wrought

Forged alloy

- Forged alloy is produced by hot forging process
- Forging of Co – Cr – Mo requires sophisticated and complicated tooling press
- These factors make it more expensive to fabricate a device from Co Cr Mo forging then from casting
- Disadvantage of casting produce large grains and metallurgically, imperfection when compared to wrought alloy and forged alloy.

Application

- Porous coated Co Cr implants have been extensively used for bone in growth application
- Sintered beads, plasma flame sprayed metal powders are used as coating on Co Cr orthopedic implants.

Ti and Ti based alloys

- Its low density and good mechanochemical properties are salient features of implant applications.
- It is relatively high cost and reactive in nature.
- Pure Ti is a very useful material have produced better results.
- The most important one Ti alloy is Ti (6% Al, 4% is widely used to manufacture implants.
- The main alloying elements of the alloy are Al (5.5 – 6.4 wt%) and Va (3.5 – 4.5 wt%)
- Mostly recently this alloy has been used for the production of hip prosthesis, fracture equipment and has largely replaced pure metal in many applications.

Structural properties of Ti and Ti alloys

- Ti is a two allotrophic materials that exists as a hexagonal crystal structure (□-Ti), temperature is 882.5^{o}C.
- Centre cubical structure above that temperature (□-Ti)
- Al tends to stabilize the □-phase, that is increase the transformation from □ to □
- Vanadium in a titanium – aluminium alloy tends to form □, □ two phase system at room temperature.

- Ti-Al 4V is generally used in one of three conditions.
  i) Wrought
  ii) Forged
  iii) Cast
- Wrought alloy is available is standard shape and size and it is annealed at 700^{o}C at using furnace cooled to 600^{o}C and air cooled to room temperature.
- Forged alloy – the typical hot forging temperature is between 900 to 980^{o}C. Hot forging produces a fine grained □-structure with the dispersion of □-phase.
- Cast alloy metallurgically stable homogeneous structure casting or annealing at approximately 840^{o}C.
- Ti is very reactive material and its surface can be modified by
  i) Oxide layer may be enhanced by suitable oxidizing treatment such as anodizing
  i) Surface can be hardened by the diffusion of interstitial atoms into surface layers.
  ii) Flame spraying of metals on the surface.
  iv) Metals can be electroplated on the surface.

Manufacture of implants

- Ti is very reactive at high temperature and burns readily in the presence of oxygen.
- It requires inert atmosphere for high temperature processing are processed by vacuum melting
- Oxidises diffuses rapidly in Ti and embedded in metals

So hot forging should be operated at 925^{o}C followed by electrochemical machining to obtain a metal implant.

OTHER METAL ALLOYS

Aluminum Alloys

- AA-8000: used for building wire
- Al-Li (aluminum, lithium, sometimes mercury)
- Alnico (aluminum, nickel, copper)
- Duralumin (copper, aluminum)
- Magnalium (aluminum, 5% magnesium)
- Magnox (magnesium oxide, aluminum)
- Nambe (aluminum plus seven other unspecified metals)
- Silumin (aluminum, silicon)
- Zamak (zinc, aluminum, magnesium, copper)
- Aluminum forms other complex alloys with magnesium, manganese, and platinum

Bismuth Alloys

- Wood's metal (bismuth, lead, tin, cadmium)
- Rose metal (bismuth, lead, tin)
- Field's metal
- Cerrobend

Cobalt Alloys

- Megallium
- Stellite (cobalt, chromium, tungsten or molybdenum, carbon)
    - Talonite (cobalt, chromium)
- Ultimet (cobalt, chromium, nickel, molybdenum, iron, tungsten)
- Vitallium

Copper Alloys

- Arsenical copper
- Beryllium copper (copper, beryllium)
- Billon (copper, silver)
- Brass (copper, zinc)
    - Calamine brass (copper, zinc)
    - Chinese silver (copper, zinc)
    - Dutch metal (copper, zinc)
    - Gilding metal (copper, zinc)
    - Muntz metal (copper, zinc)
    - Pinchbeck (copper, zinc)
    - Prince's metal (copper, zinc)
    - Tombac (copper, zinc)
- Bronze (copper, tin, aluminum or any other element)
    - Aluminum bronze (copper, aluminum)
    - Arsenical bronze (copper, arsenic)
    - Bell metal (copper, tin)
    - Florentine bronze (copper, aluminum or tin)
    - Glucydur (beryllium, copper, iron)

DENTAL MATERIALS AND ITS APPLICATIONS

- Dental materials are generally considered to compromise those materials which are employed in restoration dentistry.
- Dental materials include impression materials to copy the contour of the gum, restorative material to correct defect in natural material, appliances and dentures to replace or correct the deficiency of the grinding surface.
- Oral implants fall into 2 categories:

i. **Artificial teeth**
ii. **Dental appliances those support and anchor artificial teeth**
    - These are specialized type of transcutaneous devices that must penetrate the oral cavity. The other type of implants are totally implanted. They include devices for repairing damaged or diseased mandibles; supports for rebuilding the alveolar rich and packing for stimulating the growth of bone to correct lesions associated with periodontal diseases.
    - There are 4 main group of materials used for dental applications which includesPolymers, Composites, Ceramics material and Metal alloys.

Anatomy

- All the teeth are made up of two portions:
    i. Crown and
    ii. Root
- The crown and root are demarcated by gingiva(gum).
- The root is placed in a socket called alveolus in maxillary and mandibular (lower) bone.
- The enamel (outermost layer of the teeth) is the hardest substance found in the body and consists of almost calcium apatite crystals.
- The periodontal is another mineralized tissue whose distribution of organic matrix mineral is similar to that of regular compact bone.
- The pulp cavity collagenous fiber running in all direction and aggregated into bundles.
- The ground substance, nerve cells, blood vessels are also contained in the pulp.
- The periodontal membrane anchors the root firmly into the alveolar bone and is mostly collagenous fiber and glycoproteins.

Materials used for Dental

i. Impression materials
   - Impression materials are used to make a reproduction of gum surface as a mold or model based on which dentures and restoration materials are fabricated.
   - They are used mostly for the preparation of cost of an artificial denture.
   - The most commonly used impression materials are plaster of plastic ($CaSO_4$ □ - hemihydrate), dental stone ($CaSO_4$ □ - hemihydrate), elastic impression material which includes hydrocolloid and elastomeric materials.
   - Reversible hydrocolloid - example: agar.
   - Irreversible hydrocolloid – example: ground seaweed polymer.

ii. Bases, liners and varnishes for cavities
   - There is a large diversity of organic and inorganic materials for the purposes.
   - They can be used as barrier against other materials with aggressive pH for thermal and electrical insulation or to provide hardness and mechanical barrier.
   - These materials include Zinc polycarboxylate, cement, ionomer glass cement and varnishes.

iii. Filling and restoration materials
   - Dental amalgam has traditionally being employed for cavity filling but use of this material is controversial due to toxicity & environmental pollution by mercury.
   - Amalgam is obtained by mixing silver, tin, copper alloy powder with liquid and mercury.
   - The liquid is a paste that hardens as mercury dissolves on the surface of the alloy.
   - Alternatively cavities are filled using PMMA resins.

iv. Materials for deep cavities
   - Necrosis of the tissues at the pulp chamber and the root canal of the teeth occurs by deep cavities.
   - The nature of materials employed is very important since they contact internal tissues at root apex.
   - The materials include cement, polymers such as polyethylene, epoxy, silicon, polycarbonate which contribute to the hardness of final product and also seal the internal part of the canal.

v. Metals in dentistry
   - Metals in dentistry are mainly used to construct crowns, orthodontic wires.
   - The alloys used are gold alloy containing silver, copper, palladium, platinum and zinc.

vi. Oral Implants

vii. Dental Implants

- The endosstosis implant is inserted into the site of missing or extracted teeth to restore the original function.
- This implant is made up of stainless steel, Co-Cr alloy, Ti-Al-Va alloy and stainless steel.
- The surface of implant is coated with ceramic or polymers.

viii. Mandibular reconstruction

- Mandibular defects are more often due to some trauma or neoplasm.
- Urethane elastomer has been used as a substitute to medical devices for reconstruction of mandible at room temperature and no special equipment is required for surgery.

ix. Collagens in dentistry

- Collagen is widely used in prevention of oral bleeding, healing of mucosal lining and mucus membrane and regeneration of periodontal tissue.
- Collagen is used as a carrier substance for immobilization of various active substances used in dentistry.

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Replacement and Fixation device

Bioelectric Effect

- According to experiments, bone is considered as piezo electric material similarly collagen and apatite are considered as semiconductor which produce a PN junction diode.
- Stress on bone induces a cement which influences the alignment of tropocollagen molecules.
- SGP is a nonlinear functions of bone structure stress generated potential and has been found to be proportional to the cross linking of collagen.
- Negative potential develops in areas of bone under compressive stress that stimulates bone deposition where as tensile stress gives positive SGP which stimulates bone reabsorption.
- During bone tissue injury, a bioelectric potential develops between injured site and isolated tissue.
- This potential can range from a few mvolt to 100 mvolt.
- Tissue in active growth and regeneration shows electrode negative potential
- The bioelectric potential induces an electric current that concentrates protein electrolytes and polarisable molecule at wound site.
- Damaged tissue tend to respond to pulse electromagnetic field which results in normal structure and recovers more rapidly.
- Electrostatic field is being applied in correction of osteoporosis and osteogenesis.

Bone healing

- Blood vessels break and leads to clotting and formation of callous.
- The pH of the fracture region drops about 7.4 to 5.4.
- This change of pH aids in decalcification reabsorption and remodeling of necrotic bone.

First 2 days – 1st week

- Fibroplast from peristoneum moves to fracture site
- Capillaries proliferate into wound region.
- Osteogenic cells migrate from peripheral region to the fractures site.

1st – 2nd week

- Mucopolysacchride level decreases while collagen production is significant.
- Collagen fibre bridges between the fractures gap and the pH becomes normal.

2^{nd} – 3^{rd} week

- Collagen matrix replaces entire clot
- Chrondoblast seen between matrix and bone growth
- Calcium and phosphorous in take increases and results in bone mineral deposition.

3^{rd} – 4^{th} week

- Trabecular bone replaces chrondoblast

5^{th} – 6^{th} week

- Remodelling of trabecular bne to compact bone.

Healing process occurs in two ways

- Primary fracture healing
- Secondary fracture healing
- Resorption of fracture fragments
- New bone formation
- Remodelling
- Osteosynthesis
- Remodelling of osteons between 2 fracture ends.

Wolff's law

Wolff's law states that bone in a healthy person will adapt to the loads under which it is placed

- If more load is applied - more osteogenic activity
- Wolff's law related to the piezoelectric phenomena
- Electrical stimulation of bone fracture repair
- developed by the German anatomist and surgeon Julius Wolff

Types of Orthopedic fixation devices design

- The design principles, selection of materials and manufacturing criteria for orthopedia implants are safe for engineering products undergoing dynamic loading.
- Although it is tempting to duplicate the natural tissue with materials having same strength and shape. This has not been desirable since the natural tissues and organs have an advantage over the man made implants.
- That is their ability to adjust new set of circumstances by remodellling their micro and macrostructure.
- When we try to replace the joints or heal a fractured boen it is logical that the bone repairs should be made that the tissues should follow.
- If the bone heals faster when a compressive force is exerted, then we should provide compressing through an appropriate implant design.
- Unfortunately, the effects of compressive or tensile forces on the repair of9 the bones

are not fully understood.

- Historically speaking, until aseptic (sterile) surgical techniques was developed various metal devices such as cures, pins constructed of iron, gold silver, platinum etc were not successful largely because of infection after implantation.
- Most of the modern implant developments have been centered around repairing long bones and joints.
- Although the exact mechanism of bone fracture repair is not known at this time stability of the implant with respect to wound surface is clinically an important factor to be considered.
- Whether the fixation is accomplished by compressive or tensile force. The reduction should be anatomical and bone ends should be firmly fixed so that the healing process cannot be disturbed by unnecessary micro and macro environments.
- Surgical techniques usually involve the use of metallic fixation devices.
- **Wires**: The type of wires used is called as Kirschner wires. The simplest but most versatile implants are the various metal wires called Kirschner wires the diameter is 2.38 mm
- **Pins**: The Steinmann pins which can be used to along with Kirschner wires to hold fragments of bones together. Wires are also used to reattach greater trochanter (femun and hip) hip joint replacements. The common problems are corrosion of metals may weaken the cures . The added necessity of twisting and knotting of wires attenuates the problems since strength can be reduced by 25%.
- Pins: Steinman pins is also versatile implant and often used for internal fixation in cases when it is difficult to use a plate or when adequate stability cannot be obtained.
- The tip of the pin is designed to penetrate the bone easily when the pin is screwed into the bone.
- 3 types of tip designs are trochanter, diamond and cone.
- The trochanter tip is a most efficient in cutting and often used for cortical bone insertion.
- The fracture bones can be held together by two or more pins inserted percutaneously away from the fracture site and the pins are fixed by a device such as Hoffmann external fixation.
- **Screws**: Screws are the most widely used devices for fixation of bone fragments to each other. There are basically two types of screws: i) self tapping, ii) non self tapping.
- As the name indicates the self tapping screw cuts it own threads as it is screwed.
- The non self tapping makes less favourable although the holding power (pull out strength) of the two types of screws is about the same.
- The variations of thread design do not influence holding power.
- The radial stress transfer between the screw thread and the bone is slightly less for V shape thread than buttress thread indicating the lather can hot a longitudinal load betters.
- Pull out strength / holding strength of the screws is an important factor in the solution

of particular screw design.

- Larger screw has higher pull our strength.

Cortical bone plates.

- They are different types of fracture plates since the forces generated by the muscles in the limbs are very large bending movements the plates must be strong.
- This is especially true for the femoral and tibial plates.
- Adequate fixation of the plate to the bone with the screws over tightening may result in necrotic bone as well as deformed screws which may fail due to corrosion process.
- A bone plate divides to compress the end of the fracture bone can be achieved by using self compression plate and screw system.
- Compression plate is more favourable sign of healing.
- Large amount of callous formation results in good healing.
- The amount of callous formed is proportional to the amount of motion between plates and bone.
- Rigid plate fixation the drawback is weakening of underlying bone such that refracture may occur followed by removal of plates.
- The stiff plate carry so much of load and reabsorbed by the body
- A considerable amount of care must be exercised when fixing callacinous bone since this kind of bone has lower density, lower stiffness.
- The fixation of the end of a long bone are fixed with a combination of screw, plates, balls, nails and nut.

Spinal fixation devices.

- When the spinous element of the back bone are deformed in such a manner that the length of the element is longer than the length of posterior one.
- The resulting structure is bend back ward is called “Lordosis”.
- The opposite condition is called kyphosis.
- There are forward and backward curvature in normal spine.
- It lateral curvature of the spine is always abnormal is known as “Scoliosis”
- Spinal deformities internal and external fixations can be corrected.
- These are several designs which stability or strengthen the curvature.
- The main problem with these devices are fatigue failure and necrosis occurs due to concentrated
- As the spine is straightened it is hardened to the when fixation deice in distract the curved hooks.
- Since they liberate the spine become smaller.
- Thus multiple hooks are sometimes attached to overcome the problem.

Intramedullary devices.

- Intramedullary devices are used to fix the fracture of long bones.
- The devices inserted inside the medullary cavity.
- This type of implant should have spring could exert some elastic force inside the

bone cavity to prevent rotation of the device and to fix the fracture firmly.

- Compared to plate fixation the intramedullary device is better positioned to resists bending since it is located in the centre of the bone.
- IMD destroys the intramedullary blood supply although it does nt disturb the persisteal blood supply.
- The advantage of IMD is that it does not require the opening of a large area to operate and the device can be nailed to a small insertion.
- The long bone blood supply comes from 3 sources, i) the nutrient, ii) metaphyseal arteries, iii) periosteal arteries.
- Fracture occurs the extra osseous circulation from the surrounding soft tissue becomes active and forms the fourth source of blood supply.
- Intra medullary devices usually plates for the fixation of femoral neck
- The femoral fracture fixation which usually made to compress the broken bones together by tightening to compress the broken bones together by tightening screw which also helps to stabilize the fracture.

Interface problems with artificial joints and various fixation methods

Most frequent fixation problems are related to (1) infection, (2) wear and wear particulate,
(3) migration and failure of implants, and (4) loosening of which the "long-term loosening" of the implant is especially important.These problems manifest into osteolysis in the bone bed which is the major cause of long-term loosening mostly for the femoral stem Some major factors related to (late) loosening are (1) mismatch of the physical properties between tissues and implant, (2) biocompatibility of the implant, (3) deterioration of physical properties of implant materials, (4) surgical techniques, (5) design of the implant, (6) selection of patients, and (7) post surgical care, etc. Variables related to the total (hip) joint replacement are (1) materials), (2) design, and (3) fixation method One should keep in mind that any particular type of prosthesis is made to have a particular fixation method, is designed to be used with bone

- Methods of Fixation
- Mechanical Fixation
- Active—use of screws, bolts, nuts, wires, etc.
- Passive—interference fit and noninterference fit
- Bone Cement Fixation
- Pure cement
- Modified cement—composite cement
- Biological Fixation
- Porous ingrowth
- Modified porous ingrowth—electrical and pulsed electromagnetic field (PEMF) stimulation
- Direct (Chemical) Bonding Fixation
- Osteogenic/inductive-glass-ceramics
- Osteoconductive hydroxyapatite

HARD TISSUE REPLACEMENTS:

TOTAL HIP REPLACEMENT

Current hip prosthetic devices and techniques claims high success rate above 90% for last 10 years.

A hip replacement consists of a femoral component that is, a ball mounted on a shaft and an acetabular component having a socket into which ball is placed.

Co-Cr and Ti-Al-Va alloys are used by different manufacture for the femoral head and HDHMWPE (High density high molecular weight Polyethylene) is to cover the socket.

Several designs types with different strength are available.

Surgical Insertion procedure

i) Femoral head is diseased; the infected region is removed off.
ii) Medullary canal of femur is drilled to prepare stem of prosthesis.
iii) Cartilage of acetabulam is also reamed.
iv) PMMA bone cement is prepared and packed into medullary canal
v) Femoral strength is inserted.
vi) Alignment and articulation is

verified Materials used are

I) Metal – metal
II) Metal-HDHMWPE
III) Ceramic-HDHMWPE
IV) Ceramic-Ceramic

Solution - Bone cement act as a shock absorber (viscoelasticity) polymer and it even spreads load uniformly over large area

Disadvantages of bone cement

- Monomer vapors interfering with body functions alter the blood pressure rapidly.
- Polymerization caused temperature increases cell necrosis.
- Intramedullary cavity preparation results and blocks the bone sinusoid
- Difficulty in removal of implant
- Friction between ball and socket
- SS-PE and Co-Cr-PE reduces frictional movement
- Loosening of ace tabular and femoral components
- Improper surgical and cementing technique
- Blood clot during surgery
- Shrinkage of bone cement during polymerization

TOTAL KNEE REPLACEMENT

- Prosthesis consists of femoral, tibial, patellar components.
- It has some complicated geometry and movement
- Knee joints are two types – hinge and non-hinge
- Implantation can be done with or without
  cement Femoral component – Co-
  Cr alloy
  Tibial component – UHMWPE
  Patellar component- UHMWPE& Ti alloy
- Patella is vulnerable, small size and force is applied
- Selection of implants depends on the health of the knee, types of diseases, range of activities required
- Porous coated implant is used which allows tissue in growth giving interface of bone and implant
- It is used only for healthy knees as it requires tissue in growth
- Femoral components have fairly thin, rigid, shell with an attached fixation system to bone
- Shell should be stiff, high strength and low wear rate
- Tibial portion has broad plateau covering fibia
- Stiff metal tray supporting the polymer is used.

Disadvantages

- Loosening
- Infection
- Shrinking of tibial plateau

SOFT TISSUE REPLACEMENT

In soft tissue implants as in other applications that involve engineering, the performance of an implanted device depends on both the materials used and the design of the device or implant. The initial selection of material should be based on sound materials engineering practice. The final judgment on the suitability of the material depends on observation of the *in vivo* clinical performance of the implant. Such observations may require many years. This requirement of *in vivo* observation represents one of the major problems in the selection of appropriate materials for use in the human body. Another problem is that the performance of an implant may also depend on the design rather than the materials *per se.*

The success of soft tissue implants has primarily been due to the development of synthetic polymers. This is mainly because the polymers can be tailor-made to match the properties of soft tissues. In addition, polymers can be made into various physical forms, such as liquid for filling spaces, fibers for suture materials, films for catheter balloons, knitted fabrics for blood vessel prostheses, and solid forms for cosmetic and weight-bearing applications.

It should be recognized that different applications require different materials with specific properties. The following are minimal requirements for all soft tissue implant materials:

1. They should achieve a reasonably close approximation of physical properties, especially flexibility and texture.
2. They should not deteriorate or change properties after implantation with time.
3. They should not cause adverse tissue reaction.
4. They should be noncarcinogenic, nontoxic, nonallergenic, and nonimmunogenic.

SUTURES, SURGICAL TAPES, AND ADHESIVES

The most common soft tissue implants are sutures. In recent years, surgical tapes and tissue adhesives have been added to the surgeon's. Although their use in actual surgery is limited to some surgical procedures, they are indispensible

SUTURES

There are two types of sutures, classified as to their long-term physical in integrity: absorbable and non-absorbable. They may also be distinguished by their raw material source: natural sutures (cai2ui, silt, and ostton) and synthetic sutures Nylon, polyethylene, polypropylene, stainless steel, and tan- talu m). Sutures may also be classified according to their physical form: monofilament and multifilament

The absorbable suture, catgut, is msde of collagen derived from sheep intestinal submucosa. It is usually treated with a chrome salt to increase its strength and is cross-linked to retard resorption. Such treatment extends ihe life of caigut suture from 3-7 days up to 20-40 dayx. Table 11-1 gives initial strength data for caigut sutures according to their sizes. The calput sutures are preserved

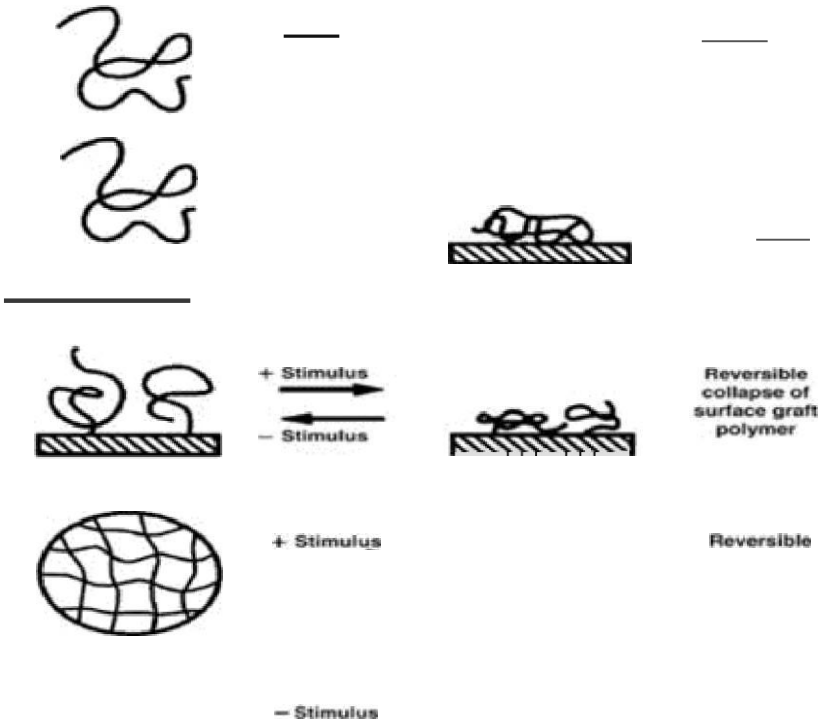

Fig.2.1 Different types of sutures

The most common implants are the futures. In recenl years surgical tapes and tlssue adhesives have added io the surgeon's armamentarium- Although their use in actual surgery is limited for some surgical proce- dures, tt ey are indispensable,

The types of sutures are classified by their physical integrity, i.e.. absorbable and nonabsorbable. The may be distinguished according to their source Df raw materials, i.e., natural sutures (catgut, silk, and cot- ton) and synthetic sutures (nylon, potyeih y gene, polypropylene, and stain- less steel), Sutures may also be classified by their physical forms, i.e., monofilament and multifilament.

An absorbable suture, cat8ui, is made of collagen and derived from sheep intestinal submucosa. It is usually treated with a chromic salt to increase its strength and retard resorption by cross-linking, Such treat- ment extends the life of a catgut suiute from L7 days up to 2M0 days. Table 9-1 gives some of the original strength of catgut sutures according to their sizes.

It is interesting to nole that the surgical knot decreases the suture strenslh of catgut by half, no matter what kind of knotting technique is used, because of stress concentration. It is suggested that the most effec- tive knotting is the square know with three ties to present loosening. Whether it is need loosely or tightly makes no measurable diPerence in the rate of wound healing, according to one study.

The catguts and other absorbable sutures (polygiycolic acid, PGA) invoke tissue reac(ions, although the effect diminishes as they are absorbed, This is true with other natural non-absorbable futures like silk and cotton, which showed higher reaction than such synthetic sutures as polyester, nylon, or polyacrylonitrile.

If the suture is contaminated even slightly, the incidence of infection increases many fold. The most significant factor of infection is the chemical structure; the geometric configuration seems to have no influence on infection. Polypropylene, nylon, and PGA sutures develop least infection

compared to other suture materials, such as stainless steel, plain and catgut, and polyester sutures.

Surgical Tapes

Surgical tapes are supposed to offer a means of avoiding pressure necrosis, scar tissue formation, problems of stitch abscesses, and weakened tissues. The problems with surgical tapes are similar to those experienced with Band-Aids, i.e. , (1) misalignment of wound edges, (2) poor adhesion

Maxillofacial implant types

Titanium implants comprising of bone plates, screws and dental implants have transformed the concept of management in maxillofacial trauma, correction of dentofacial deformities, reconstruction of jaws after ablative surgery and restoration of lost stomatognathic apparatus. Cranio-maxillary facial region is a complex structure having structural elements arranged in a series of columns, arches and buttresses with intervening thin bones providing lateral support to primary structural members. Bone plates and screws when engaged to secure thin plates of bone, fractured bony fragments and osteotomised segments, provide rigid fixations.

Moreover approximation, fixation and stabilisation of bony fragments in anatomic alignment promotes healing of bone by primary intention with direct in-growth of capillaries and osteogenic cells across the fragments and thereby restoring the lamellar bone. Although bone plates were introduced into Maxillofacial surgery by Christiansen (1945)and thereafter plates borrowed from orthopaedics were modified and employed to manage unstable fractures, but it was only after 1970s that with technological advances, principles of fixation and knowledge of biomechanics was incorporated in bone plates system. Initially bone plate implants were fabricated in stainless steel, then in vitallium. Currently the material of choice is Titanium. Titanium dental implants support dental prosthesis in fully or partially edentulous patients having compromised alveolar ridges where conventional methods will not deliver satisfactory results.Implant materials
The basic requirements for successful outcome of material are that it should be biocompatible, corrosion resistant, must possess adequate mechanical property to withstand stress, produce least artifacts under imaging like CT Scan and MRI and interfere minimally in normal growth, remodelling and development of bone. The materials used for implants at present are metals, ceramics and polymers. Metallic components are exclusively used in bone plate, screws and dental implants because of their higher strength and contourability. Ceramics including calcium phosphate preparations, bioglass and alumina have excellent biocompatibility but they are brittle and cannot be contoured or adapted to anatomic site. Polymers like polylactic and polyglycolic acid implants which are bioresorbable cannot be used in stress areas as they do not have adequate strength and rigidity. Metallic components currently in use are stainless steel, chrome-cobalt alloy and titanium.

Stainless steel possesses good structural and mechanical characteristics but has compromised biological response. It is susceptible to corrosion, lacks homogenicity and exhibits porosity which provides undesirable stress concentration area. Vitallium has got better biocompatibility and resistance to corrosion vis-a-vis stainless steel but is too rigid and is difficult to adapt along anatomical geometry. The metal which fulfils the requirements of ideal material currently is Titanium.

Titanium

Titanium possesses all the requisite properties. Biocompatibility and resistance to corrosion is due to ability to form a stable dioxide layer of 2 to 20 nm thickness in milli seconds when exposed to air, water and electrolytes. This layer protects the metal from any chemical attack even in aggressive body fluids. Even if this layer is distorted by shear forces from relative movement, repassivation occurs in biological environment in presence of oxygen and electrolytes. The modulus of elasticity of titanium is 10 (PSI $x10^6)^2$ which is nearer to bone having the modulus of elasticity of 2.4 (PSI $\times 10^6)^2$. This allows distribution of shearing stress evenly at the implant bone surface. Titanium also osteointegrates with bone tissues and is a base metal for dental implants. Surgeon has successfully used indigenously developed Titanium bone plates and screws in maxillofacial surgery.

Bone plate and screws

The bone plate and screw implant for osteosynthesis are fabricated either in pure commercial titanium or from alloyed form. Titanium and its alloy provide mechanical properties specific for bone plates and screws. A plate is made with lower elasticity, better deformability and lower hardness, so that it can be adapted accurately to anatomic contours whereas screws are fabricated to have higher elasticity and tensile strength and low deformability.

Bone plate systems available in Maxillofacial surgery are compression and non compression mini plate type. Another type is a microplate system which is indicated for a nasoethemoidal, infraorbital and frontal sinus wall fractures.

Dental implants

Titanium is the base metal for dental implants. The ability of the metal to osteointegrate with the bone surface and getting anchored within bone tissue enables implant to withstand the masticatory load transmitted through prosthesis. Titanium possesses molecular binding sites that facilitate the absorption of proteoglycans in presence of dioxide layer formed on its surface which then serve as a substrate for biological and cellular adhesions. This leads to direct ingrowth of bone cells on the implant surface with no intervening connective tissue. The other factor influencing osteointegration is the minimal adsorption of platelets on the titanium surface, thus clot formation on the implant surface is hindered which is otherwise responsible for fibrous tissue formation. To achieve the higher success rate and bone anchorage, surface area of implant is increased by plasma spraying either with titanium particles or by hydroxyapatite (HA) coating. The HA becomes ionised and is converted into plasma stream that condenses in multiple layer on the metallic implant surface in the form of partially amorphous and partially crystalline ceramic coatings.

In plasma coated implants the particles of titanium in plasma state is sprayed over the smooth commercially pure titanium to prepare titanium plasma spray (TPS) implants. It not only increases the surface area by six times but also increases the bone strength of the surface coating by 33%. This results in more implant bone interface and good osseointegration. Titanium implants are not available from indigenous sources and the imported system is costly.

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SCHOOL OF BIO AND CHEMICAL ENGINEERING

DEPARTMENT OF BIOMEDICAL ENGINEERING

UNIT – III - Biomaterials – SBM1304

POLYMERS AND APPLICATIONS

POLYMERS IN BIOMEDICAL USE

Polymers: Polymers are large molecules built by repetition of small simple chemical unit (monomers)

Polymers are of various types.

i) Linear
ii) Branch
iii) Cross-linked

- Homopolymer is the simplest and made up of identical units linearly
- Oligo polymer
- It has less than 10 monomer units eg. Oligostyrene, copolymers made up of two monomer units by polymers. Eg: methylvinyl ether copolymer.
- Types of copolymer chain
- Random : –A – A – B – A – B – A – A – A – B –
- Alternate: – A – B – A – B – A – B –
- Block: – A – A – A – B – B – B – A – A – A –
- Graft:

```
|
B                B
|                |
B                B
|                |
– A – A – A – A – A – A – A –
```

Classification of polymers

Natural and synthetic

- It occurs naturally in the nature eg. Cotton, silk, protein, wool and rubber
- Synthetic: it is from low molecular weight compound eg: polyethylene, PVC and nylon

Inorganic and organic

- The main side chain is made up of carbon atom eg: H, N, 0 is attached to main chain

Inorganic

- It main chain is made up of atom other than carbon eg: glass, silicon, rubber

Thermoplastic	Thermosetting
Heat is applied It becomes soft then its reshaped Eg: PE, PVC	Heat is applied It is infusible and insoluble mass Eg: Epoxy resins

Plastics, Elastomers, fibres and liquid resins.

Classification of ultimate forom

Plastics: It shaped to hard and tough particles eg: PVC and PMMA

Elastomers

- It is vulcanized into rubbery product with strength and elongation. Eg: Silicon rubber and natural rubber.

Fibres

- Long filament with length 100 times the diameter. Eg. Nylon.

Liquid resins

- It is used as adhesive and ceiling agent. Eg. Epoxy adhesive.

Synthesis of polymerisation

- Takes place by two mechanism: i) addition polymerization, ii) condensation polymerization.
- Addition polymerization: Rearrangement of bond, Double or triple bond breakage. It requires 3 steps: i) initiation, ii) elongation, iii) termination.
- Condensation polymerization: elimination of small molecules or atoms (H_2O).
- Polymers in biomedical use: it is widely used in surgery, dentistry, ophthalmology, orthopedic, pharmacy, etc.
- Polyethylene: Simplest hydrocarbon polymer. $-(CH_2 - CH_2)-$ n
- Preparation: Reacting ethylene gas at high pressure (100 – 300 MPa) at 180 – 250^{O}C in presence of O_2 (0.1%) or peroxide catalyst.
- Grade: LDPE – 6000 – 40,000 – branched polymer high density
  HDPE > 40,000 – 2 Million – Linear polymer
  UHMWPE > 5 million – ultra high molecular weight ethylene

Specific properties

i) Low cost
ii) Easy processability
iii) Excellent chemical resistance
iv) Toughness and flexibility
v) Excellent electrical insulation

Properties of different grade of PE

vi) LDPE
- High to ear strength
- Low density
- Extreme flexibility
- Chemical and moisture resistant

vii) HDPE
- High density
- Stiffness
- Low gas permeability
- High tensile strength
- Chemical resistance

Applications

- LDPE : It is used widely in sheet and film
- HDPE: It is widely used in container, drum and gas tank
- KHMWPE: It is widely used in orthopedic implant, total knee and hip joint replacement.
- Fabrication of acetabular up in artificial joints.

Polypropylene (PP)

$-(CH_2 - CH)-_n$

$\quad\quad\quad\quad |$

$\quad\quad\quad CH_3$

- It has 2 conformations
- Isotactic – methyl group on one side
- Syndiotactic –methyl group on alternate side
- Molecular weight : 5×10^5
- Lightest polymer

Properties

- High stiffness and hardness
- High tensile strength
- High strength to weight ratio
- Melting point is $100^{O}C$. It can be sterilized
- Insoluble at room temperature
- Good mechanical and dielectrical property
- When heated at above melting point, it is dissolved, chlorinated to aromatic hydrocarbons.

Applications

- It is used as a sutures, i.e. monofilament of PP for prolene

$$-\left(C - N - R - N - C - O\,R - O\right)-_{n}$$

- Common urethane linkage (– O – CO – NH)
- Presence of additional O_2 atom gives flexibility

Properties

- It is not resistant to abrasions
- High resistance to breaking
- High modulus of elasticity
- Resistant to fatigue
- Good bio and blood compatibility

Applications

- Segmented PV used in extruded blood tubings.
- Crosslinked PU – long term surgical implants
- PU copolymers – used to fabricate heart arrest device and aortic patch grafts
- Polyether PV – commonly used for heart surgery. It has good mechanical property and hydrolytic stability.
- Polymethyl methacrylate (PMMA)
- It is prepared by radical polymerization of acetone (acrylic acid derivative)
- It is cast molded (or) machined
- It is referred as plexi glass (or) organic glass
- Available as 2 components

- Powder – small PMMA spheres / beads
- Liquid – having monomers
- It is mixed in ratio 2:1 and donga made which cures in ten minutes.
- It is used in dental fillings.

Properties

- Very brittle, excellent light transparency
- High refractive index (1.4 g)
- Excellent chemical resistivity
- Highly biocompatible
- Good strength and life period
- Soluble in ketone, chlorinated hydrocarbon
- Amorphous in nature.

Application

- Used in contact lens preparation
- Implantable ocular lens.
- Bone cement for joint fixation
- Dentures
- Maxillofacial prosthesis
- In orthopedic surgery, it is used in hip replacement.
- Polytetrafluoroethylene (PTFE)
- Teflons
- It is similar to PE but replaced by fluorine
- Molecular weight 610 □ 10^6
- It has unique stability – extreme inertness, strength of covalent bonds

Properties

- Good chemical and thermal stability
- High crystalline melting point (> 250^oC)
- High thermal stability
- Extremely resistant to chemical attack
- High dielectric strength
- Unique non adhesion and anti frictional property
- High density (2.15 – 2.2 g/cm^3
- Low tensile strength
- Low modulus of elasticity
- Low surface tension.

Applications

- Tissue tolerance of PTFE graft is good healing and rapid.
- Used in cardiovascular circulation
- Sutures used for fixation of heart valve prosthesis
- Tabe fine application it is used as graft
- Sheets and films used for in bypass surgery reconstruction madillofacial area
- PTFE shunt is used to carry CSF from brain to venous system for the treatment of hydrocephalus
- Polyhydroxyethylmethacrylate (PHEMA) (hydron)
- Rigid acrylic polymerization dry and in water becomes a gel
- Depending on fabrication, (3 – 90%) can be made of water.
- Easily machined while drying
- It is used in preparation of contact lens

Polyvinyl alcohol (PVA)

- Tensile strength
- Wear resistance
- Semipermeability

Application

- It is used for preparation of synthetic cartilage reconstructive joint surgery.
- It holds synorial fluids in joint.

Disadvantage

- It cannot be steam sterilized

Hydrogels: eg: P-HEMA and PVA after uses of hydrogel

- The first hydrogel polymer developed is the polyhydroethyl methacrylate (PHEMA) or poly HEMA which can absorb water more than 30% of its weight.
- This property makes it useful for soft lens application.
- Hydrogels are made by polymerization of certain hydrophilic monomers with small amount of cross linking agents such as ethylene glycol dimethacrylate (EDGA).
- The hydrogel can change its structure according to pH, salt concentration and temperature.
- They are basically cross linked polymer with hydrophic group. They also contain carboxylic acid group.
- A common polymer used to make hydrogel is sodium polyacrylate

- The polymer usually exist in the shape of randomly coiled molecules in the absence of Na^+ if the salt is removed, the changes on the oxide ions along the polymer chain repel each other and the chain tend to uncoil.
- In this state, the hydrogel can absorb over 500 times its own weight of pure water.
- This ability of hydrogel to absorb much water is useful for making soft contact lenses, baby napkins, wound dressing and drug delivery system.
- When salt is added to the hydrogel the chain starts to change their shape and water is lost from the gel.
- Na^+ now take up the place of water and hydrogel gets coiled again.

Use of hydrogel in wound dressing.

- A wound dressing is put over a cut to keep the skin healed.
- The hydrogel is applied as a thin layer which is moist and smoothening.
- It stops the wound drying out and protect it from infection.
- The hydrogel can control bleeding and does not stick to the surface so it can be removed easily without damaging the stain.

Silicon rubber

- Silicon natural and synthetic rubber have been used for fabrication of implant.
- Rubber (or) elastomer are defined as a material that at room temperature can be stretched repeatedly to at twice its original length and upon release of the stress returns immediately with force to its approximate original length.
- This phenomenon helps in the cross linkage between the chain that holds the chain together.
- The amount of cross linking for natural rubber controls the flexibility of the rubber, the addition of 2 – 3% of sulfur results in flexible rubber
- While addition of 30% of sulfur makes it a hard rubber.
- Rubber contain antioxidants to protect them against decomposition by oxidation, hence improving aging properties.
- Fillers such as carbon black or silver powder are also used to improve the physical properties.
- Silicon rubber is one of the few polymers developed for medical se.
- The repeating unit is dimethyl siloxane which is polymerized by condensation polymerisation to give (PDNS) polydimethyl siloxane.
- Low molecular weight polymers having low viscosity.
- It can be cross linked to make high molecular weight rubber like material.
- Medical grade silicon rubbers contain Stannous octate as a catalyst and can be mixed with base polymer at a time of implant fabrication.

- There are three grades of si8licone rubber : i) Hard, ii) Medium, iii) Soft

Properties of silicon rubber

- They are chemically resistant
- They are stable over a wide range of temperature
- They are easily sterilized and biocompatible
- They are durable: good electrical insulation, possess thermal and oxidative stability at high temperature, flexibility and elasticity at low temperature.

Advantages

- Due to flexibility, silicone implants can be compressed through a small incision.
- Since the body cannot bond with silicon or grow into it, it builds a scar tissue wound it.
- And silicone implants can be removed easily.

Disadvantage

- Silicone has a sticky surface structure, hence there will be more contamination.
- It may contain toxic materials.

Applications

- It is used in cardiovascular appliances because of blood compatibility.
- They are mostly used as breast implant it can be replaced in disease or destroyed finger joints.
- It can be used for maxillofacial surgery

Biodegradable polymer (BDP)

- Biodegradable of synthetic polymer is developed only in recent years and primarily response in growing problem of waste disposal of plastics.
- All biopolymer undergoes enzymatic degradation.
- Factors affecting rate of degradation.
- Polymer site (molecular weight presence of functional group in or on main chain
- Physical or morphological state: crystalline, amorphous
- Environmental condition: ph – temperature – salt concentration.

Major applications

- Adhesives, temporary scaffolding, temporary barrier, drug delivery matrix.

Temporary scaffold: Eg. Absorbable sutures

- Surgery causes temporary weaknesses and needs artificial support
- Sutures hold tissues together until collagen synthesis takes place
- 70-80% of collagen synthesis occurs at first third week and 20 – 30% of collagen synthesis occurs in 3 – 5 months.

Temporary barrier

- It is important in the field of tendon, spinal coral and open heart surgery.
- After surgery, surgical adhesions caused by blood clotting and fibrosis between sliding surface of tendons and between cardiac and pericardiac stack which causes pain.
- So this biodegradable polymer act as a temporary barrier to prevent adhesion and they degrade gradually.
- Drug delivery matrix: Drug Delivery Biodegradable (DDB) matrix is used to deliver the drug and degrades at a predictable rate by drug diffusion mechanism from the matrix where the drug is incorporated.

Design

- Solubilisation, ionization followed by solubilisation, enzymatic hydrolysis, simple hydrolysis.

BDP in Biomedical use or in medicine PVA

- It is used in creams and cosmetics as a water soluble thickening agent.
- Used as an artificial tears in dry eyes.
- In contact lens, it acts as a wetting system.
- Copolymer of methyl vinyl ether and maleic anhydride
- It is used as a coating agent on the surface of drug to prevent damage of drug in stomach by acetic environment.
- Co-polymer of PE Oxide : It act as a temporary mechanical support to tissue.
- Degradation by simple hydrolysis within 2 – 12 weeks.
- It is made as film or fiber and used as a BDP.
- Copolymer of L-latic, Dlatic and glycolic: It should bear load during bone fracture heating.
- Copolymer polyglycolic acid / polylactic acid
- It act as suture material and it is
- Under the name DEXON VICRYL
- It is used to deliver the drug at a predicable absorption rate
- It is also used as a drug delivery matrix

- Polydioxanone: under the name PDS.
- Monofilament structure and act as a suture
- Advantage it has less affinity, for the attachment of bacteria.
- Polyglyconate: copolymer of trimethylene carbonate and polyglycols acid.
- Under the name MAXON
- Less inflammation and scar tissue formation.

STERILIZATION

STERILIZATION is the process by which all living micro-organisms both pathogenic and non-pathogenic including spores are killed.

Microorganism in polymerizing implant.

- Microorganism posses variable capacities to adhere to the polymer surface.
- Staphpylococci is predominant organism followed by Pseudomonas, Klebsiella, Serratia (curd contaminant red colour pigment) followed by Candida.

Polymeric sterilization

- Most polymeric implant materials cannot be treated by steam or dry heat.
- As their thermosensitive, in such situation treatment by gamma radiation or chemical agent employed
- radiation with dose of 2.5 M radiation has been found to be suitable to sterilize PE tetraphthalate (PET)

Microorganism possess variable capacities to adhere to the polymer surface. Staphpylococci is predominant organism followed by Pseudomonas, Klebsiella, Serratia (curd contaminant red colour pigment) followed by Candida.

The prevention of surgical site infection in health care areas is largely dependent on the rigorous adherence to the principles of aseptic techniques by all personnel who performs any invasive procedures on patients, the sterility of all items directly used in such procedures and the disinfections of all surfaces and other items in the immediate environment. Surgical instruments, linen and heat sensitive items are sterilized by the method recommended by the manufacturer. No disposable items designed for sterile single use should be processed.

METHODS OF STERILIZATION

It is essential for a sterilizing agent to be in contact with every surface of each item or device to be sterilized for the specified period of time at the specified temperature.

Physical Method

Chemical method

Physical Method

Physical Method

Heat – is the earliest, the safest and surest method of sterilization. It may be dry (hot air ovens infra-red conveyor ovens) or moist (steam).

Dry heat, at normal atmospheric pressure.

Hot air ovens – these are electrically heated and usually with an internal fan to provide and even distribution of heat. Sterilizing time is one hour at 160ºC. This is suitable for ophthalmic instruments, glassware and sealed jars.

Moist heat, at a raised atmospheric pressure

Steam autoclave (steam under pressure) Steam sterilization is the most inexpensive and effective method of sterilization. Steam under pressure permits permeation of moist heat to porous substances by condensation and results in destruction of all microbial life. This is the usual method of sterilizing surgical instruments, dressing, drapes, swabs, laps sponges and culture media.

COLD METHOD

Gaseous Sterilization

a. Ethylene Oxide (EO) –

This is a well established technique for sterilizing heat labile articles. It is colorless at ordinary temperatures, has an odor similar to that of ether and has an inhalation toxicity similar to that of ammonia dioxide or fluorinated hydrocarbons (FREON).

It can be used for sterilizing vascular and bone grafts, delicate instruments, plastic articles such as disposable syringes, surgical instruments such as cystoscopes, catheters, bacteriological media and vaccines.

Before EO sterilization, objects also need to be **cleaned thoroughly** and wrapped in a material that allows the gas to penetrate.

Chemical indicators for EO should be used with each package to show that it has been exposed to gas sterilization process.

Gas sterilizers are recommended to be checked at least once a week with commercial preparation spores, usually Bacillus atropheus formerly Bacillus subtilis var. niger.

All objects processed by gas sterilization also need **special aeration** according to manufacturer's recommendation before use to remove toxic residues of EO.

In general, an exposure period of 3 to 7 hours is necessary for complete sterilization. Temperature for sterilizing is 21º C to 60º C 70º F to 140º F).

ADVANTAGES OF EO:

EO sterilization should be used only if materials are heat sensitive and unable to withstand sterilization by saturated steam under pressure. EO is easily available and is effective against all types of microorganisms. EO easily penetrates through masses of dry materials; does not require high temperatures, humidity or pressures. nEO is non- corrosive and non- damaging to items.

DISADVANTAGES OF EO:

It is lengthy process in the long exposure and aeration periods.

EO sterilization is expensive and more complex process.

Liquid EO may produce serious burns on exposed skin if not immediately removed.

Insufficiently aerated materials can cause irritation, burns of body tissues, hemolysis of blood and diluents used with EO cause damage to some plastics.

It is toxic and can cause **Cancer**. Precautions should be taken to protect personnel

OTHER METHODS

a. **Gamma Radiation**

This involves the use of gamma radiation from a Cobalt 60 source and is used commercially.

b. **Ultraviolet light**

This is a form of surface radiation and its penetrating capacity is poor, so it is used for sterilizing surfaces, bone chips, grafts and blades.

c. Plasma (Sterrad)-

Autoclave - Low Temperature Hydrogen Gas Sterilizers. It is used to sterilize delicate instruments. Spore testing should be performed at the same interval as testing of other sterilizers.

LIQUID CHEMICAL STERILIZATION

When used properly liquid chemo sterilizers can destroy all forms of microbial life including bacterial and fungal spores, tubercle bacilli and viruses.

Liquid chemicals can be used for sterilization when steam, gas or dry heat is not indicated or available.

Aqueous Formaldehyde- is one of the oldest chemo sterilizers known to destroy spores; it is rarely used because its pungent odor is objectionable.

Aqueous Glutaraldehyde- is more rapid and less irritating than formaldehyde solutions. Instruments must be free of bioburden and completely immersed in activated aqueous glutareldehyde solution for 10 hours to achieve sterilization.

During immersion all surfaces of the instruments must be rinsed thoroughly with sterile distilled water before being used. Any period of immersion less than 10 hours will not kill spores that may be present and must be considered as only a disinfection process.

Built materials for biomedical application

- This process results in destruction of all form of microorganism (bacteria and spores)
- The only disadvantage of this irradiation of polymer, it can alter the chemical nature of polymer
- Ethylene oxide is a gas mostly used for the sterilization of medico surgical materials.
- Advantage is it is very efficient, rapid and large spectrum action.
- Formaldehyde is utilized as aerosol or in gaseous state in operation theatre.
- Gluteraldehyde has been employed in concentration of above 2 – 2.5% for the decontamination of medico surgical materials at room temperature.
- Gluteraldehyde should be removed as much as possible by rinsing with water.

POLYMER DERERIORATION

- Undesireable change in the properties of materials due to metabolic activity of m.o
- Polymer deterioration due to

1. Chemical factors
2. Thermal factors
3. Physical factors

Deterioration affect the main back bone chain, side groups and molecular arrangement

1. Chemical factors

- Linear polymer usually cut randomly
- Low density polyethylene is converted into lower crystallinity
- Decrease mechanical properties

  Ex:
- Isoprene rubber react with ozone
- Rubber become brittle
- The by product of degradation is HCl
- Cause irritation to surrounding tissue

2. Thermal effect – sterilization

- Essential for all implanted biomaterials
- Sterilization may results in polymer deterioration
- Dry heat sterilization temp between 160 – 190oC
- Above the melting point of polyethylene & PMMA
- Oxidation will occur
- Steam sterilization – high steam pressure at low temperature – 121oC

Chemical agents

• Chemical agents such as ethylene oxide

Propylene oxide gas

Hypo chloride solution widely used

Chemical sterilization takes longer time

Chemical agents cause polymer deterioration

3. Physical factors

Radiation sterilization

- UV rays

- Gamma rays
- Cobalt 60 – emit gamma rays
- Sterilization of medical equipment
- Radiation source of medical radiotherapy – cancer treatment
- Radiation source for pest insect sterilization
- Radiation source for food irradiation and blood irradiation
- Cause polymer deterioration

Mechano chemical effect

- Polymer is stored in water or saline solution will decrease the strength
- consequence of the mechanochemical degradation of polymers is fatigue
- polymer melt during processing or under conditions of mechanical fatigue at lower temperatures (e.g., in cross-linked rubbers)

Environmental effect

- Host environment is very hostile
- Polymers start to deteriorate as they are implanted
- Natural polymeric materials degraded by tissue enzymes
- Polymer deteriorates in physiological solution under invitro and invivo
- Hydrophilic polymers react with body fluids and undergo rapid deterioration
- Original physical properties of implant will be changed

  Example

- Polyolefins will lose flexibility and becomes brittle

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SCHOOL OF BIO AND CHEMICAL ENGINEERING

DEPARTMENT OF BIOMEDICAL ENGINEERING

UNIT – IV - Biomaterials – SBM1304

BIOCERAMICS

- Refractory, polycrystalline compound, inorganic in nature
- Oldest synthetic material
- It can be single crystals (sapphire) polycrystalline (alumina HAP), glass ceramics (bioglass).

Physical Properties

- Generally hard
- High melting point
- Low conductivity for electricity and heat
- Low tensile strength
- Difficult to shear

Classification: based on chemical reactivity

- Bioinert – alumina, zirconia, titania, carbon,
- Bioactive – ceravital and bioactive glasses, HAP
- Resorbable ceramics – TCP and HAP
- Nonresorbable ceramics: Alumina and carbon

Bioinert ceramics

- Alumina: Chemically inactive
- Available in -alumina
- For implant use, 99.5% pure almina +0.1% SiO_2 and alkali (Na_2O)
- Natural alumina : Sapphire (or) ruby

Properties

- High corrosion and wear resistanace
- High rigidity and hardness
- Good biocompatibility
- Reasonable strength (depends on grain size and porosity)
- Mechanical properties depend on its grain size.

Application

- Orthopedic application hip and knee prosthesis
- Reconstructive maxillofacial surgery
- Dental implants – teeth roots (porous)

Important pre requisites of alumina

- Surface finish
- Small grain size
- Biomechanically correct design
- Exact implantation techniques
- Good manufacturing technology

Zirconia yttria stabilished zirconia

- Properties : Structure changes with temperature, at room temperature, monoclinic structure, 1000 – 1100ºC, 2000ºC: cubic
- High bending strength and fracture toughness.

Application

- Orthopedic prosthesis
- HAP coated zirconia used in dental implants have a longer life.
- Shoulder prosthesis

Carbon

- Iinert bioceramic material has unique properties.
- Possess two bonds
- Covalent bonding: between hexagonal layers, high strength
- Vanderwaal's bond: between parallel layers, less stiffness and strength.
- Between parallel layers
- Less stiffness and strength.

Properties.

- Good biocompatibility
- High strength and modulus

Types

- Low temperature isotropic carbon (LTI)
- Good bonding strength
- Good thrombo resistance
- Frictional properties and high elastic strain.
- Vitreous carbon
- Glass blocking appearance
- Small size
- Good resistance, strength, less than LTI

- Ultra LTI – (ULTI)
- Used as coating in implants
- High biocompatibility

Application

- Isotropic pyrolitic carbon – vascular implants
- Carbon coatings – heart valves, blood vessel grafts, percutaneous devices.
- VLTI – Valve coating (carbon absorb protein easily)
- LTI – restorative dentistry
- Surface reactive ceramics: gives controlled surface reactivity based on chemical bond
- Glass ceramics – bioglass – applied as coating for stainless steel, Co – Cr alloys – high mechanical stability biocompatibility
- Excellent mechanical and thermal properties
- Vary only in composition.

Surface reactivity composition

- Inclusion of 5 – 15% of B_2O_3 more reactive
- Drawback : Brittle, not used in joint implants.
- **Application**: Fillers for bone cement, dental composites and coatings.
- **Bioglass**: SiO_2 CaO Na_2O P_2O_5
- **Ceranital**: SiO_2 $CaONa_2OP_2O_5$ $MgOK_2O$ ($Al_2O_3TiO_3Ta_2O_6$)
- **Layer formation**: Calcium phosphate SiO_2

Properties

- Good tensile strength
- Good resistance to scratching, abrasions

Hydroxyapatite (HAP)

- $Ca_{10}(PO_4)$ $(OH)_2$
- Hexagonal structure
- Ratio of Ca/P – 1.66
- Synthesis – $Ca(OH)_2$ + H_3PO_4 – in aqueous solution: 105^oC – powdered and sieved.
- Chemically equivalent to bone mineral – forms strong biological bond.
- Stimulates osteo induction – osteogensis
- Osteo integration – interface between implant and must happen else implane bone rejected.
- Biological performance based on osteointegration with an increased load bearing capacity.

Thermal behavior of MAP

- Increase in temperature – structure is modified
- Shows presence of : i) lattice water, ii) absorbed water
- HAP subjected to ~ 1200^{o}C – water is driven out – produces partially hydrated HaP
- Above 900^{o}C – weight loss
- 1050^{o}C HAP decomposes
- $Ca_{10}(PO_4)_6(OH)_2$ → 2 $Ca_3(PO_4)_2 + CaP_2O_9 + H_2O$ > 1350^{o}C
- → $(Ca_3PO_4)_2$ → $Ca_3(PO_4)_2$ → irreversible reaction.
- Ceramic degrade in the order : → Tricalcium phosphate (TCP) > →TCP > HAP

Application

- Used as fillers to replace amputated bone or as coating to promote bone ingrowth.
- HAP is widely and used as bone implants
- Experiment done with dog's tibia and femur
- There is direct chemical attachment to bone and there is no degradation.
- Used as synthetic roots and healing place without complications.
- No rejection is seen
- Used in biological chromatography as support material for protein purification.
- HAP column used in HPLC
- It is used as sealing agent
- Used as coating materials on metals

Properties

- Lacks toxicity
- It possess direct contact with bones
- Stimulates bone growth

Disadvantages

- It is brittle in nature and it posses or mechanical properties

Bioceramic coating on metal implants and Bone Bonding

A **coating** is a covering that is applied to the surface of an object, usually referred to as the **substrate**. The purpose of applying the coating may be decorative, functional, or both. The coating itself may be an all-over coating, completely covering the substrate, or it may only cover parts of the substrate. An example of all of these types of coating is a product label on many drinks bottles- one side has an all-over functional coating (the adhesive) and the other side has one or more decorative coatings in an appropriate pattern (the printing) to form the words and images.

Paints and lacquers are coatings that mostly have dual uses of protecting the substrate and being decorative, although some artists paints are only for decoration, and the paint on large industrial pipes is presumably only for the function of preventing corrosion.

Functional coatings may be applied to change the surface properties of the substrate, such as adhesion, wetability, corrosion resistance, or wear resistance. In other cases, e.g. semiconductor device fabrication (where the substrate is a wafer), the coating adds a completely new property such as a magnetic response or electrical conductivity and forms an essential part of the finished product.

A major consideration for most coating processes is that the coating is to be applied at a controlled thickness, and a number of different processes are in use to achieve this control, ranging from a simple brush for painting a wall, to some very expensive machinery applying coatings in the electronics industry. A further consideration for 'non-all-over' coatings is that control is needed as to **where** the coating is to be applied. A number of these non-all-over coating processes are printing processes.

Many industrial coating processes involve the application of a thin film of functional material to a substrate, such as paper, fabric, film, foil, or sheet stock. If the substrate starts and ends the process wound up in a roll, the process may be termed "roll-to-roll" or "web-based" coating. A roll of substrate, when wound through the coating machine, is typically called a **web**.

Coatings may be applied as liquids, gases or solids.

Functions of coatings

- Adhesive – adhesive tape, pressure-sensitive labels, iron-on fabric
- Changing adhesion properties
    - Non-stick PTFE coated- cooking pans
    - Release coatings e.g. silicone-coated release liners for many self-adhesive products
    - primers encourage subsequent coatings to adhere well (also sometimes have anti-corrosive properties)
- ✓ Optical coatings
    - Reflective coatings for mirrors
    - Anti-reflective coatings e.g. on spectacles
    - UV- absorbent coatings for protection of eyes or increasing the life of the substrate
    - Tinted as used in some coloured lighting, tinted glazing, or sunglasses
- Catalytic e.g. some self-cleaning glass
- Light-sensitive as previously used to make photographic film
- Protective
    - Most paints are to some extent protecting the substrate
    - Hard anti-scratch coating on plastics and other materials e.g. of titanium nitride to

reduce scratching, improve wear resistance, etc.
        - Anti-corrosion
            - Underbody sealant for cars
            - Many plating products
        - Waterproof fabric and waterproof paper
        - antimicrobial surface
- Magnetic properties such as for magnetic media like cassette tapes, floppy disks, and some mass transit tickets
- Electrical or electronic properties
    - Conductive coatings e.g. to manufacture some types of resistors
    - Insulating coatings e.g. on magnet wires used in transformers
- Scent properties such as scratch and sniff stickers and labels

Coating processes

Coating processes may be classified as follows:

Vapor deposition

Chemical vapor deposition

Main article: Chemical vapor deposition

- Metalorganic vapour phase epitaxy
- Electrostatic spray assisted vapour deposition (ESAVD)
- Sherardizing
- Some forms of Epitaxy
    - Molecular beam epitaxy

Physical vapor deposition

Main article: Physical vapor deposition

- Cathodic arc deposition
- Electron beam physical vapor deposition (EBPVD)
- Ion plating
- Ion beam assisted deposition (IBAD)
- Magnetron sputtering
- Pulsed laser deposition
- Sputter deposition
- Vacuum deposition
- Vacuum evaporation, evaporation (deposition)

Chemical and electrochemical techniques

- Conversion coating
    - Autophoretic, the registered trade name of a proprietary series of autodepositing coatings specifically for ferrous metal substrates[1]
    - Anodising
    - Chromate conversion coating
    - Plasma electrolytic oxidation
    - Phosphate (coating)
- Ion beam mixing
- Pickled and oiled, a type of plate steel coating
- Plating
    - Electroless plating
    - Electroplating

Spraying

- Spray painting
- High velocity oxygen fuel (HVOF)
- Plasma spraying
- Thermal spraying
    - Plasma transferred wire arc thermal spraying
- The common forms of Powder coating

Roll-to-roll coating processes

Common roll-to-roll coating processes include:

- Air knife coating
- Anilox coater
- Flexo coater
- Gap Coating
    - Knife-over-roll coating
- Gravure coating
- Hot melt coating- when the necessary coating viscosity is achieved by temperature rather than solution of the polymers etc. This method commonly implies slot-die coating above room temperature, but it also is possible to have hot-melt roller coating; hot-melt metering-rod coating, etc.
- Immersion dip coatingKiss coating
- Metering rod (Meyer bar) coating
- Roller coating
    - Forward roller coating
    - Reverse roll coating
- Silk Screen coater

- Rotary screen
- Slot Die coating
  - Extrusion coating[2] - generally high pressure, often high temperature, and with the web travelling much faster than the speed of the extruded polymer.
  - Curtain coating- low viscosity, with the slot vertically above the web and a gap between slotdie and web.
  - Slide coating- bead coating with an angled slide between the slotdie and the bead. Very successfully used for multilayer coating in the photographic industry.
  - Slot die bead coating- typically with the web backed by a roller and a very small gap between slotdie and web.
  - Tensioned-web slotdie coating- with no backing for the web.
- Inkjet printing
- Lithography
- Flexography

Composites

- Composite materials are a combination of more materials having different set of properties from their consequent material thus the combination of two or more discrete type of materials results superior properties not exhibited by the individual materials their significant properties are: high strength, heat resistance, stiffness and stability.

Classification of composite material

- It is classified into two types.
- Natural composites
- Artificial composites

Natural composites eg: Wood, bone, bamboo, concrete tc.

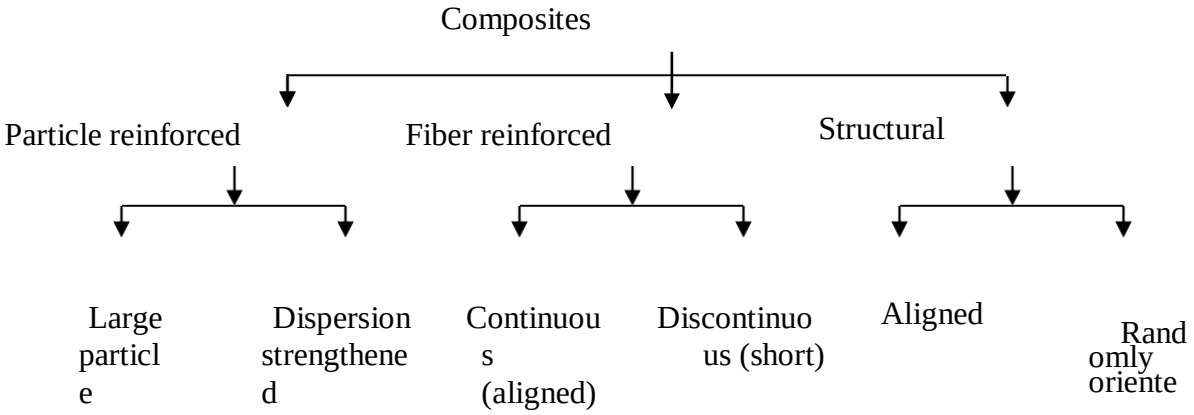
- Wood consist of organic material (lignin and cellulose fiber) in its structure which provides the required strength for various application.
- In bone the fibrous protein called collagen is apetite which produces the required strength.
- Artificial composite: Reinforced carbon (RCC) in this steel rods are embedded in the concrete mix and produces the required strength.
- The concrete mix is added with steel rods results in RCC structure which leads to take heavy load, which cannot be carried out by concrete alone.
- Glass Reinforced Plastic (GRP) which has combined properties of glass, glass fibers and plastic.

Structure of composite material

- Matrix and reinforced material
- This matrix is base material which is surrounded by other material known as reinforced

material

- The base material can be continuous while the reinforcement is more essential, it may be by means of chemical reaction.
- Mechanical stability between the matrix and reinforcement, physical bonding between matrix and reinforcement through Vanderwall's force.



Particle reinforced: Large particle composites: Constituents are metal, polymer and ceramics. Eg. i) Concrete in which cement is a matrix while sand and gravel act as a particular to form the composites, Cermets which are made up of ceramics and metal matrix Ceramic like carbides are enhanced on metal like Cobol, Ni, Fe, form metal matrix.

Application: the addition of hard carbide result in high strength high tensile modulus.

Dispersion strengthened: They are produced to improve the mechanical strength.

The uniform dispersion of fine particle of hard and inert material are used. Eg. Strength of nickel alloy can be enhanced by adding fine dispersed particle 30% volume of thoria nickel (TD).

Fiber reinforced composites:

- Continuous and aligned fiber component
- The fiber is aligned parallel in single direction
- The longitudinal aligned fibers are brittle in nature
- They show uniaxial stress strain relationship with more efficiency
- They are anisotropic in nature (different properties in different direction)
- Two important parameters should be considered: i) specific strength = tensile strength / specific gravity, ii) specific modulus : modulus elasticity / specific gravity.
- Discontinuous and alignment fiber composites.
- The fiber reinforced are not continuous that is aligned partially in the longitudinal direction.
- More demand due to increased moduli of elasticity (90%) and tensile strength (50%)
- The discontinuous reinforcement material are known as filter.
- There are in different shape like microsphere, platelets, viscous etc.
- Discontinuous and randomly oriented fiber composite: The fiber are short and discontinuous this type leads to increase in modulus only, in some portion of the volume, fraction of the fiber.

Preparation of composite material

Fiber reinforced material

↓

Pre peg (bulk of material in cold condition)

↓

method Mostly used for silica and oxide of

↓

composite material Fiber is feeded to up drum

↓

Slurry contains matrix

↓

powder Fiber reaches the

↓

slurry

Matrix fiber coated on the

↓

↓

fiber Pre peg is obtained

↓

Dried and cut

↓

Arranged in form of

↓

stack

Binder is removed at high temperature using furnace 1800^{O}C

↓

Stacks are

↓

removed Hot

↓

pressed

Reinforced composite material are obtained

Applications of composite

- Dental filling composites: silver amalgam and gold are commonly used for posterior and anterior teeth.
- Acrylic resin and silicate cement are used in the anterior teeth but they have less life and clinical failure
- Dental composite resin – widely used for posterior and anterior teeth.
- Porous implant: It allows tissue in growth.
- Porous implant has permanent anchorage.
- Porous implant composites are of two types: a)Porous filled with tissue, b) implant filled with tissue.
- It is widely used on bone compatible implant.
- Pore size of the implant is of biological important larger than 150 µm has good tissue in growth and permanent anchorage.
- Pore size less than 75 µm does not posses tissue in growth.
- Porous coating: It is widely used to anchor artificial root canal treatment of dental implant.
- Fibrous and particulate composite in orthopedic implant.
- Inclusions are added to increase stiffness, strength, fatigue and other properties.
- Carbon fiber incorporated into High Density Polyethylene (HDPE) in total
  knee replacement.
- Fiber are added to provide near resistance
- Fibers are also incorporated into PMMA bone cement which improves the mechanical property.
- Metal wires are used as macroscopic fiber to reinforce PMMA cement in spinal cord stabilization surgery.
- Inclusions of bone particles in PMMA cement improves stiffness and fatigue life.

Bioglass

- A material is said to be bioactive,
- inorganic bioactive materials
- Bioactive glasses are silicate based, containing calcium and phosphate
- the formation of bone-like hydroxyapatite layers and the biological interaction of collagen with the material surface
- used in dentistry,
- specifically replacement materials,
- biocompatibility and
- long-term survival of the material
- The materials used at that time were mostly metallic,
- which caused corrosion and eventual failure by the aggressive nature of body fluids.
- better biocompatibility of implant materials
- resulted in the new concept of bioceramic materials that would mimic natural bone tissue.

Compositions

- Bioactive glasses have different families and each family has a different composition.
- Some classes of bioactive glasses, like Bioglass™ (45S5), are now being used intraorally as bone grafting material after gaining FDA approval.
- The original bioglass (45S5) composition is:
- 45% silica (SiO 2),
- 24.5% calcium oxide (CaO),
- 24.5%sodium oxide (Na2O), and
- 6% phosphorous pentoxide (P2O5) in weight percentage.
- Minerals that occur naturally in the body (SiO 2 , Ca, Na 2 O, H, and P) are the constituents of bioglass
- The surface of a bioglass implant, when subjected to an aqueous solution, or body fluids, converts to a silica-CaO/P2O5 -rich gel layer
- This gel layer resembles hydroxyapatite matrix so much that osteoblasts were differentiated and new bone was deposited
- Ca5(PO4)3(OH) is the chemical formula for hydroxyapatite,
- a natural mineral form of calcium apatite and usually written as Ca 10 (PO) 6 (OH) 2.

- 45S5 is able to form HCAP (hydroxycarbonated apatite) in less than 2 hours and binds to tissues.
- Certain compositional range of bioactive glass containing SiO2, Na2O, CaO, and P2O5 like ordinary soda-lime-silica glasses in specific proportions shows bonding to bone.
- Three important compositional features of these glasses differ from traditional Na2OCaO- SiO2 glasses:
- (1) less than 60 mol. % SiO2,
- (2) high-Na2O and high-CaO content, and
- (3) high-CaO/P2O5 ratio.
- High amounts of Na2O and CaO as well as relatively high CaO/P2O5 ratio make the glass surface highly reactive in physiological environments
- Other bioactive glass compositions developed over few years contain no sodium or have additional elements incorporated in the silicate network such as fluorine , magnesium, strontium, iron , silver

Applications

- Bioglass as a graft material
- Bioglass as endosseous implant
- Bioglass as remineralizing agent
- Bioglass as antibacterial agent
- Bioglass in delivery of drugs and growth factors
- Bioglass in bone tissue engineering

Bioglass as a graft material

- The limitations associated with the use of autografts and allografts development of bone graft substitutes.
- To repair massive bone defects caused by disease and trauma
- many glass and glass-ceramic compositions.
- The bioactive glass bond with connective tissue through the formation of collagen meshwork.
- Bioactive glass with its interconnected porosity has added advantages in hard-tissue prosthesis.
- The porous structure supports tissue in/on growth and improves implant stability by biologic fixation.

Bioglass as endosseous implant

- biocompatible metallic implants are strong, their bonding ability to bone tissue is very low
- so coatings have drawn attention as a method to improve their adherence.
- bioglass as the most promising implant material- in vivo study on Baboons.
- Bioglass caused ankylosis, usually by direct deposition of bone on the implant surface
- bioglass gel layer reducing from outward to inward providing mechanical compliance like the periodontal membrane in the natural tooth
- Infection less normal tissue healing with new bone formation as sighted in radiographs made bioglass

Bioglass as remineralizing agent

- The characteristic osteogenic activity of bioactive glass made it worth its trial in management of hypersensitivity by dentinal tubules. A new dentifrice formulation containing a modified bioglass material
- excellent treatment for dentine sensitivity.
- NovaMin® is the branded ingredient
- dental products designed to give immediate and long-lasting relief from tooth sensitivity.
- S53P4 induced tissue mineralization at the glass-tissue interface
- bioglass in treatment of caries prophylaxis, in dentinal hypersensitivity, as root apex sealer, and as metal implant coating.
- Dentine treated with melt-driven bioglass showed an apatite layer
- Bioerodible gel films to be useful in the delivery of re-mineralizing agents

Bioglass as antibacterial agent

- bioglass in aqueous environment have antibacterial activity
- dentifrice and has demonstrated strong anti-microbial behavior in-vitro as well as in-vivo.
- bioglass is an efficient antibacterial agent and its antibacterial effect was attributed to its alkaline nature

Bioglass in delivery of drugs and growth factors

- new advanced drug delivery systems with better drug control and prolonged action
- A drug delivery system should be inert, biologically compatible, good mechanical strength, good from the aspect of patient comfort.

- It should have ability to carry high doses of the drug,
- with no risk of accidental release; and
- easy in administering,
- removal,
- fabrication, and sterilization.
- Bioglass has been tried as a vehicle for drug delivery
- Vancomycin on bioglass carrier has been tested for treating osteomyelitis
- anti-inflammatory drug ibuprofen was released in the first 8 hours when immersed in simulated body fluid.

Bioglass in bone tissue engineering

- Tissue engineering and regenerative medicine aims to restore diseased or damaged tissue
- biodegradable scaffolds made from engineered biomaterials.
- bioactive glasses and related bioactive composite materials represent promising scaffolding materials.
- Scaffolds using biocomposite nanofibers and nanohydroxyapatite were naturally prous,
- facilitated good cell occupancy, vascularity, movement of nutrients, and metabolic waste products.
- bioinert with bioactive glass ceramic templates, produced increased osteoblast proliferation and differentiation.
- human fetal osteoblasts to adhere, migrate, proliferate, and mineralize into bone and bone defect filling

Conclusion

- Bioactive glasses with various compositions are now used for wide range of applications.
- Bioactive glasses have become an area of interest for researchers and research is still continuing on various aspects of these glasses.
- a bright future of these glasses in the field of medicine and dentistry can be easily predicted.
- limitation of low mechanical strength and low fracture resistance
- easily overcome by altering the composition and using in low load bearing areas
- the limitations of bioglass are minimal as compared to the versatile strength and huge foray of uses.

- Bioglass is a boon to the field of Medicine

HYDROXYAPATITE

- Hydroxyapatite (HAp) is the major mineral constituent of vertebrate bones and teeth.
- It has been well documented that HAp nanoparticles can significantly increase the biocompatibility and bioactivity of man-made biomaterials.
- Bone is a composite consisting mainly of calcium phosphate (69%), water (9%) & collagen (20%). Other organic substances, such as proteins & polysaccharides are present in small amounts.
- The collagen, which gives the bone its elastic resistance, acts as a matrix for the deposition and growth of minerals.
- Among the CaP salts, hydroxyapatite ($Ca_{10}(PO4)_6(OH)_2$ is the most similar to the mineral part of bone.
- The HAp crystals have the shape of needles40–60 nm in length, 20 nm in width, and 1.5–5 nm in thickness.
- Hydroxyapatite: $Ca_{10}(PO4)_6(OH)_2$
- Ca/P = 10/6 = 1.67

Applications of CaP in dentistry

1) Replacement for bony and periodontal defects & alveolar ridge
2) Tissue engineering systems
3) Bioactive coating on metallic osseous implants
4) Filler for reinforcing dental resins
5) Stimulate formation of reparative dentin better than Ca $(OH)_2$
6) Repair of mechanical bifurcation perforation
7) Apical barrier formation
8) Pulp capping

Advantages of nanosized HAp

1. Nanosized HAp has higher surface area and surface roughness resulting in superior surface functional properties of nanosized HAp compared to its microphase counterpart.
2. Mimic the bone mineral in composition and structure.
3. Promote osteointegration and subsequent bone tissue formation.
4. The best material to use for bone replacement and regeneration
5. Enhanced resorbability and much higher bioactivity than micron-sized ceramics.
6. Capability of decreasing apoptotic cell death and hence improving cell proliferation and cellular activity related to bone growth.
7. Improved cell proliferation and differentiation.
8. Better cell adhesion and cell-matrix interactions.

Challenges during synthesis of nanosized HAp

1. Formation of phase impurities (other CaP salts) during synthesis of HAp particles.
2. Difficulties in controlling size, size distribution, morphology, crystallinity, stoichiometry and degree of particle agglomeration.

The most common methods for synthesis of HAp

1. Chemical precipitation
2. Combination procedures
3. Hydrothermal method
4. Synthesis from biogenic sources
5. Sol-gel method

1. Dry methods

Dry methods do not use a solvent, unlike wet methods. Advantages

1) Simple procedure
2) Low cost: relatively inexpensive raw materials
3) Produce highly crystalline HAp
4) Suitable for mass production of HAp powder
5) Not strongly influenced by the processing parameters
6) Mostly, do not require precisely controlled conditions

Disadvantages

1) Large size of particles (in case of solid-state synthesis)
2) Low phase purity of HAp (in case of mechano-chemical process)

Types of dry methods

1. Solid-state
2. Mechanochemical

1.1. Solid-state synthesis

* Precursors are first milled and then calcined at a very high temperature (e.g. 1000 °C).
* The precursors can be calcium- and phosphate-containing chemicals of various types or a previously prepared CaP salt.
* The high temperature of calcination leads to formation of a highly crystallized structure.
* Advantages
* Simple procedure.
* Low cost
* Suitable for mass production of HAp powder
* The method of choice for commercial production
* Disadvantages
* Heterogeneity in phase composition owing to the small diffusion of ions during the reaction.
* Unattractive both scientifically & technologically

1.2. Mechanochemical method

* Sometimes known as mechanical alloying.
* Used for fabrication of nanocrystalline alloys and ceramics.
* The materials are ground on a planetary mill while the molar ratio between the reagents is kept at the stoichiometric ratio.
* Increasing the milling time leads to a decrease in crystallite size.
* The method consists mainly of mixing Ca and P, maintaining Ca/P ratio and pH.
* The powder mixture is placed in a ball mill and is subjected to high energy collision from the balls, and thus mechanical force is used to achieve chemical processing and transformation.
* Milling media such as Zirconia, alumina, stainless steel etc.
* Maintaining the ball mass ratio is critical.

Disadvantages

* Contaminations
* Long processing time
* No control on particle morphology
* Agglomerates

2. Wet methods

3. Aqueous solutions of phosphate and calcium ions.
4. Advantages
5. Precise control over the morphology and size of particles
6. The most popular in scientific researches
7. The most promising methods for the synthesis of nanosized HAp.

Disadvantages

1) Difficulties in controlling the crystallinity and phase purity of nanoparticles
2) Time-consuming makes some wet procedures unsuitable for production of large quantities of HAp
3) Low preparation temperature (compared to dry methods) resulting in:
    * Generation of CaP phases other than HAp
    * Lowering of the crystallinity
    * Various ions in the aqueous solution can be incorporated into the crystal structure.

2.1. Conventional chemical precipitation

* The simplest route for synthesis of nanosized HAp.
* Note: At room temperature and pH 4.2, HAp is the least soluble and usually the most stable CaP phase in an aqueous solution.
* The precipitation reaction is usually conducted at pH values higher than 4.2 and temperatures ranging from room temperature to temperatures close to the boiling point of water.
* Ca^{2+} source: calcium hydroxide or calcium nitrate
* $PO4^{3-}$ source: orthophosphoric acid or diammonium hydrogen phosphate
* A typical procedure involves the dropwise addition of one reagent to another under continuous and gentle stirring, while the molar ratio of elements (Ca/P) is kept at stoichiometry according to its ratio in HAp (1.67).
* The resultant suspension may be aged under atmospheric pressure or immediately washed, filtered, dried and crushed into a powder.

It is the most common method.

- **Advantages**

1) Simplicity
2) Ready availability
3) Relatively inexpensive raw materials.
4) Low reaction temperatures
5) Low operating costs

2.2. Hydrolysis method

* HAp nanoparticles can be prepared by the hydrolysis of other CaP phases, including dicalcium phosphate anhydrous (DCPA), dicalcium phosphate dihydrate (DCPD) and tricalcium phosphate (TCP).

* Hydrolysis of octacalcium phosphate (OCP) has not been of great interest for the preparation of HAp particles, probably because of the slow rate of OCP hydrolysis and/or the ability of OCP to incorporate impurities.

Aqueous hydrolysis of CaP phases into HAp usually proceeds by dissolution and precipitation processes.

2.3. Sol-gel method

* The conventional sol-gel process involves the preparation of a 3D inorganic network by mixing alkoxides (or other suitable precursors) in either an aqueous or an organic phase.
* This is followed by aging at room temperature, gelation, drying on a hot plate.
* And finally removing of organic residues from the resulting dried gel using post-heat treatment (calcination).
* The crystallite size and crystallinity of which can increase with increasing the calcination temperature.

In other words, Ca and P precursors are mixed & pH is fixed (adjusted) with ammonia or ammonium hydroxide followed by ageing, filtration, drying and calcinations.

To avoid cracking in a target 3-D monolith structure it may be necessary to age the gel before drying.

Advantages

1) Low temperature formation
2) Improving the chemical homogeneity of the resulting powder
3) A stoichiometric structure with a large surface area and a small cluster size
4) The bioresorbability of the sol-gel HAp is higher than conventional powder and is close to biological apatite.

Disadvantages

1) High cost of some of the starting materials, especially alkoxide- based precursors.
2) Generation of secondary phase (usually calcium oxide, CaO).
3) Secondary CaO phase is harmful to the biocompatibility of HAp.

Note: Attempts have been made to remove the coexisting CaO, either through washing of the calcined powder using a dilute acid solution (mainly HCl) or through increasing the aging time.

2.4. Hydrothermal method

* One of the most common methods for preparation of HAp.
* The third most popular method after the conventional precipitation and combination methods.
* Reaction of chemicals in an aqueous solution at elevated temperature and pressure.
* Hydrothermal synthesis can be considered a chemical precipitation in which the aging step is conducted at a high temperature (typically above the boiling point of water) inside an autoclave or pressure vessel.
* Performed at lower temperatures than solid-state reactions.
* Other low temperature methods such as wet chemical precipitation and sol-gel synthesis require post heat treatment to crystallise the HA; whereas crystalline HA can be produced in one step via hydrothermal synthesis.
* The initial stage is mixing the calcium and phosphorous precursors followed maintaining the Ca/P ratio at a constant value of 1.67. The solution is heated in a sealed vessel (autoclave).
* The mixing is then allowed to age, and subsequently washed and filtered. Finally it is dried in an oven and calcined.

* The amount of HAp is limited to the size of the reaction vessel.
* The startingreagents and H_2O should occupy 50–60% of the autoclave volume.

Advantages

The formed Hap is highly crystalline.

Disadvantages

1) Need expensive equipments
2) Poor capability to control the morphology and size of HAp nanoparticles

2.5. Emulsion method

* Two immiscible liquids (such as water and organic) stabilized by the presence of surfactants.
* Note: Immiscible: incapable of mixing or attaining homogenity
* Surfactants can reduce the surface tension of the immiscible liquids, resulting in a dispersed phase confined to nanometer scale.

Surfactants can subsequently be removed easily by calcination.

Advantages

1) Reduces nanoparticles agglomeration.
2) Reduces the particle size.
3) Controls the morphology (spheres, rods, discs, etc.).
4) Simple procedure
5) Low synthesis temperature (around room temperature)
6) Occurs without any high-temperature requirement

2.6. Sonochemical method

* Chemical reactions activated by powerful ultrasound radiation.
* The first step is mixing Ca and P precursor, maintaining Ca/P ratio and pH as a constant value followed by the passage of ultrasonic waves, then drying and calcination.

Advantages

1) Accelerates the reactions & the growth of HAp crystals.
2) More uniform, smaller& purer crystals with minimal agglomeration.
3) Single phase HAp could be synthesized after 15-60 min sonication.

3. High-temerature processes

Used to burn or partially burn the precursors.

Advantages

High-temperature processes can be performed by 2 techniques:

1) Combustion: has received more attention.
2) Pyrolysis

3.1. Combustion

* A conventional process used to prepare various oxide ceramics.
* Combustion processing of HAp involves a very rapid exothermic reaction.
* At first, the aqueous solutions of $Ca(NO_3)_2$ and $(NH_4)_2HPO_4$ are first mixed, followed by adding concentrated HNO_3 (an oxidizing agent) to dissolve the resulting white precipitate. A single or a mixture of two or more fuels (e.g. citric acid, succinic acid, urea and glycine) is subsequently incorporated into the resulting solution.
* The reaction can be initiated by heating the mixture in a furnace at a low temperature (e.g. 300 °C), then a sudden increase in temperature to a maximum value.
* The final step is the fast cooling of mixture to induce maximum nucleation and to prevent any further particle growth.
* Different fuels have proved to be capable of delivering different flame temperatures ranging from 100 to 900 °C (e.g. citric acid: 150 °C; succinic acid: 425 °C; urea: 800 °C; glycine: 890 °C).
* A vigorous exothermic reaction occurs between the fuel and oxidizer; the gaseous products of this reaction spontaneously combust. This gives rise to a very high local temperature that causes the formation of a solid calcium phosphate powder. This process can be completed in less than 20 minutes.
* Depending on the fuel used, the product formed may be either crystalline or amorphous. Both require a calcination step; to remove organic residues and crystallize the phase formed, respectively.

Advantages

1) Quickly produce powderwith high purity in a single step operation.
2) Inexpensive raw materials
3) Relatively simple
4) Good chemical homogeneity

3.2. Pyrolysis (spray pyrolysis)

* In general, during HAp synthesis, some post treatments and/or long-term aging under elevated temperatures may be required to achieve a high crystalline product.
* By contrast, Rapid pyrolysis produces stoichiometric, homogeneous, and highly crystalline HAp.

* Pyrolysis method can also be classified under a broad category known as aerosol methods (or gas-phase methods)

* Particles can be formed from reactants in a gas phase generated by physical evaporation of liquid precursors.
* Spray pyrolysis involves spraying the precursor solutions into a flame or a hot zone of an electric furnace using an ultrasonic generator.
* This is then followed by reaction of the generated vapors and gases at high temperatures to produce final powder, typically in an aggregated and agglomerated form.

In fact, the high temperature leads to complete evaporation of precursor droplets followed by nucleation and growth of nanoparticles in the gas phase.

Disadvantages

1) Small decomposition of HAp into α-TCP, because of high temperature of flame (usually above 2000 °C).

2) Secondary aggregates are usually formed.
3) Poor control over the processing variables.

4. Synthesis from biogenic sources

* Biogenic sources: e.g. biowastes, eggshell and exoskeleton of marine organisms.

The larger and higher macroporosity of the structure, similar to the natural cancellous bone, has been reported to result in earlier bone mineralization during the implantation; and hence corals- generated HAps are claimed to be more beneficial to bone repair applications.

* Expected to attract more attention in the near future.
* Can produce HAp blocks or particles.

Application

Bone tissue engineering

Bone void fillers for orthopaedic, traumatology, spine, maxillofacial and dental surgery.

Orthopedic and dental implant coating

Restoration of periodontal defects

Edentulous ridge augmentation

Endodontic treatment like pulp capping

Repair of mechanical furcation perforations and apical barrier formation

Fillers for reinforcing restorative glass ionomer cement (GIC) and restorative composite resin

Desensitizing agent in post teeth bleaching

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SCHOOL OF BIO AND CHEMICAL ENGINEERING

DEPARTMENT OF BIOMEDICAL ENGINEERING

UNIT – V - Biomaterials – SBM1304

OPTHALMOLOGY, CORROSION AND TESTE

Introduction

- Eye implants are used to restore functions of cornea, lens, vitreous humor, etc. to maintain and improve the eye vision.
- Various biomaterials used in ophthalmology are:
  - **i.** Viscoelastic solutions
  - **ii.** Intraocular lens
  - **iii.** Contact lenses
  - **iv.** Eye shields
  - **v.** Artificial tears
  - **vi.** Vitreous replacements
  - **vii.** Correction of corneal curvature (lasik laser surgery)
  - **viii.** Scleral buckling materials.

Contact lenses

- It is used to correct ametropias (refractive index error).
- It is used cosmetically to improve the appearance of damaged eye and enhance eye color.
- In ocular surfaces, disorder such as:
  - Chronic corneal ulcers
  - Recurrent erosions
  - Pain in bulbous keratopathy (corneal edema)
  - Entropion
  - Therapeutic – bandage lenses
- Therapeutic contact lenses may be considered a bandage on the cornea and thus they have also been called Bandage lenses.
- Lenses placed in direct contact with the cornea to correct vision.

Desirable properties of contact lens

i. High oxygen permeability to minimize lens interference with corneal respiration.

ii. Good wettability by tears and resistance to deposition of protein, mucous, lipid, microorganisms and other foreign substances on the lens surface.

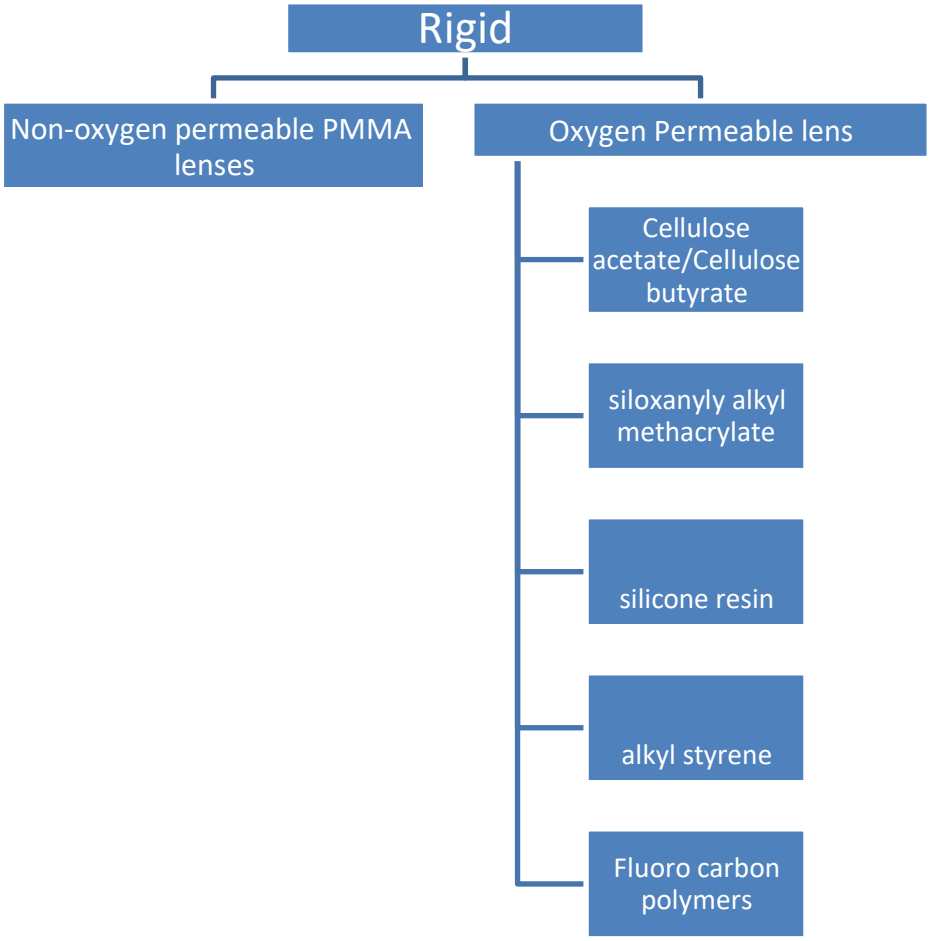
Materials used for contact lenses

i. Rigid

ii. Elastomer

iii. Hydrogel

Materials used for construction of contact lens



Contact lens must be thin with sufficient flexibility.

Elastomeric lens

i. Silicone rubber

- Made of cross-linked poly-methyl-phenyl-vinyl silicones.
- It has highest O_2 permeability of all contact lens materials.
- Silicone rubber lenses-Good O_2 permeability (drawback is hydrophobic ocular intolerance).

- It interacts with lipid components from tears and preservative solutions.

ii. Acrylic rubber
    - Made of cross-linked co-polymers of n-butyl acrylate with n-butyl methacrylate.

Hydrogel lenses(Also known as Soft contact lens)

i. Low water content
    - Made from cross linked 2-hydromethyl methacrylate polymer.
    - Contains methacrylic acid to inhibit growth of fungi, bacteria, protein & mucous layer.
    - Determines the hydration and reactivity of lens to diverse contaminants.
    - Another approach to increase oxygen permeability of polymeric material to increase the diffusion of O_2 by creating small channels in lens materials.

ii. Medium and High water content
    - Consists of co-polymers of vinyl pyrrolidone with 2-hydroxyethyl methyl acrylate or methyl methacrylate

Eye Shields

- These are used in the treatment of basement membrane associated diseases corneal abrasions, erosions, epithelial defect, cataract extraction penetrating kertoplastin and other diseases the cause eye inflammation.
- Once applied to eye these shield absorb fluid from ocular surface and begins to dissolve.
- The surface polymers in use are: Hydrogels, polyvinyl alcohol, silicone rubber and collagen.
- Eye Shield – thin clear, pliable, collagen film (0.0127-0.77mm thick).
- In a spherical shell shape with the diameter of 14.5mm and base curvature of 9mm are used as eye shield of relief of discomfort.
- Eye shield is used to prolong the delivery of antibacterial, antifungal,

antiviral and anti-inflammatory agents.

Artificial tears

- Keratoconjunctivitis sicca is a dry eye syndrome characterized by either decreased tear formation.
- Symptoms range from mild ocular discomfort to severe ocular pain.
- Artificial tears are added as substitute. The commonly used are methyl cellulose, polyvinyl alcohol, hyaluronic acid, chondroitin sulphate.

Corrosion

- Corrosion is one of the major process that affects the metal and alloy that are used as implants in the body.
- Corrosion may be regarded as the unwanted reaction of the metallic component with the environment which it exists.
- During this process, metal ions are lost from the metal surface to form either a solid corrosion product or one that is soluble in the environment.

Corrosion Reaction

- Corrosion in the aqueous medium of the body fluid is an electrochemical process.
- The electrochemical reactions that occur on the surface of the surgically implanted alloy are identical to those observed during exposure to sea water.
- The metallic components of the alloy are oxidized to ionic form and the dissolved oxygen is reduced to hydroxyl ion.
- The electrons that are released during oxidation are consumed in the reduced reaction.
- Corrosion of stainless steel implant is mainly affected by pitting.

Pitting Corrosion

- It refers to the formation of small cavities or holes at the surface of material which is protected by the presence of an adherent tenacious and self-healing thin films.
- The formation of pit is attributed with the interaction of certain

aggressive ions with the films at location where it is defective or weak in nature.

- The pit may be visible to naked eye in some cases but in general they are invisible and dangerous to the extent they can allow the formation of stress, corrosion, cracking or fatigue crack.
- The importance of pitting significantly depends on the nature of the surface layer or due to the film that has formed on the surface due to the interaction of material with the environment.
- Thus it state of passivity is forced on the material which safeguard the material from general corrosion slowing down the dissolution process at the surface.

Biocompatibility Testing (Biological Test)

- Theoretical part should be followed before developing a medical device.
- Biological test for three different groups:
  i. Surface devices.
  ii. External communicating devices.
  iii. Internal devices.

Various Biological Test

i. Cytotoxicity

- Invitro interaction of material with simplest organisms like cell, the cytotoxicity test can be done. There are three ways to the extract of biomaterials:
  - ✓ Exposing the cells to the extract of biomaterials
  - ✓ Indirect contact via diffusion layer like agar.
  - ✓ Direct contact with surface.
- Direct contact:

Immersing biomaterial in an extractant (culture medium) Incubation at 37°C for 24 hours.

↓

Extractant liquid filtered

↓

off Diluted

Cells exposed to these dilutions for different periods of time.

- Cells are directly inoculated onto the material surface, the disadvantage is that it is difficult to obtain reproducible number of cells on test material as they are easily washed off when it is flooded with the medium.
- The suitable way is to inoculate small drop of extract and incubate such that cells adapt to the surface and then the well is filled and the cytotoxicity is observed.
- It is simple technique and less experience.

ii. Genotoxicity

- Mutagenic material increases the rate of mutation of either individual genes or chromosal mutation.
- Genotoxicity can be determined by both invivo and invitro condition.
- Invitro, the gene mutation can be done by AMES test.
- Invivo chromosal damage can be done by Micronucleus test.
- There are two types of mutagens: One type can damage DNA directly and the other damages DNA indirectly with intermediate conversion step.
- This genotoxicity test determines the mutagenic potential of extract material on a mammalian cell culture.

iii. Carcinogenicity testing

- Carcinogenicity potential is evaluated through implantation on rodents using non carcinogenic material polyethylene as control.
- It needs a extended time period 1 year to exhaustive.
- If the test is negative, it is not sure that they may not induce carcinogenic response once induced.
- Example: Breast Prosthesis.

iv. Reproductive toxicity/Reproducibility toxicity

- It is similar to carcinogenicity and mutagenicity test.
- This test is usually done to determine the toxic level of intra uterine devices, energy depositing devices and resorbable

devices.

- The test is designed to determine the toxicity during reproductive cycle of the cell.
- New experiments have been done using transgenic animals whose DNA is replaced by human DNA.

v. Irritation and Sensitization

- To estimate the potential of irritation of the extract.
- The amount of leachable causes allergic reactions.
- Allergic to nickel containing metal alloys in contact with skin, in women wearing non-noble jewels.
- Patch test is done to determine the host is susceptible to allergen.
- This test is done by treating the Guinea pigs with patch embedded extract of material and untreated patch as control to the other Guinea pig.
- If the animal is allergic to leachables, erythema (redness) and edema (swelling) object at regular intervals.

vi. Systemic toxicity

- It is done to evaluate the possible toxicity in living body caused by leachables from devices at sites distant from the implant site.
- Material may be biocompatible but the leached components are toxic in nature.
- Toxicity depends not only on chemistry but also on the quantity released in unit time.
- Every compound has a threshold value above which the toxicity becomes evident.

vii. Blood compatibility

viii. Biofunctionality test

- Material selected for prosthesis construction may be a biomaterial but may not be a biocompatible for life.
- Invivo performance is different from the theoretical point of view.
- Example: shaped material may degenerate under biological attack.
- It is necessary to perform suitable physical and chemical

test considering the physiological condition.

- Stimulation test is done to check how prosthesis behave in different and extreme situations.
- It is called as biofunctionality test as they are designed to check the bioperformance of prosthesis during its functioning.

Material Surface Characterization

- Material surface characterization done by following methods:
  i. Electron spectroscopy for chemical analysis (ESCA) or X-ray photospectroscopy
  ii. Infra-red Spectroscopy
  iii. Secondary ion mass spectrometry
  iv. SEM
  v. STM
  vi. AFM

i. ESCA

- ESCA provides unique information about a surface that cannot be absorbed by other technique.
- ESCA is expensive and generally requires experts to perform the measurement.
- ESCA is otherwise called as XPS (X-ray photoelectron spectroscopy).
- X-ray are focused upon specimen. The interaction of X-rays with atom in the specimen causes the emission of your inner shell electrons.
- The energy of this electron is measured and its value provides information about the nature and environment of the atom from where it has been obtained.

Working

- The sample is introduced into a preparation chamber and pumped down to 10^{-6} torr pressure.
- A gate valve between the introduction chamber and analytical chamber

is opened and the specimen is moved into analysis chamber.

- In the analysis chamber, a 10^{-9} torr pressure, the specimen is positioned on contemporary instrument using a microscope or TV camera.
- And the X-ray source is turned ON.
- The ranges of electron energies to be absorbed are controlled by computer with the retardation lens on the spectrometer.
- First a wide scan is made in which the energies of all the emitted electrons are detected.
- The narrow scans are made in which each of the elements detected with a wide scan is examined in higher resolution.

ii. Infra-red Spectroscopy

- Attenuated total reflectance mode (widely used for biomaterial)
- The infra-red light provides information on the vibration of atomic and molecular unit.
- It is a standard analytical method that can reveal information on specific chemistry and orientation of structure.
- By using FTIR spectrometer, great improvement in signal to noise ratio and spectral accuracy can be analyzed.
- This high SN ration, the small absorption signal associate with the extremely small mass of material in a surface region can challenge the sensitivity spectrometer.
- The attenuated total reflectance (ATR) mode of sampling has been used more often in biomaterial studies.
- The penetration depth into the sample is 1 to 5 □m.

ATR is not surface sensitive but absorbs a broad region near the surface

Viscoelastic solution

In ophthalmic surgical procedures such as intraocular lens implantation, cataract surgery, retinal detachment repair, etc. , there exists a need for viscous, gel-like compositions to fill the chambers of the eye to protect sensitive tissue such as the corneal endothelium from trauma.

A composition and surgical method involving the use as an ophthalmic viscoelastic surgical material of an aqueous solution containing at least 1.5 %, by weight, of a water soluble polyvinylpyrrolidone or polyvinylpyrrolidone copolymer having a molecular weight greater than 500,000 and a viscosity greater than 5,000 centipoises.

The most employed materials are solutions of hyaluronic acid (HA), chondroitin sulfate (CS) and methylcellulose (MS); HA being the most widely used. However, HA is e trememly expensive. Furthermore, it requires extraordinary purification to remove as much proteinaceous immunogenic material as possible but still may provoke immune reactions in some patients. The use of HA and all other currently available viscosurgical materials for ophthalmic surgery is also often accompanied by significant undesirable intraocular pressure (IOP) rise which necessitates washing from the eye at the end of surgery and may also require antiglaucoma therapy. Even though HA is normally irrigated from the eye following its use in ocular surgery, transient potentially hazardous episodes of IOP rise have been known to occur. Sterilization and shelf-life stability are other problems associated with HA and other currently available materials. They are subject to significant degradation by thermal or radiation sterilization methods making safe sterile processing difficult and expensive. Ambient temperature instability also necessitates refrigerated shipment and storage. In contrast, the materials of the present invention are far more stable, may be readily autoclave sterilized without degradation and may be stored at room temperature safely for long periods of time.

It has also been suggested to employ an aqueous solution of high molecular weight, carboxymethylcellulose (CMC) as a viscosurgical material. U.S. Patent Application Serial No. 903,445, filed September 4, 1986, discloses the use of a solution of high molecular weight carboxymethyl¬ cellulose as an ophthalmic viscoelastic surgical material. Although CMC represents a significant improvement over other known viscosurgical materials, especially in ease of purification and lower cost, its use may still be accompanied by some transient IOP rise following surgery.

The below-listed terms are employed throughout the specification and claims and they are defined as follows:

1) "Viscoelastic" material refers to certain viscous solutions or compositions having the requisite viscous gel-like properties which enable their use to fill the anterior chamber of the eye.

2) "Viscosurgical" material or technique refers to the viscoelastic surgical materials inserted in the eye or the surgical techniques employed to fill the anterior chamber of the eye during cataract, lens implant, etc., surgeries.

3) "PVP" as used herein refers to any water soluble physiologically acceptable polyvinyl-pyrrolidone.

4) "Physiologically acceptable" is employed to refer to materials which, when in contact with tissues in the body, are not harmful thereto.

Vitreous Implants

Eye **implants** are used to restore functionality of cornea, lens, **vitreous** humor etc. ... These **biomaterials** include visceolastic solutions, intraocular lenses, contact lenses, eye shields, artificial tears, **vitreous** replacements, correction of corneal curvature and scleral buckling materials. An introduction to ophthalmic biomaterials and their application through tissue engineering and regenerative medicine.

Biomaterials have contributed in recent years to numerous medical devices for the restoration of eyesight, improving many patients' quality of life. Consequently, biomaterials and regenerative medicine are becoming increasingly important to the advances of ophthalmology and optometry. Biomaterials and regenerative medicine in ophthalmology reviews the present status and future direction of biomaterials and regenerative medicine in this important field. Biomaterials and design; Selected polymeric materials for orbital reconstruction; Physicochemical properties of hydrogels for use in ophthalmology.

- Development of new polymers and new medical devices for treating eye diseases
- Surface modification and characterization of medical devices
- Biocompatibility of devices
- Drug delivery systems and technologies

Acrylate adhesives

Acrylate adhesives differ from other polymer types in their ability to be cured rapidly by exposure to UV and/or visible light. Their main advantage overheat-curing **adhesives** is in bonding heat-sensitive electronic devices in 5 to 30 seconds at room temperature.

Microsurgical suturing of ocular, corneal, wounds is often associated with numerous drawbacks including post-operative astigmatism and requires a relatively high level of skill from the surgeon. Sutures can also provoke inflammation, lead to vascularization, and increase the risk of microbial infection, among other problems. Ocular adhesives are promising

alternatives to sutures. Sealants or adhesives have been used in ophthalmology for nearly five decades. These materials are typically polymers that are applied as fluids at the ocular wound site and are chemically or physically crosslinked to bind and hold tissues. Ocular adhesives not only prevent the patient and the surgeon from experiencing the drawbacks of sutures, but also can potentially offer important functionalities that are otherwise not easily attained. Some of these key added functionalities could be of great benefit to the patient, e.g. the feasibility to match the adhesive biomechanical properties to those of the native tissue, so the wound healing progresses without limiting tissue movement or affecting its function. Moreover, the adhesive material can be functionalized with pharmacological or biological compounds that prevent infection and inflammation and/or promote tissue regeneration.

Synthetic adhesives are materials often used in a wide spectrum of healthcare applications, including ophthalmology. These materials offer high tunability of a number of characteristics for specific ophthalmic applications such as chemical compositions, mechanical properties, tissue adhesiveness, and degradation kinetics. Moreover, synthetic adhesives present added benefits with regard to ease of manufacturing, high purity, and low cost. The most widely explored synthetic adhesives used in ophthalmology are based on cyanoacrylates and linear PEG derivatives.

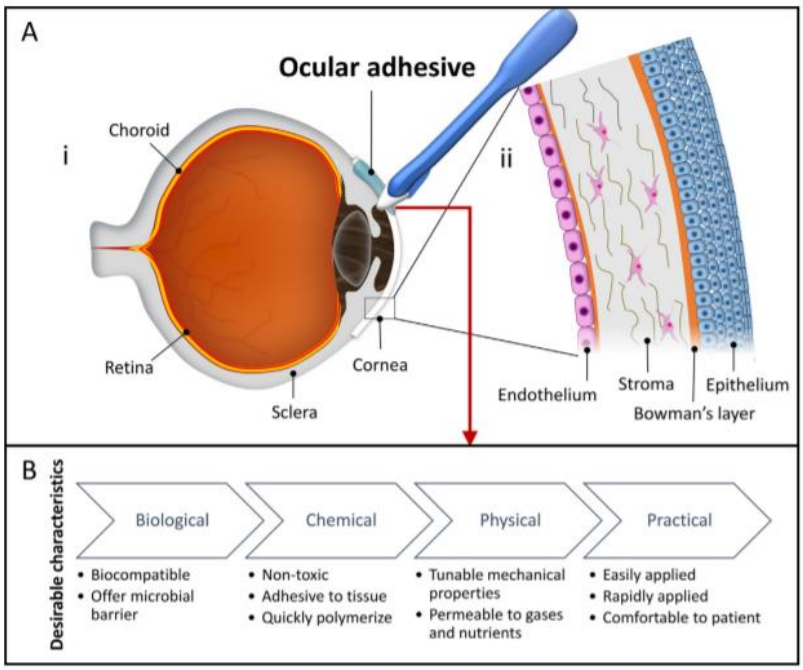


Fig. 1. Eye anatomy, cornea structure, and desirable characteristics of an ocular adhesive. (**A**) Anatomy of (i) eye and (ii) cornea. (**B**) Biological, chemical, physical, and practical characteristics that an ideal ocular adhesive should exhibit.

Scleral buckling materials for retinal detachment

Scleral buckling surgery is a common way to treat **retinal detachment**. It is a method of closing breaks and flattening the **retina**. A **scleral buckle** is a piece of silicone sponge, rubber, or semi-hard plastic that your eye doctor (ophthalmologist) places on the outside of the eye.

Scleral buckling is an ophthalmic surgical technique that has been successfully employed as a primary or adjuvant procedure to repair rhegmatogenous retinal detachments for over 60 years. In the past two decades, pneumatic retinopexy and vitrectomy have been added to the retina surgeons' reattachment armamentarium. Although considerable debate persists regarding the optimal form of treatment for many types of retinal detachments, scleral buckling is declining in popularity, particularly in regard to pseudophakic cases. Still, it remains a valuable procedure in many instances, and scleral buckling techniques should continue to be part of retina surgical education in the years ahead.

Scleral buckling surgery is a common way to treat retinal detachment. It is a method of closing breaks and flattening the retina.

A scleral buckle is a piece of silicone sponge, rubber, or semi-hard plastic that your eye doctor places on the outside of the eye .The material is sewn to the eye to keep it in place. The buckling element is usually left in place permanently.

The element pushes in, or "buckles," the sclera toward the middle of the eye. This buckling effect on the sclera relieves the pull (traction) on the retina, allowing the retinal tear to settle against the wall of the eye. The buckle effect may cover only the area behind the detachment, or it may encircle the eyeball like a ring.

By itself, the buckle does not prevent a retinal break from opening again. Usually extreme cold (cryopexy) or, less commonly, heat (diathermy) or light (laser photocoagulation) is used to scar the retina and hold it in place until a seal forms between the retina and the layer beneath it. The seal holds the layers of the eye together and keeps fluid from getting between them.

Other facts about the surgery

- The surgery takes place in an operating room, usually on an outpatient basis (you go home the same day).
- Local or general anesthesia may be used.
- Before the surgery, your eye doctor may patch both of your eyes and have you stay in bed to keep the detachment from spreading. Right before surgery, he or she

will use eyedrops to dilate your pupils and may trim your eyelashes to keep them out of the way.

- A first-time surgery usually lasts 1 to 2 hours. Repeat surgeries or more complex detachments may take longer.

Pathophysiology

retinal detachment occurs when the combination of factors that promote retinal detachment overwhelms the normal attachment forces. This is due to a combination of retinal breaks, vitreous changes inducing a retinal break and vitreoretinal traction, and intraocular fluid currents.

Retinal breaks are traditionally classified as holes, tears, or dialyses. Retinal holes are full-thickness retinal defects that are typically not associated with persistent vitreoretinal traction in their vicinity. They usually occur as a result of localized atrophic intraretinal abnormalities. Retinal tears are usually produced by an acute PVD due to excess vitreoretinal traction at sites of significant vitreoretinal adhesions. Vitreous traction usually persists at the edge of a tear, which promotes progression of the retinal detachment. Dialyses are circumferential retinal breaks that occur at the ora serrata. Although most are associated with blunt ocular trauma, dialyses can occur spontaneously.

Aging of the human vitreous (synchysis senilis) is characterized by liquefaction of the vitreous gel and progressively enlarging pools of fluid (lacunae) within the gel. These optically empty liquid spaces coalesce with aging. Extensive liquefaction within the vitreous cavity leads to a reduction in both the shock-absorbing capabilities and the stability of the gel. Posterior vitreous detachment (PVD) usually occurs as an acute event after liquefaction of the vitreous gel reaches a critical degree. The precipitating event is probably a break in the posterior cortical vitreous in the region of the macula.2 This is followed by the immediate passage of intravitreal fluid into the space between the cortical vitreous and retina. Characteristically, this rapid movement of fluid and the associated collapse of the remaining structure of the gel result in extensive separation of the vitreous gel and retina posterior to the vitreous base, especially in the superior quadrants. Partial PVDs usually progress rapidly (within days) to become complete, although they do not always separate from the entire posterior retina. Vitreoretinal traction has a number of causes, which range from simple action of gravitational force on the vitreous gel to prominent transvitreal fibrocellular membranes. Gravitational force is important and probably accounts for the high percentage of superior retinal tears (80%). However, rotational eye movements, which exert strong forces on all vitreoretinal adhesions, are probably more

important causes of ongoing vitreoretinal traction. When the eye rotates, the inertia of the detached vitreous gel causes it to lag behind the rotation of the eye wall and, therefore, the attached retina. The retina at the site of a vitreoretinal adhesion exerts force on the vitreous gel, which causes the adjacent vitreous to rotate. The vitreous gel, because of its inertia, exerts an equal and opposite force on the retina, which can cause a retinal break or separate the neural retina farther from the pigment epithelium if subretinal fluid is already present (Figure 2). When the rotational eye movement stops, the vitreous gel continues its internal movement and exerts vitreoretinal traction in the opposite direction.

Continuous flow of liquid vitreous through a retinal break into the subretinal space is necessary to maintain a rhegmatogenous retinal detachment, because subretinal fluid is absorbed continually from the subretinal space via the RPE. Trans-break flow is encouraged by vitreoretinal traction, which tends to elevate the retina from the RPE. Rotary eye movements cause liquid currents in the vitreous to push against the gel adjacent to the retinal break and to dissect beneath the edge of a retinal break into the subretinal space (Figure 2) Subsequent eye movements also have an inertia effect on the subretinal fluid that favors extension of the retinal detachment.

Management

Rhegmatogenous retinal detachment are indications for vitreoretinal surgery. The three major surgical methods are scleral buckling, vitrectomy, and pneumatic retinopexy (PR). Combinations of all three are frequently employed.

Surgery

Localized indentation of the sclera, choroid, and pigment epithelium beneath a retinal break alters the anatomical and physiological factors associated with the production of a retinal detachment. The fundamental goal of scleral buckling is the functional closure of all retinal breaks, so that normal physiological forces can maintain a permanent state of attachment. Drainage of subretinal fluid and scleral buckling will usually close the responsible break(s) immediately. In a non-drainage procedure, functional closure of retinal breaks can result from several beneficial effects of a scleral buckle, including (1) reduction of vitreoretinal traction by displacing the eye wall and retina centrally; (2) displacement of subretinal fluid away from the location of the retinal break and scleral buckle; (3) postoperative increase in the height of the scleral buckle; (4) approximation of the retinal break and adjacent vitreous gel; (5) increase in resistance to fluid flow through the retinal break, with consequent increase in the relative

reattachment forces; and (6) alteration in the concave shape of the eyeball, resulting in a change in the effect of intraocular currents that encourage liquid vitreous to enter the subretinal space. These effects are non-exclusive and are probably synergistic, and they are also important in drainage cases. Although contemporary scleral buckling procedures routinely include the creation of a chorioretinal burn with cryotherapy or laser to induce adhesion from reactive scaring, such an adhesion is not always necessary to maintain retinal reattachment.

Principles of scleral buckling

The most important skill required in surgery for retinal detachment is the ability to detect all retinal breaks and additional areas of vitreoretinal pathology. Scleral buckling is performed to produce functional closure of retinal breaks responsible for retinal detachment and to reduce the chances of recurrent detachment. Various kinds and shapes of silicone rubber elements are used, including segments of silicone sponge as well as solid silicone shaped into bands for encircling the eye and into additional forms to augment the width and height of the buckle in selected areas. The specific configuration of the scleral buckle depends upon a number of factors. Following localization and treatment of retinal breaks and areas of vitreoretinal degeneration, the silicone buckling element is secured to the scleral surface, usually with sutures or scleral tunnels. Drainage of subretinal fluid is often performed. Intravitreal gas or air injection is sometimes employed in conjunction with scleral buckling. Problems encountered at any point of the procedure may require modifications in technique, often leading to a vitrectomy surgery.

Scleral buckle configuration

The location, number, size, and types of retinal breaks are important variables affecting the selection of a specific buckling technique. Similarly, the presence of vitreoretinal degeneration, with or without retinal breaks, and of significant vitreoretinal traction unassociated with retinal breaks should be considered in the preoperative assessment. If retinal breaks, vitreoretinal degenerative disorders, and significant vitreoretinal traction are present in multiple quadrants, a circumferential buckle is usually favored. A single retinal break unassociated with additional significant problems may be managed with an isolated segmental buckle, if not with pneumatic retinopexy.

The anterior-posterior dimensions of retinal break(s) and areas of significant vitreoretinal degeneration and vitreoretinal traction are also important considerations in planning a buckling procedure. Scleral buckles should support all edges of the retinal breaks and associated areas of vitreoretinal degeneration. In general, the buckling effect should extend into the zone of the vitreous base to eliminate current and future traction forces.

The internal changes caused by scleral buckling are determined by the size, shape, and consistency of the buckling material, the width of the suture bites placed to attach the silicone rubber to the sclera, the tightness of the tied sutures, and the extent to which an encircling element is tightened. A "high" scleral buckle is associated with a significant displacement of intraocular volume. In order to avoid large increases in intraocular pressure, drainage of subretinal fluid, paracentesis, or removal of liquid vitreous is usually necessary, particularly in eyes with compromised aqueous outflows.