



Lecture 4
Non-Blood Interfacing Implant





1.0 Introduction

- Non-blood interfacing soft tissue implants are used to augment or replace natural soft tissues or to redirect specific biological function.
- Soft tissue in the body such as:
 - Connective tissues: skin, ligament, tendon, cartilage
 - Vascular tissue: blood vessel, heart valves
 - Organs: heart, pancreas, kidney
 - Other: eye, ear, breast



- Duration of implantation:
 - Short term function – made of absorbable materials.
 - Long term function – made of non-absorbable materials.



2.0 Requirement for soft tissue implant

- Exhibit physical properties (flexibility and texture) which are equivalent or comparable to those called for in the product profile.
- Maintain the expected physical properties after implantation for a specific period.
- Elicit no adverse tissue reaction
- Display no carcinogenic, toxic, allergenic, and or immunogenic effect
- Achieve assured sterility without compromising the physiochemical properties.



3.0 Sutures and Allied augmentation device

1. SUTURES

- Used to repair incision and laceration
- Suture material can be classified in various way:
 1. According to their origin
 - Natural or Man made
 2. According to their absorption ability
 - Absorbable or Non-absorbable
 3. According to their configuration
 - Monofilaments or Multifilament
 - Braided or twisted



Absorbable surgical sutures

NATURAL COLLAGEN			
Generic name	Trade name	Raw material	Description
Plain catgut		Sub mucosa sheep intestine	Have a life 3-7 days
Chromic catgut		Chromic salt treated serous of beef intestine	Enhance cross linking of collagen which increase life to 20-40days
Collagen E	Beef flexor tendon chromic collagen	Salt treated beef flexor tendon	

Absorbable SYNTHETICS sutures

Generic name	Trade name	Raw material	Description
Polyglycolic acid	Dexon S	Homopolymer of glycolic acid	Rough surface – tendency to harbour microorganism that can provoke inflammatory response maintain 50% of its tensile strength in the tissue for 25 days.
Polyglycolic acid	Dexon plus	Homopolymer of glycolic acid, coated with lubricant	
Polyglycolic acid	Dexon II	Homopolymer of glycolic acid, coated with polycaproate	
Polyglactin acid	Vicryl	Copolymer of lactide-glycolic acid coated with calcium stearate	Absorbed faster than Dexon, maintain 50% of its tensile strength in the tissue for 30 days. Rough surface – tendency to harbour microorganism that can provoke inflammatory response
Polydioxanone	PDS	Polymer of paradioxanone	Monofilament sutures, less affinity for bacteria Quit stiff and difficult to ties
Polydioxanone	PDS 2	Modified PDS	
Polyglyconate acid	Maxon	Copolymer of trimethylene methylene carbonate and polyglycolic	Monofilament sutures, Preferable than PDS due to its easy knot formation and atraumatic passage through tissues. 8



Non-absorbable sutures

NATURAL FIBERS			
Generic name	Trade name	Fiber properties	Description
Cotton	-	Twisted natural cotton	-
Linen	-	Twisted long-staple flax	-
Silk	-	Natural silk fibers spun by silkworms twisted, untreated	Good workability with knot security Swells on implantation, results in painful and difficult suture removal process

NON – ABSORBABLE SYNTHETIC FIBERS SUTURES

Generic name	Trade name	Fiber properties	Description
Nylon	Dermalon, ethilon	Polyamide 6,6- monofil	High tensile strength Too stiff – possibility of cutting tissue and knot loosening
Polypropylene	Prolene	Monofilament	Posses high tensile strength Best resistance to infection Smooth
Polyester	Dacron Mersilene	PET monofilament PET braided	Very similar to silk in workability & knot security Less tissue reactivity Higher tensile strenght than silk Rough surface -coated
Metal sutures		Monofilament, twisted or braided	
Stainless steel suture wire			Used in orthopaedic, thoracic surgery, nerve ending clipping



Allied augmentation device

- Surgical tape
 - Avoiding minimize necrosis, scar tissue formation
- Staple
 - Made of metal such as titanium
 - Facilitate closure of large surgical incision produced in procedures such as Caesarean



4.0 Tissue adhesive

- Used for repair of fragile, non-suturable tissues
 - Liver, kidney, lung
- Important criteria of tissue adhesive:
 1. Be able to wet and bond to tissue
 2. Be capable of onsite formation by the rapid polymerization of a liquid monomer without producing excessive heat or toxic by products
 3. Absorbable
 4. not interfere with the normal healing process
 5. Easily applied during surgery.



4.0 Tissue adhesive

- Two common type tissue adhesive currently be used are based on:
 - Alkyl-o-cyanoacrylates
 - Low strength
 - Limited to use in traumatized fragile tissue (such as spleen, liver and kidney)
 - Fibrin
 - Derived from fibrinogen-clotting component of blood
 - Limited mechanical strength
 - Used mostly as sealant and for joining delicate tissue as in nerve anastomoses

Tissue adhesive





5.0 Percutaneous Implants

- Refers to implants that cross the skin barrier
 - In contact with both the outside environment and the biological environment
- Used for connection of the vascular system to external 'organs'
 - Dialysis
 - Artificial Heart
 - Cardiac bypass



5.0 Percutaneous Implants

- Also used for long term delivery of medication or nutrition
- Ideal percutaneous implant should:
 - Form a tight seal with a tissues such that it resist mechanical motion and moderate manipulations from outside.



5.0 Percutaneous Implants

- Main problems
 - Attachment of skin (dermis) to implant cannot be maintained for a sustained time since the dermal tissue cells turn over continuously
 - Implant can be extruded or invaginated due to growth of skin around the implant
 - Any opening can also allow the entrance of bacteria, which may lead to infection



5.0 Percutaneous Implants

- Materials:
 - Hydroxyapatite based
 - Have less extrusion problems than silicone rubber implant



6.0 Artificial skin

- One type of percutaneous implant – contact both external and biological environment
- Goals:
 - Adhere to large burned surfaces
 - Prevent loss of fluids, electrolytes and molecules
 - Prevent infection



6.0 Artificial skin

- The first synthetic skin was invented by John F. Burke, chief of Trauma Services at Massachusetts General Hospital in Boston, and Ioannis V. Yannas, chemistry professor at Massachusetts Institute of Technology in Cambridge.
- It contained polymers from shark cartilage and collagen from cowhide.



- When somebody has more than 50% burn injuries, could not survive without transplantation of skin.
- It was mostly take from animals or cadavers. But there were problems with acceptance and infection.
- This problem solve by using artificial skin



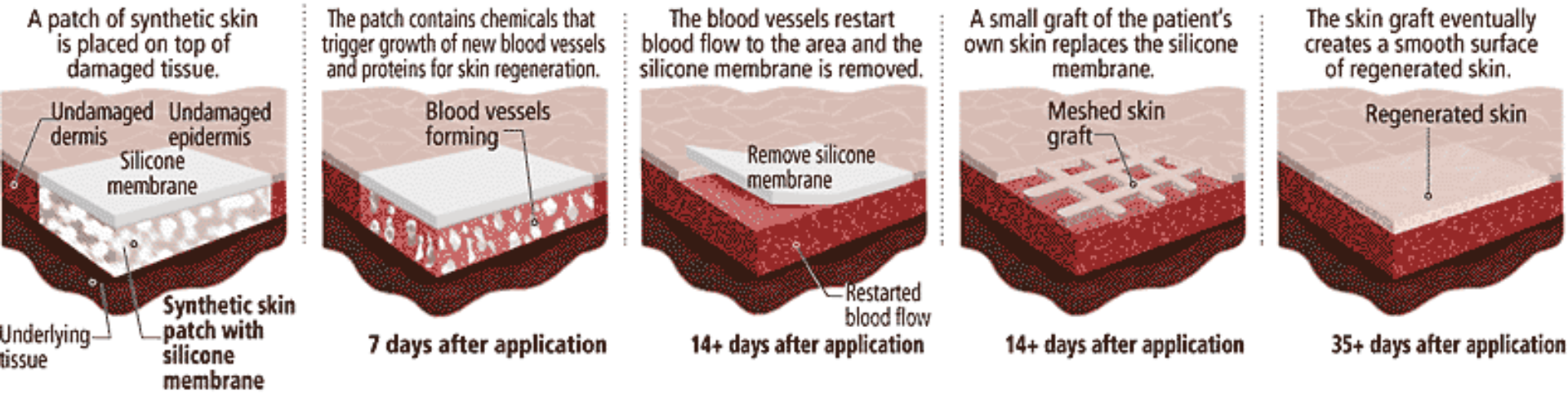
6.0 Artificial skin

- Design ideas:
 - Graft should be flexible enough to conform to wound bed and move with body
 - Should not retain so much moisture so that edema (fluid accumulation) would not develop under the graft



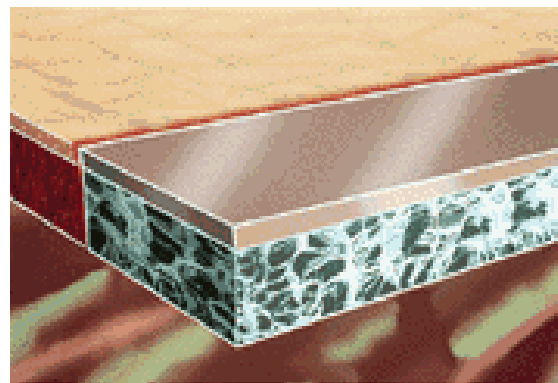
6.0 Artificial skin

The healing process of synthetic skin



Source: Integra LifeSciences Corporation

WENDY WAHMAN/SEATTLE POST-INTELLIGENCER





6.0 Artificial skin

- Possible material used:
 - Polymeric or collagen based membrane.
 - Some are too brittle and toxic for use in burn victims
 - Flexibility, moisture flux rate and porosity can be controlled
 - Culturing cells in vitro from the skin of burn patient for covering the wound
 - Does not require removal of significant portions of skin



7.0 Maxillofacial Implant

- Two types of maxillofacial implants
 1. Extraoral
 2. Intraoral
- Designed to replace or enhance hard or soft tissue in the maxilla, mandible and face



7.0 Maxillofacial Implant

1. Extraoral Implant
 - Material used: Polymers such as
 - Copolymers of vinyl chloride and vinyl acetate
 - PMMA
 - Silicones
 - Polyurethane rubbers



7.0 Maxillofacial Implant

- Extra oral material requirement:
 1. Match the patients skin in colour and texture
 2. Be chemically and mechanically stable
 3. Not creep, change colours or irritate skin
 4. Be easily fabricated



7.0 Maxillofacial Implant

2. Intraoral implants
 - Used for repairing maxilla, mandibular and facial bone defects
 - Material used:
 - Bone defect:
 - Tantalum
 - Titanium
 - Co-Cr alloys
 - Soft tissue (gum, chin)
 - Silicone rubber
 - PMMA



8.0 Eye Implants

- Currently used for two general applications
 - Cosmetic restoration
 - Restoration of function

8.1 Contact lenses

- A **contact lens** is a corrective, cosmetic, or therapeutic lens usually placed on the cornea of the eye.



Type of contact lenses

- Contact lenses are classified in many different manners:
 - **Function:**
 - Corrective contact lenses : designed to improve vision
 - Cosmetic contact lenses : designed to change the appearance of the eye.
 - Therapeutic contact lenses
 - Soft lenses are often used in the treatment and management of non-refractive disorders of the eye.
 - A bandage contact lens protects an injured or diseased cornea from the constant rubbing of blinking eyelids thereby allowing it to heal.
 - They are used in the treatment of conditions including , dry eyes, corneal ulcers and erosion,
 - Contact lenses that deliver drugs to the eye have also been developed



8.0 Eye Implants

■ By constructional material

- Glass: caused eye irritation, and were not wearable for extended periods of time.
- PMMA:
 - These PMMA lenses are commonly referred to as "hard" lenses.
 - Drawbacks:
 - No oxygen is transmitted through the lens to the cornea, which can cause a number of adverse clinical events.



8.0 Eye Implants

- Soft lenses:
 - Comfortable
 - Increased oxygen permeability
 - Silicone hydrogel
 - high oxygen permeability
 - the lenses more hydrophilic



8.0 Eye Implants

■ **By wear time**

- A *daily wear* contact lens is designed to be removed prior to sleeping.
- An *extended wear* (EW) contact lens is designed for continuous overnight wear, typically for 6 or more consecutive nights.
- Newer materials, such as silicone hydrogels, allow for even longer wear periods of up to 30 consecutive nights; these longer-wear lenses are often referred to as *continuous wear* (CW).
- Generally, extended wear lenses are discarded after the specified length of time.



8.0 Eye Implants

■ **By frequency of replacement**

- The various soft contact lenses available are often categorized by their replacement schedule.
- The shortest replacement schedule is single use (daily disposable) lenses, which are disposed of each night.
- These may be best for patients with ocular allergies or other conditions, because it limits deposits of antigens and protein.
- Single use lenses are also useful for people who use contacts infrequently, or for purposes (e.g. swimming or other sporting activities) where losing a lens is likely.



8.0 Eye Implants

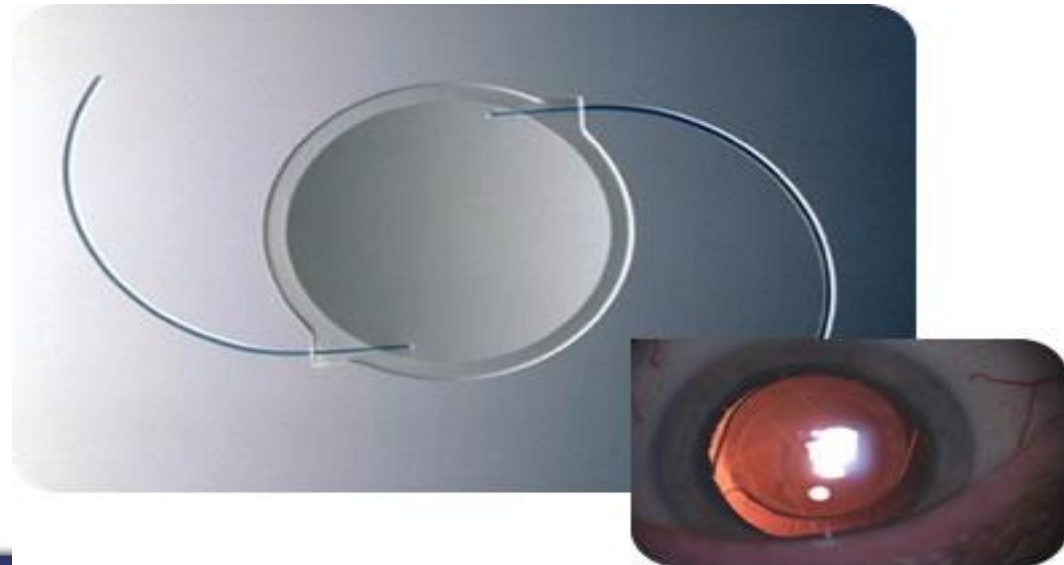
8.2 Intraocular lenses (IOL)

- Are implanted surgically to replace the original eye lens to restore function.
- In cataract, eye lenses become cloudy and need to be removed surgically.

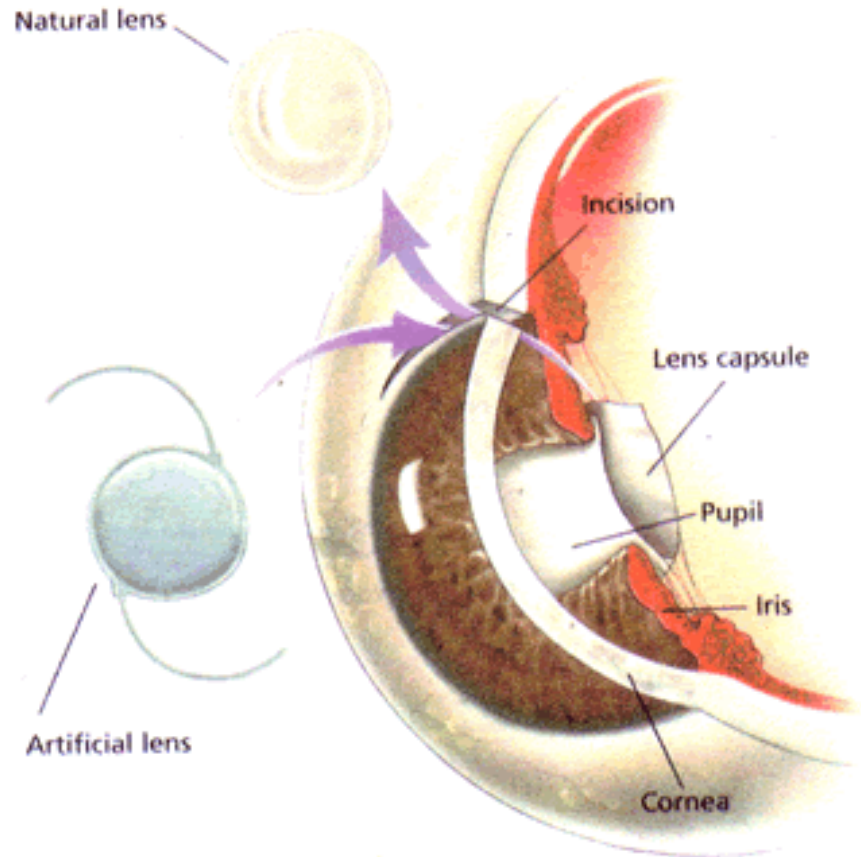
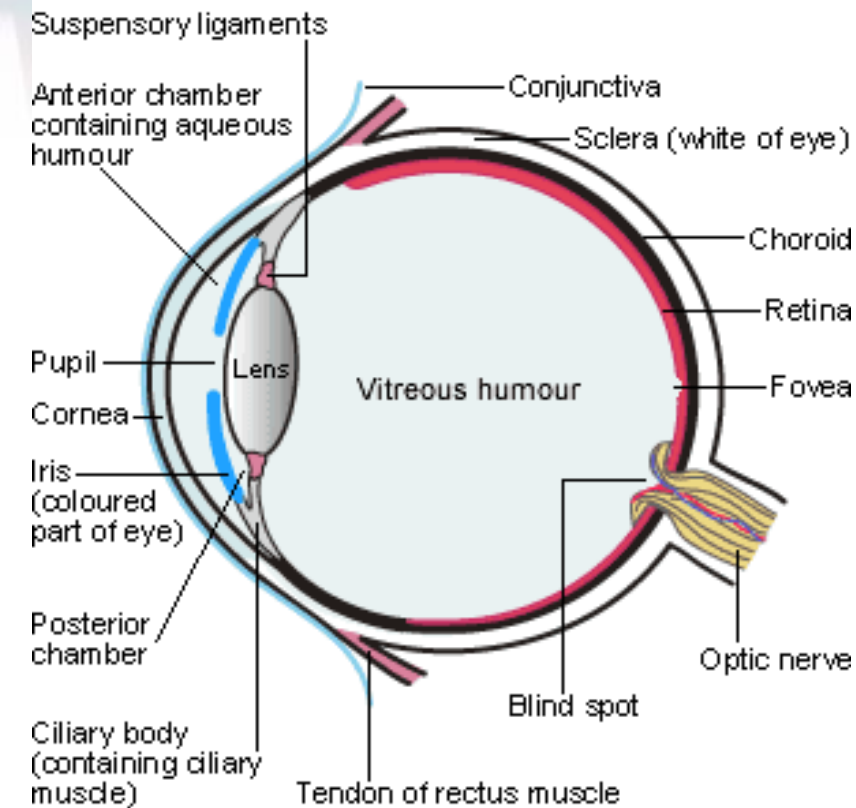


8.0 Eye Implants

- Material used:
 - Transparent acrylics-PMMA
 - soft foldable inert materials
 - The lens able to be folded and inserted into the eye through a smaller incision.



8.0 Eye Implants





9.0 Cochlear implant

■ What is a cochlear implant?

- A cochlear implant is an implanted electronic hearing device, designed to produce useful hearing sensations to a person with severe to profound nerve deafness by electrically stimulating nerves inside the inner ear.



9.0 Cochlear implant

- These implants usually consist of 2 main components:
 - The externally worn microphone, sound processor and transmitter system.
 - The implanted receiver and electrode system, which contains the electronic circuits that receive signals from the external system and send electrical currents to the inner ear.
- Currently made devices have a magnet that holds the external system in place next to the implanted internal system.
- The external system may be worn entirely behind the ear or its parts may be worn in a pocket, belt pouch, or harness (tie together).



9.0 Cochlear implant

■ Who uses cochlear implants

- Cochlear implants are designed to help severely to profoundly (deeply) deaf adults and children who get little or no benefit from hearing aids.
- Even individuals with severe or profound "nerve deafness" may be able to benefit from cochlear implants



9.0 Cochlear implant

- **How does a cochlear implant work?**
 - A cochlear implant receives sound from the outside environment, processes it, and sends small electric currents near the auditory nerve.
 - These electric currents activate the nerve, which then sends a signal to the brain. The brain learns to recognize this signal and the person experiences this as "hearing".
 - The cochlear implant somewhat simulates natural hearing, where sound creates an electric current that stimulates the auditory nerve. However, the result is not the same as normal hearing.



10.0 Breast implant

- A **breast implant** is a prosthesis used to enlarge the size of a woman's breasts for cosmetic reasons or to reconstruct the breast (e.g. after a [mastectomy](#); or to correct genetic deformities),



10.0 Breast implant

- Enlargement of breast with used materials such as:
 - Paraffin wax
 - Silicone fluid
 - By direct injection or by enclosure in a rubber ballon
- Problems with direct inject:
 - Progressive instability
 - Loss of original shape and texture
 - Infection and pain



10.0 Breast implant

- Use of sponge made of polyvinyl alcohol material failed due to ingrowth of tissue into pores, calcified with time
 - Resulted in marble breast syndrome
- Tissue engineered breast
 - fat or normal breast tissue derived from patient.
- Silicone balloon filled with silicone gel or saline and fixed to underlying tissue
 - Tissue ingrowth into a polymer mesh that applied on the posterior surface.