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Medical Textiles: Application of Implantable Medical Textiles

Shah Md. Maruf Hasan [α], Md. Shahjalal [σ], Jaglul Hoque Mridha [ρ] & A. M. Riasat Alam [ω]

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I. Introduction

Medical textiles are also known as Healthcare Textiles. The medical textile industry has diversified with new materials and innovative designs. Evolving polymer technology has yielded a wide range of applications of implantable medical textile devices. The Medical textile products are obtainable in woven, knitted and non- woven structure based on the area of application. Increasingly, synthetic fibre is being utilized in the manufacturing of these products.

Medical Textiles are defined in various ways, according to David Rigby Associates.

"The Medical Textile or Medtech application area "embraces all those technical textiles used in health and hygiene products"

"Textile Terms & Definitions" defines Medical Textiles as - "A general term which describes a textile structure which has been designed and produced for use in any of a variety of medical applications, including implantable applications."

II. Classification of Medical Textiles

a) Non-implantable materials

These materials use in external application on the body and may or may not make contact with the skin.

b) Implantable materials

These materials used in effecting a repair to the body whether it be wound closure (sutures) or replacement surgery (vascular grafts, artificial ligaments, artificial cartilage, etc.).

c) Extracorporeal devices

These are extra corporeally mounted devices used to support the function of vital organs, such as kidney, liver, lung, heart pacer, etc. The extracorporeal devices are mechanical organs that are used for blood purification and include the artificial kidney (dialyzer), the artificial liver, and the mechanical lung. The function and performance of these devices benefit from fiber and textile technology.

d) Healthcare/hygiene products

Healthcare and hygiene products are a rising sector in the field of medicine and surgery. The range of products available is vast, but typically they are used either in the operating theatre or on the hospital ward for the hygiene, care, and safety of staff and patients.

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Table 1: Medical textile products, raw materials and function.

	Product Name		Fiber type	Fabric type	Function
Implantable Materials	Sutures	Biodegradable	Collagen, Lacticide, Polyglycolide	Monofilament, braided	used tohold body tissues together after an injury or surgery
		Nonbiodegradable	Polyamide, Polyester, PTFE, Polypropylene, Silk	Monofilament, polyglycolide braided	Used to hold body tissues together after an injury or surgery
	Soft Tissue Implants	Artificial tendon	PTFE, polyester, polyamide, silk, polyethylene	Woven, braided	Used in Achilles tendon repair with studies on equine subjects.
		Artificial ligament	Polyester, carbon	Braided Nonwoven	An artificial ligament is a reinforcing material that is used to replace a torn ligament
		Artificial cartilage	Low-density polyethylene		To mimic the functional properties of natural cartilage in the human body.
		Artificial skin	Chitin		
		Artificial cornea	Polymethyl methacrylate, corneasilicone, collagen		The device is a huge step forward for people with corneal blindness who have rejected human tissue.
	Orthopedic implants	Artificial bones/joints	Silicone, polyacetal, Polyethylene		used in bone grafts
	Cardiovascular implants	Vascular grafts	Polyester, PTFE	Knitted, woven	Used to make a path to flow blood one area to another
		Heart valves	Polyester	Woven, knitted	Implanted in the heart of a patient with the valvular heart disease.
	Wound care	Absorbent Pad	Cotton, Viscose	Nonwoven	The functions of these materials are to provide protection against infection, absorb blood and exudate, promote healing
Non- implantable Materials		Wound contact layer	Silk, polyamide, viscose, Polyethylene	Knitted, woven, nonwoven	
	Bandages	Simple inelastic/elastic	Cotton, viscose, elastomeric yarns	polyamide, Woven, knitted, nonwoven	To hold Dressings in place over wounds.
		Light support	Cotton, viscose, elastomeric	Woven, knitted, nonwoven yarns	
		Compression	Cotton, polyamide, elastomeric yarns	Woven, knitted	
		Orthopadic	Cotton, viscose, polyester polypropylene, polyurethane foam	Woven, nonwoven	
	Plasters		Viscose, plastic film, cotton polyester, glass, polypropylene	,Knitted, woven, nonwoven	Protects the wound and scab from friction, bacteria, damage, and dirt.
	Gauzes		Cotton, viscose	Woven, nonwoven	It is especially useful for dressing wounds where other fabrics might stick to the burn or laceration
	Lint		Cotton	Woven	
	Wadding		Viscose, cotton linters, wood pulp	Nonwoven	
Extracorporeal devices	Artificial kidney		Hollow viscose, hollow		Remove waste products from patients polyester
	Artificial Liver		Hollow viscose		Separate and dispose of patients plasma, and supply fresh plasma
	Mechanical lung		Hollow polypropylene,		Remove carbon dioxide from patients hollow silicone, and supply fresh blood membrane
	Surgical clothing	Gowns	Cotton, polyester, Polypropylene	Nonwoven, woven	
		Caps	Viscose	Nonwoven	
		Masks	Viscose, polyester, glass	Nonwoven	
	Surgical covers	Drapes	Polyester, polyethylene	Nonwoven, woven	
		Cloths	Polyester, polyethylene	Nonwoven, woven	
	Bedding	Blankets	Cotton, polyester	Woven, knitted	
		Sheets	Cotton	Woven	
		Pillowcases	Cotton	Woven	
Healthcare/hygiene products	Clothing	Uniforms	Cotton, polyester	Woven	
		Protective Clothing	Polyester, polypropylene	Nonwoven	
	Incontinence diaper/sheet	Cover stock	Polyester, polypropylene	Nonwoven	
		Absorbent layer	Wood fluff Superabsorbent	Nonwoven	

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III. Surgical Suture

Surgical suture is a medical device used to hold body tissues together after injury or surgery. The application generally involves using a needle with a defined length of thread. Biocompatibility is of prime importance if the textile materials are to be accepted by the body and following four key factors will determine how the body reacts to the implants.

These are as follows:

1) The most essential factor is porosity which determines the rate at which human tissue will grow and encapsulate the implant.
2) Small circular fibers attach with human tissue better than larger fibers with irregular cross sections.
3) Toxic substances must not realease, and the fiber should be free from surface contamination like lubricants and sizing agents.
4) The property will influence the success of the implantation in terms of its biodegradability.

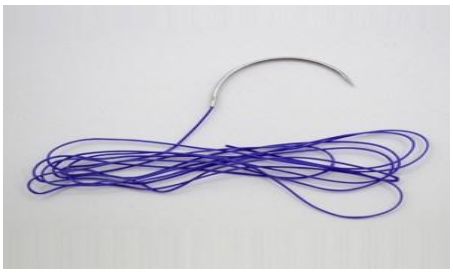


Figure 1: Surgical suture

a) Types of Sutures

There are different types of sutures.

First, Suture materials are either absorbable or nonabsorbable.

Absorbable sutures don't require to remove from body. This is because enzymes found in the tissues of the body naturally digest them.

Nonabsorbable sutures will need to be removed by your doctor at a later date or in some cases left in permanently.

Second, we can classify suture according to the actual structure of the suture material. Such as monofilament suture and braided suture. Monofilament sutures consist of a single thread. This allows the suture to pass through tissues easily. Braided sutures consist of several small threads braided together. This can lead to better security, but at the cost of the increased potential for infection.

Third, we can also classify sutures as either being made from natural or synthetic material.

b) Types of absorbable sutures

- *Gut:* This natural monofilament suture uses for repairing internal soft tissue wounds or lacerations. It shouldn't use for cardiovascular or neurological procedures. The body has the strongest reaction to this suture and will often scar over. It does not commonly use outside of gynecological surgery.
- *Polydioxanone (PDS):* This synthetic monofilament suture can use for many types of soft tissue wound repair (such as abdominal closures) as well as for pediatric cardiac procedures.
- *Poliglecaprone (MONOCRYL):* This synthetic monofilament suture uses for general use in soft tissue repair. This material shouldn't be used for cardiovascular or neurological procedures.
- *Polyglactin (Vicryl):* This synthetic braided suture is to repair hand or facial lacerations. It shouldn't be used for cardiovascular or neurological procedures.

c) Types of nonabsorbable sutures

Some examples of nonabsorbable sutures can be found below. These type uses generally for soft tissue repair, including for both cardiovascular and neurological procedures.

- *Nylon:* A natural monofilament suture.
- *Polypropylene (Prolene):* A synthetic monofilament suture.
- *Silk:* A natural braided suture.
- *Polyester (Ethibond):* A braided synthetic suture.

d) Suture Selection and Techniques

There are many different suture techniques. Some of them are:

i. *Continuous sutures*

This technique involves a series of stitches that use a single strand of suture material. This type can place rapidly and is also strong since tension is distributed evenly throughout the continuous suture strand.

ii. *Interrupted sutures*

This suture technique uses several strands of suture material to close the wound. This technique leads to a securely closed wound. If one of the stitches breaks, the remainder of the stitches will still hold the wound together.

iii. *Deep sutures*

This type places under the layers of tissue below (deep) to the skin. They may either be continuous or interrupted. This stitch is often used to close fascial layers.

iv. *Buried sutures*

This type is applied so that the suture can find inside this type of suture is typically not removed and is useful when large sutures use deeper in the body.

v. *Purse-string sutures*

This types places around an area and tightened much like the drawstring on a bag. For example, this type use in our intestines to secure an intestinal stapling device.

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vi. *Subcutaneous sutures*

This type places in our dermis, the layer of tissue that lies below the upper layer of our skin. Short stitches place in a line that is parallel to our wound.

e) Raw Materials

Natural sutures are made of catgut or reconstituted collagen, or from cotton, silk, or linen. Polyglycolic acid, a glycolide-lactide copolymer; or polydioxanone, a copolymer of glycolide and trimethylene carbonate may make synthetic absorbable sutures. Polypropylene, polyester, polyethylene terephthalate, polybutylene terephthalate, polyamide, nylons or Goretex are the raw materials of synthetic nonabsorbable sutures. S stainless steel is the raw materials of some special types of suture.

f) The Manufacturing Process

The manufacturing of sutures for surgical use is not very different from the production.

Preparation of raw polymer- Raw polymers are combined (polymerized), forced through a die and discharged as tinny pellets.

Forming individual filaments by extruder machine -The machine melts the polymer, and the liquid flows through the tiny spinneret (looking something like a shower head) forming many individual filaments.

Drawing of filaments- After extrusion, these are stretching between two rollers. It increases five times their original length.

Manufacturing of sutures- Some sutures are producing as monofilaments. Others are braided or twisted. The monofilament is winding onto bobbins, and the bobbins keep onto an automatic braiding machine.

Secondary Processing-After braiding, the suture undergoes several stages of secondary processing. Non-braided type will also go through these steps after extrusion and initial stretching. This step might take only a few minutes. The suture passes over a hot plate, and any lumps, snags, or imperfections are ironed out.

Annealing- The annealing oven subjects the suture to high heat and tension, which orders the crystalline structure of the polymer fiber into proper shape.

Coating- Absorbable coatings include Poloxamer 188 and calcium stearate with a glycolide-lactide copolymer. Nonabsorbable coating include wax, silicone, fluorocarbon.

Surgical needle preparation- The surgical needles are made at another plant, and also shipped to the finishing plant. The needles are made of fine steel wire and drilled lengthwise

Quality control-This step the suture conforms to the proper diameter, length, and strength, look for physical defects and check the dissolvability of an absorbable suture in animal and test-tube tests.

Sterilization- Next, the suture and attached needle are inserted into a foil packet and sterilized. Sterilization differs according to the suture material.

g) Suture removal

When sutures remove will depend on where they are on your body. According to American Family Physician, some general guidelines are as follows:

- Scalp: 7 to 10 days
- Face: 3 to 5 days
- Chest or trunk: 10 to 14 days
- Arms: 7 to 10 days
- Legs: 10 to 14 days
- Hands or feet: 10 to 14 days
- Palms of hands or soles of feet: 14 to 21 days

To remove sutures, the doctor will first sterilize the area. They'll pick up one end of your suture and cut it, trying to stay as close to the skin as possible. Then, they'll gently pull out the suture strand.

IV. Artificial Skin

When the skin has been damaged through disease or burns the body cannot act fast enough to manufacture the necessary replacement cells. Wounds like skin ulcers, suffered by diabetes, may not heal, and limbs must be amputated. Burn victims may die from infection and the loss of plasma.

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Artificial skin- is a collagen scaffold that induces regeneration of the skin in mammals such as humans.

The skin is the largest organ in the human body. It is made up of three layers the epidermis, dermis, and hypodermis (fat layer). The epidermis is the outer layer of skin that keeps vital fluids in and harmful bacteria out of the body. The dermis is the inner layer of skin that contains blood vessels, nerves, hair, follicles, oil, and sweet glands. Severe damage to large areas of skin exposes the human organism to dehydration and infections that can result in death.

Traditional ways to dealing with losses of the skin grafts from the patient (autografts) an unrelated donor cadaver. The former approach has the disadvantage that there may not be enough skin available, while the latter suffers from the possibility of rejection or injection until the late twentieth century skin grafts constructed from the patient skin. This method created a problem when the skin had been damaged extensively, making it impossible to treat severely injured patients entirely with outgrafts.



Figure 2: Artificial skin

a) Raw Materials

The raw materials needed for the production of artificial skin falls into two categories, those are biological components and necessary laboratory equipment. Most of the donated tissues come from neonatal foreskins removed during circumcision. One foreskin can yield enough cells to make four acres of grafting material. Manufacturer separates fibroblasts from the dermal layer of the donated tissue. Then he testes fibroblasts for viruses and other hazardous pathogens such as HIV, hepatitis B and C, and mycoplasma. The mother's medical history is recorded. The fibroblasts require to store in glass vials and frozen in liquid nitrogen at -94°F (-70°C). It should keep frozen until the fibroblasts needs to grow cultures. In the collagen method, keratinocytes are also extracted from the foreskin, tested and frozen. To grow fibroblasts on mess scaffolding need polymer in combination of molecules of lactic acid; the same elements used to make dissolving sutures. The compound undergoes a chemical reaction resulting in a larger molecule that consists of repeating structural units.

In the collagen method, a small amount of bovine collagen needs to extract from the extensor tendon of young calves. The collagen is mixed with an acidic nutrient, and stored in a refrigerator at 39.2° F (4°C).

Laboratory equipment includes glass vials, roller bottles, grafting cartridges, molds, and freezers.

b) The Manufacturing Process

The manufacturing process is deceptively simple. Its function is to trick the extracted fibroblasts into believing that they are in the human body so that they can communicate with each other in the natural way to create new skin.

i. *Mesh scaffolding method*

- In this process the manufacturer thaw and expand fibroblast. The fibroblasts need to transfer from the vials into roller bottles, which resemble liter soda bottles. Then the bottles keep their sides for three to four weeks for rotting. The rolling action allows the circulation of oxygen, essential to the growth process.
- Cells should transfer to a culture system. The cells are removed from the roller bottles, combined with a nutrient-rich media, flowed through tubes into thin, cassette-like bioreactors housing the biodegradable mess scaffolding, and sterilized with beam radiation. As the cells flow into cassettes, they adhere to the mesh and begin to grow. The cells flow back and forth for three to four weeks. Leftover suspension should remove each day as well as fresh nutrient should add. Oxygen, p^H, nutrient flow, and temperature are controlled, and temperature must control by the culture system. As the new cells create a layer of dermal skin, the polymer disintegrates.
- Growth cycle completed. When cell growth on the mesh completed, the tissue rinsed with more nutrient-rich media. Add cryoprotectant to the media. Finally cassettes store individually with label and frozen.

ii. *Collagen method*

- Cells are transferred to a culture system. A small amount of the cold collagen and nutrient media approximately 12% of the combined solution is added to fibroblasts. The mixture turns into molds and allotted to come to room temperature. As the collagen warms, its gels, trapping the fibroblasts and generating the growth of new skin cells.
- Keratinocytes added. Two weeks after the collagen added to the fibroblasts the extracted keratinocytes are thawed and seeded onto the new dermal skin. They are allowed to grow for several days and then exposed to air, including the keratinocytes to form epidermal layers.
- Growth cycle completed. The new skin is stored in sterile containers until needed.

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V. Artificial Cartilage

Artificial cartilage is a synthetic material made of hydrogels or polymers that aims to mimic the functional properties of natural cartilage in the human body. Tissue engineering principles use to create non-degradable and bio-compatible material that can replace cartilage while creating a useful synthetic cartilage material; certain challenges need to overcome. First cartilage is an avascular structure in the body, and therefore does not repair itself. This creates issues in the regeneration of the tissue. Artificial cartilage also needs to be stably attached to its underlying surface, bone lastly in the case of creating synthetic cartilage to be used in joint spaces, high mechanical strength under compression needs to be an intrinsic property of the material.

a) Components

Water (almost 80%), Chondrocytes, Collagen, Proteoglycans, Glycoproteins. Most of the synthetic cartilages are Kevlar based, or Poly Vinyl Alcohol (PVA) based.

1) *Water*- Water makes up 80% of cartilage.
2) *Chondrocytes*- Chondrocytes are the cells that produce and maintain the cartilaginous matrix. They are separately dispersed throughout cartilage and only make up 2% of the total volume of cartilage. Chondrocytes vary in size, shape, and concentration depending on their location in articular cartilage.
3) *Collagen*- Collagen is a structural protein present in the extra cellular matrix (ECM) of cartilage. Collagen is composed of a triple helix structure of polypeptide chains and offers shear and tensile properties to the cartilage ECM.
4) *Proteoglycans*- Proteoglycans are the second most abundant macromolecule ECM of cartilage. Proteoglycans consist of a linker protein along with a core protein to which glycosaminoglycans (GAGs) attach. The most common GAGs are chondroitin sulfate and keratin sulfate. Proteoglycans attach to a control chain usually hyaluronic acid, via a linker protein to create larger proteoglycan aggregates. Proteoglycans are hydrophilic and therefore attract and restrain water molecules. This provides cartilage with its intrinsic ability to resist compression.
5) *Glycoproteins*- Many other glycoproteins are present in cartilage ECM in small amounts that help maintain structure and organization. Specially-lubricin helps to create a lubricating surface on the cartilage for joint mobility. Fibronectin and integrin other glycoproteins present that help in adhesion of chondrocytes to the ECM.

b) Structure

There are structural tree zones in articular cartilage including superficial tangential zone, a transitional zone, a middle transitional zone, and a deep zone. In the transitional zone, collagen fibers are aligned parallel to the surface and become gradually randomly aligned while moving into a deep area. Collagen fibers in the suitable region are aligned parallel to the surface to restrict shear stresses. Similarly, collagen fibers are aligned perpendicular to the surface in the deep zone to restrict compressive forces. Between bone and deep zone lies calcified cartilage. Cell arrangement also varies between the zones in deeper zones chondrocytes are stacked into columns while in the superficial zones they are arranged randomly. In the superficial regions, the cells are also more entangled, while in deeper zones they are more spherical.



Figure 3: Artificial cartilage

Many people with joint injuries would benefit from a replacement for cartilage.

Articular cartilage has a characteristic shock absorbing effect attribute to its viscoelastic properties.

c) Synthetic cartilage

i. *PVA*

We use Poly (vinyl alcohol) (PVA) hydrogels in this study. It was difficult to meet the mechanical properties of articular cartilage using this hydrogel. There were no inflammatory or degenerative changes in articular cartilage or synovial membrane surround this artificial PVA cartilage. PVP hydrogels were also studied. They exhibit high hydrophilicity, biocompatibility, and complexing ability. When used as a blend of PVA/PVP hydrogel, they produced similar internal 3D structure and water content as natural articular cartilage. The best mechanical properties and friction system were blended hydrogel with one wt % PVP. Due to the inter-chain hydrogen bonding, adding PVP to the pure PVA proved a better option. They acted with a characteristic viscoelastic behavior of articular cartilage. [9]

ii. *Kevlar based*

The new Kevlar-based hydrogel recreates the magic of cartilage by combining a network of tough nanofibers from Kevlar—the "aramid" fibers best known for making bulletproof vests—with a material commonly used in hydrogel cartilage replacements, called polyvinyl alcohol, or PVA.

In natural cartilage, the network of proteins and other biomolecules gets its strength by resisting the flow

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of water among its chambers. The pressure from the water reconfigures the network, enabling it to deform without breaking. Water is released in the process, and the network recovers by absorbing water later.

VI. Artificial Ligament

Ligament is a short band of tough, flexible fibrous connective tissue which connects two bones or cartilages or holds together a joint. It is also known as articular ligament. Ligaments are generally subject to a lot of wear and tear and also carry the risk of septic arthritis. The usage of the ligament varies based on the type of operation. Ligaments are nowadays replaced artificial means through surgery. Artificial ligaments are formed by polyester, silk, Poly Tetra Fluoroethylene (PTFE). Polyethylene terephthalate- (PET-) based artificial ligaments (PET- ALs) are commonly available in anterior cruciate ligament (ACL) reconstruction surgery.

An artificial ligament is a medical device made up of textile fibers and used for joining ends of bones the requirement of a prosthetic ligament are:

- Extensive tough but have just the right stiffness to match the compliance of a ACL.
- It must have the durability to withstand high tensile loads for millions of cycles without wear.
- And it must be perfectly tolerable to the hos.

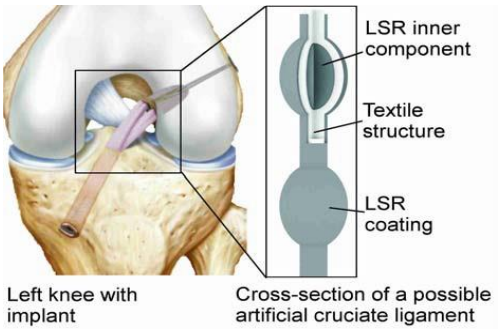


Figure 4: Artificial Ligament

There are various types of artificial ligaments in the market. The most prominent are:

a) Carbon fiber prosthetic

This type of ligament is available with carbon fiber coated with collagen, and an absorbable polymer such as polylactic acid (PLA) and polycaprolactone is a biodegradable polyester with a low melting point of around 60°C. The PLA is meant to resorb and the carbon fibers degraded as a new tissue developed encouraging tissue generation without permanently replacing it.

b) Gore-tex permanent prosthesis

The Goretex ligament prosthesis is composed of a long fiber of expanded polytetrafluoroehylene (PTFE). The ultimate strength is about three times that of human ACL and the result from cyclical creep tests and the bending fatigue testing seem to identify Gore-tex as the strong synthetic ACL replacement in terms of pure materials stability.

c) Dacron

This implant is a composite of four tightly woven polyester strips wrapped in a sheath of loosely woven structure designed to minimize abrasion of the graft and act as a scaffold for fibrous tissue in growth.

d) LEEDS-KEIO artificial ligament (Supplementary)

With the design to design a graft that combined the properties of a permanent prosthesis and a tissue-promoting scaffold, Fujikawa and seldom developed the Leeds-Keio artificial ligament a polyester mesh-like structure anchored to the femur and a tibia with a bone plugs. This mesh was intended as a scaffold for soft tissue growth through the articular and extra-articular sections of the ligaments, eventually uniting the bone plugs. The implant was considered sufficiently flexible to be suitable with a maximal tensile strength of approximate 2100 N (Newton), which significantly exceeds that of the average young adults' natural ACL (about 1730 N)

VII. Conclusion

A brief overview of the application of implantable medical textile products in various areas of medical sectors for the healthier life and betterment of human being. The development of new item will help the patients to overcome their suffering in previous days. This study provided an overview of the innovative, intelligent and smart textile products related to medical textiles, particularly implantable medical textile products such as surgical sutures, artificial skin, Artificial cartilage, and artificial ligaments.

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