

## Medical and healthcare devices: materials perspective

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People are special. The importance and need for the research and development into medical and healthcare devices can never be overstated. In the 21st century, medical and healthcare devices play a more vital role in our lives than ever before. A wide range of materials are being used for producing numerous medical and healthcare devices for a variety of end use. In this manuscript, historical development of wound care dressings and products are reviewed. The characteristics and requirements of modern wound dressings are summarized. A core part is devoted to the description of the materials used in medical and healthcare devices. Selected synthetic polymers are listed with their applications in medical and healthcare devices. The advantages and limitations of fibres, metals, ceramics and composites are denoted. Textile structures are highlighted with their applications in medical and healthcare devices.

**Keywords:** Materials for Medical and Healthcare Devices, Medical Textiles, History and Requirements of Wound Dressings.

### I. INTRODUCTION

Materials classified as fibre and polymer, metal and alloys, ceramics, textiles, and composites constitute the subject of this review. These materials have their own advantages and limitations. Fibre and polymers are useful from the viewpoint of their biodegradability and biocompatibility. Metal and alloys are suitable for implants like bone plates and screws. Ceramics appear to promote/allow tissue bonding. Textile structures can be designed for a wide variety of products used in healthcare and medical devices. Composites usually find their application when a broader range of properties are required. Earlier histories of wound care dressings and products as well as requirements of modern wound dressings are also included for the purposes of completeness and continuity of the review.

### II. HISTORICAL DEVELOPMENT OF WOUND CARE DRESSINGS AND PRODUCTS

Egyptian papyruses from 1550 to 1650 BC provide specific details of wound washing, preparation and application of plasters of honey, plant fibres, animal fat, and bandage the wound [1]. Modern day scholars believe that the lint may have been used for its absorbency, the grease for its barrier properties, and the honey for its antibacterial effects [2]. The Greek physician Galen of Pergamum (120-201 A.D.) noted empirically that wound heals optimally in a moist environment [2; 3]. Nevertheless, for nearly 2000 years, therapeutic efforts were focused on drying the wound site, with absorptive gauzes, and this was the mainstay of wound management [3; 4]. In 1962, Winter [5] showed that moist environment facilitates faster wound healing and dressings play a vital role in ensuring a desirable environment. In contrast, excessively dry wound healing environments actually caused further tissue death [3; 6]. After this finding, research and development activities focused highly on wound care materials to provide a moist environment for rapid healing. Earlier dressings were designed to keep the wound dry.

In the latter half of the 20th century, as clinical data accumulated in support of moist wound healing, manufacturers began producing polymer-based occlusive wound dressings which are designed to preserve and protect a moist wound environment [2-4]. Modern occlusive wound dressings may be

either fully occlusive (impermeable to fluids and gases) or semi occlusive (impermeable to fluids and partially permeable to gases like oxygen and water vapour) [7]. Not only do these dressings speed re-epithelialisation; they also stimulate collagen synthesis and create a hypoxic environment at the wound bed that promotes angiogenesis [8-10]. An added benefit of moisture-retentive dressings is that many patients experience pain relief with their use [11-14].

Despite the initial fears that occlusive dressings would promote wound infection, it has now been shown that they actually decrease infection rates as compared to non-occlusive dressings [15]. This difference is likely attributable to occlusive dressings' ability to maintain a more effective barrier against external contamination [16; 17]. Additionally, some occlusive dressings decrease the pH at the wound surface, helping to create an environment inhospitable to microbial growth [9].

While moisture is essential for proper healing, excessive wetness on the wound bed can be problematic. Occlusive dressings applied to highly exuding wounds may cause maceration of the surrounding skin. Overhydrated, macerated tissue is soft, white, and friable with a tendency to break down, which can delay wound healing or make the wound deteriorate further [18; 19]. Furthermore, the fluid from chronic wounds may actively interfere with the healing process. Chronic wound fluid inhibits fibroblast proliferation [20; 21] and contains proteases that destroy extracellular matrix material and growth factors [22-24]. The ideal wound dressing should thus absorb exudates without excessively drying the wound [3].

### III. MAIN CHARACTERISTICS AND REQUIREMENTS OF MODERN WOUND DRESSINGS

Since 1970s, the use of dressings that keep wound tissues moist has been associated with increased healing rates, improved cosmesis [25]; reduced pain [25]; reduced infection [26]; and reduced overall health care costs. Some of the requirements of an ideal wound dressing are as follows [1; 27; 28; 29]:

1. absorbing exudates and toxic components from the wounds surface;
2. maintaining a high humidity at the wound/dressing interface;
3. allowing gaseous exchange;
4. providing thermal insulation;

5. protecting the wound from bacterial penetration;
6. being non-toxic; and
7. easily removable without causing trauma to the wound.

The properties that were added later include: (i) having acceptable handling qualities; and (ii) being sterilisable and comfortable [30]. However, the actual choice of the dressing is always influenced by the clinical features of the wound, the physician's knowledge and experience; and patient's preference [31].

#### IV. MATERIALS USED IN MEDICAL AND HEALTHCARE DEVICES

There are a number of materials in use for producing healthcare and medical products for a variety of end use. Hence, materials used in healthcare and medical devices/products are difficult to categorise. However, the materials used in healthcare and medical devices/products include synthetic polymers, natural fibres and metals; monofilament and multifilament yarns; woven, nonwoven, knitted, crochet, embroidery and braided structures; and composite materials [32; 33]. A brief description of the above-mentioned materials is given below.

##### 1. Fibres and Polymers

All fibres are not suitable for medical application. Non-toxicity, sterilisability, biocompatibility, biodegradability, good absorbability, softness, non-carcinogenic and anti-allergen are some of the desirable properties. Table 1 illustrates application of synthetic polymers in healthcare and medical devices/products.

TAB. 1. Synthetic polymers and their application in healthcare and medical devices/products [34]

Synthetic Polymers	Applications
Polyvinylchloride (PVC)	Blood and solution bag, surgical packaging, IV sets, dialysis devices, catheter bottles, connectors, and cannulae
Polyethylene (PE)	Pharmaceutical bottle, nonwoven fabric, catheter, pouch, flexible container, and orthopaedic implants
Polypropylene (PP)	Disposable syringes, blood oxygenator membrane, suture, nonwoven fabrics, and artificial vascular grafts
Polydimethylacrylate (PMMA)	Blood pump and reservoirs, membrane for blood dialyzer, implantable ocular lens, and bone cement
Polystyrene (PS)	Tissue culture flasks, roller bottles, and filterwares
Polyethyleneterephthalate (PET)	Implantable suture, mesh, artificial vascular grafts, and heart valve
Polytetrafluoroethylene (PTFE)	Catheter and artificial vascular grafts
Polyurethane (PU)	Film, tubing, and components
Polyamide (PA)	Packing film, catheters, sutures, and mold parts

The main advantages of the fibre and polymer as compared to metal or ceramics materials are ease of manufacturability to produce various shapes (latex, film, sheet, fibre, etc.); ease of secondary process ability; reasonable cost; and availability with desired mechanical and physical properties. Depending on biodegradability, fibres can be classified as follows:

- a) **Non-Degradable Fibres:** Fibres that take more than six months to degrade and absorb by the body. They include synthetic fibres e.g. polyamide, Polyester, Polypropylene, Polytetrafluoroethylene (PTFE), Carbon, Polyvinylidene fluoride (PVDF) and Polyurethane.
- b) **Degradable Fibres:** Fibres that can be absorbed by the body within two or three months. Examples – Alginate, Chitin, Chitosan, Gelatine, Collagen, Cotton, Viscose and other protein fibres.
- c) **Resorbable Fibres:** Fibres that can be fully degraded and are absorbed by the body within few weeks. Examples – Polydioxanone (PDS), Poly-glycolic Acid (PGA) and Poly-lactic Acid (PLA).

##### 2. Metal and Alloys

Metals that can be tolerated in the body in small amounts are used for implants. Metals are used as passive substitutes for hard tissue replacement such as total hip and knee joints, fracture healing aids as bone plates and screws, spinal fixation devices and dental implants because of their excellent mechanical properties and corrosion resistance. Some metallic alloys are used for more active roles in devices such as vascular stents, catheter guide wires, orthodontic arch wires, and cochlea implants. Sherman vanadium steel was first used for bone plates and screws, however, is no longer used. Metals used in biomedical application include Fe, Cr, Co, Ni, Ti, and Ta. Due to the following drawbacks, some metals can be deemed unsuitable for biomedical application:

- High density
- Release of metal ions that can cause allergic tissue reactions

High stiffness compared to natural tissue – can cause stress shielding, as illustrated in Figure 1.

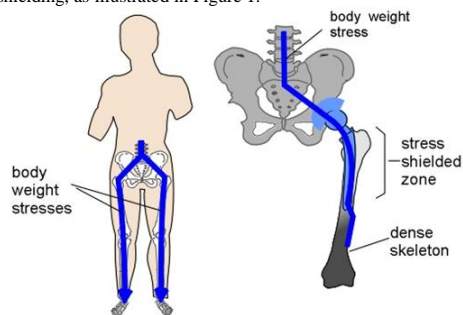


FIG. 1. (Color online) Stress shielding [35]

##### 3. Ceramics

Ceramics are defined as the art and science of making and using solid articles that have, as their essential component, inorganic non-metallic materials. Ceramics are made by using very fine powders by high temperature sintering and pressure for medical applications. They appear to promote/allow tissue bonding. Bulk inert ceramics  $Al_2O_3$  and  $ZrO_2$  offer excellent in vivo corrosion and wear resistance. Bioactive and surface reactive biodegradable ceramics and glasses have been developed. The desired properties of implantable ceramics are; nontoxic, non-carcinogenic, non-allergic, non-inflammatory, biocompatible, and functional for their lifetime in the host.

##### 4. Textiles

Medical textiles can be categorised into four separate and specialised areas of application as follows [33]:

- a) Non-implantable materials – wound dressings, bandages, plasters, etc.
- b) Extracorporeal devices – artificial kidney, liver, and lung
- c) Implantable materials – sutures, vascular grafts, artificial ligaments, artificial joints, etc.
- d) Healthcare/hygiene products – bedding, clothing, surgical gowns, cloths, wipes, etc.

Different fabric structures are employed to engineer a wide variety of products used in healthcare and medical devices/products. Table 2 illustrates the application of main textile structures in healthcare and medical devices/products.

TAB. 1. Textile structures for healthcare use and their main applications [36]

Structures	Applications
Woven	Gauze dressings, compression bandages, plaster, vascular prostheses, scaffolds, surgical gowns, drapes, and hospital textiles such as sheets, blankets, pillowcases, uniforms and operating room textiles
Knitted	Compression bandages, vascular prostheses, stents, ligaments and tendons, surgical hosiery, blankets, wound dressings, stockings, elasticated net garments, pressure garments, finger bandages, support bandages, flat bandages and spacer materials for knee braces
Nonwoven	Surgical gowns, caps and masks, absorbent layers, wipes, fleeces, protective clothing, diapers, feminine hygiene products, incontinence products, wound dressings and scaffolds.
Crochet	Compression bandages for compression therapy, cast cloth for orthopaedic casting bandages, wound dressings, bandages and implants
Embroidery	Implants
Braiding	Sutures, soft tissue ligaments and implants

A brief description of commonly used textile structures and their properties are given below:

**a) Woven Structure**

Woven fabric are made on a loom by interlacing longitudinal or warp yarn and transverse or weft yarn at right angles. The simplest structure called plain weave is widely used in medical application, shown in Fig. 2. Woven fabrics are dimensionally very stable, relatively inextensible. Another important feature of the fabric is that porosity can be varied from nearly zero value (plasters and bandages) to very high value (gauze dressing). A major drawback of the structure is the tendency to fray at selvedge when cut to fit an application. To avoid the drawback, a special woven structure called 'Leno' is reported in which two warp yarn twist around a weft [29].

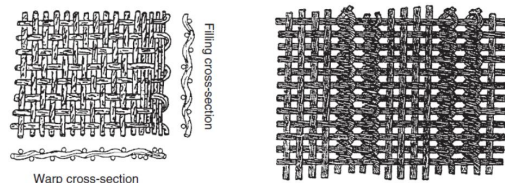


FIG. 2. Plain Weave and Leno Weave

**b) Knitted Structure**

Knitting can be classified as weft knitting and warp knitting. In weft knitting, loops are formed substantially across the width of the fabric whilst in warp knitting loops are formed substantially across the length of the fabric, as shown in figure 3. As the name implies, weft threads make the loop in weft knitting and each warp thread makes the loops in warp knitting.

Compared with woven structure, knitted structures are more flexible and conformable. Unlike woven structure, the knitted structure does not fray at the cut edge. Knitted bandages offer better drape properties than woven structure, especially when three-dimensional conformability is required. Due to the loop structure, porosity of the knitted structure tends to be high [29].

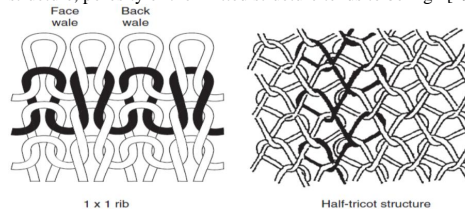


FIG. 3. Weft Knit and Warp Knit Structures

**c) Needle-punched Nonwoven Structure**

Unlike woven and knitted structure, needle-punched nonwoven structure consists of web of fibre. The bonding of the fibre web is achieved by the penetration of needle through the structure. The manufacturing process is faster and more economical than weaving and knitting process. Nonwoven structure is more homogeneous, resilient and softer than woven and knitted structure. The needle-punched nonwoven structure is used in padding layer in order to provide cushioning effect to the limb, and distribute pressure evenly, particularly, to protect bony prominences from excessive pressure. The fabric also offers good absorbency and wicking properties [29].

**5. Composites**

The term "composite" is usually implied for those materials in which the distinct phases are separated on a scale larger than the atom, and in which the properties, such as the elastic modulus, are significantly altered in comparison with those of a homogeneous material. Engineered multicomponent materials are designed that possess a broader range of properties. The composite materials offer a variety of advantages in comparison with the homogeneous materials such as higher stiffness, higher strength, and lightweight materials as well as highly resilient and compliant materials. Some of the applications of the composites in healthcare and medical devices are: dental filling composite, reinforced methyl methacrylate bone cement, and ultra-high-molecular weight polyethylene and orthopaedic implants with porous surfaces. Fibre Reinforced Polymers are the most widely investigated composites for medical devices applications.

**V. CONCLUSIONS**

Owing to a wide range of fabric structures, textile structures appear to be the most competent source of materials for medical and healthcare devices. Textile structures can be found in applications from surgical gowns to implants. Due to the excellent properties of the fibres and polymers e.g. non-toxicity, biocompatibility, biodegradability, good absorbability etc., they are also considered a strong candidate for wound care dressings and products. Despite the advantages of metal and alloys for direct application in medical and healthcare devices, some limitations e.g. high density, high stiffness, risk of metal ion release, challenge their usage.

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