Chapter 9

Materials for Medical Devices

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Introduction

The selection of suitable materials is a crucial step in medical device design and influences the safety and performance of medical devices. It should be done during the early phases of product development, particularly when the functional requirements of the device are assessed (Pietzsch et al., 2009; Allen, 2018). Materials selection is based on the appropriateness of the materials in terms of design flexibility, cost-effectiveness, product safety, quality, and performance (Shang & Woo, 1996). This chapter discusses the considerations in choosing suitable materials for medical devices, highlights the challenges faced in Africa with regard to medical device materials, and provides recommendations on the way forward.

Selection of materials

The selection of medical device materials demands an understanding of the materials with particular focus on attributes ranging from physical performance and manufacturing constraints, to budget limitations and supply chain logistics (Ramesh & Sivaramanarayanan, 2013; Hurlstone, 2018). Normally, the selection starts with a wide choice which is trimmed down to two or three candidates which are subjected to testing in order that informed choices can be made (Choi, Kim & Ha, 2008; Ramesh & Sivaramanarayanan, 2013). A set of selection criteria should be defined to guide the process (Choi et al., 2008).

Material properties

A wide range of materials is used in the manufacture of medical devices. The materials include metals, ceramics, polymers, and composites, and they can be used singly and in combination (Batchelor & Chandrasekaran, 2004; Patel & Gohil, 2012). The selection of materials is not only based on their ability to perform the intended functions, but also their ability not to initiate side effects such as damaging the surrounding tissue, in cases where the devices are implanted or come into close contact with the body, or inducing a wider health problem. This demands a circumspect consideration of different parameters to decide whether or not a material and at a particular grade is appropriate for use in a medical device (Bhat & Kumar, 2013). According to Allen (2018), three areas should be emphasised when selecting materials, namely, device needs and regulations; application and performance; and manufacturing and costs. These three areas embrace several categories which are not limited to the material only, but to decision making such as innovating versus using available choices, and building versus buying.

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Typically, the selection of materials is based on functionality and biological and chemical attributes (Geddes & Roeder, 2003).

Mechanical properties of materials need to be considered when selecting materials for medical devices. The ability of a material to withstand mechanical forces such as its tensile strength, fracture hardness, elasticity modulus, and fatigue resistance, must be considered (Lantada & Morgado, 2013). For example, rigid plastic materials are typically used for components such as housings, fittings, fasteners, and connectors because of their strength and stiffness (Larson, 2016). Engineered thermoplastics can withstand low and high temperatures which render them suitable for applications where changes in temperature may influence outcomes (Ramesh & Sivaramanarayanan, 2013). Metals are used in implants and prostheses for their mechanical properties and particularly for their high static and dynamic strength (Lantada & Morgado, 2013). Nanomaterials are emerging as good candidates for orthopaedic devices (Ying, 2001; Bhat & Kumar, 2013).

Examples of materials that are suitable for specific biomedical applications, include polymers used as implant material for cardiovascular applications such as vascular grafts, stents, prosthetic heart valves, catheters and heart assist devices (Jaganathan et al., 2014). Their suitability for these applications results from their biocompatibility, which makes them preferable to metallic biomaterials (Helmus & Hubbell, 1993). Heart valves are manufactured mainly from polyurethane material which is formulated and optimised to exhibit the desired chemical (degradation resistance, non-toxicity) and mechanical (strength and toughness, flex life, elasticity) properties (Saidi & Douglas, 2016).

Titatum alloys are widely utilised for metallic orthopaedic implants due to their light weight, superior biocampability, low stiffness and low cost (Buechel & Pappas, 2015). Hydrogels made from the cross-linking of natural and synthetic hydrophilic polymers to resemble living tissue, are mainly used in the manufacture of contact lenses, tissue engineering scaffolds, drug delivery systems, hygiene products and wound dressings (Caló & Khutoryanskiy, 2015). This is because they possess unique attributes such as high water content, softness, flexibility and biocompatibility.

A key question to consider in the selection of the materials for that come into contact with body tissues such as implantable devices is how they will perform inside the body, which is very sensitive to foreign objects (Batchelor & Chandrasekaran, 2004). When selecting materials for such devices, emphasis should be on biological factors (Lantada & Morgado, 2013). Consideration of biocompatibility is important in establishing the ability of a particular material to be in contact with tissues of the human body without causing unacceptable harm (Geetha et al., 2009). It is imperative that the material not adversely affect the host environment of interaction such as bone and soft tissues, plasma composition, as well as intra and extracellular fluids (Patel & Gohil, 2012). Materials used for medical devices which involve body contact should be chemically stable, biocompatible, safe, non-carcinogenic, non-toxic, non-allergenic and non-inflammatory (Lantada & Morgado, 2013). The focus of biocompatibility, however,

is not simply on the ability of the material to remain inert in the body, but its ability to perform a function in the body (Patel & Gohil, 2012).

Corrosion resistance is an important parameter in the selection of metallic implants because contact with corrosive body fluid is inevitable (Singh & Dahotre, 2007). Chemical reactions due to corrosion can adversely affect implant devices, for example dissolved metal ions can accumulate in tissues, near the implant or they may be transported to other parts of the body causing harm to the body (Patel & Gohil, 2012). The materials used for medical implants require a careful assessment of how they respond to tissues to address safety and functionality concerns, as implant-associated protein adsorption and conformational changes can invoke immune reactions. Protein adsorption and cell interactions may be addressed through engineering of surface properties to improve implant biocompatibility (Tang, Thevenot & Hu, 2008).

Regulation

To ensure compliance with good quality assurance practices, it is necessary to consider the regulations governing the use of the materials for medical devices (Leuschrier, 1992; Ying, 2001). In general, the medical device industry is highly regulated and compliance with regulatory standards is a basic requirement.[1] Adherence to regulatory standards for the materials used in medical devices often marks the difference between success and failure in medical device design (Lantada & Morgado, 2013). There are international standards which focus specifically on the materials used in medical devices; these include ISO Standard 10993 for biological evaluation of medical devices and the ISO 9000 series on quality and procedures (Young, 1994; Kotzar et al., 2002). These standards are useful in the selection of materials for medical devices as they facilitate objective comparisons of possible alternatives and provide guidance in choosing reliable suppliers.

Manufacturing and processing requirements

Materials for medical devices are produced in various ways; these range from traditional processes such as milling, turning and shaping, to more recently introduced techniques such as additive manufacturing. Additive manufacturing converts 3D digital models into 3D objects by constructing them layer by layer under computer control (Douglas, 2014). One example of this kind of manufacturing technology is 3D printing. The technologies available for manufacturing, the costs involved, and the skills needed to produce the materials, impact on the choice of materials for medical devices.

Challenges in Africa

A medical device industry in Africa is largely absent resulting in over-reliance on imports from foreign companies (De Maria, Mazzei & Ahluwalia, 2015). This, combined with limited

[1] For further information on medical device regulation, refer to the chapter "The regulation of medical devices in Africa" elsewhere in this book.

academic programmes in biomedical engineering in most African countries, results in limited research and development activity in biomedical engineering in general, and also in materials for medical devices in particular. Thus, local medical device development for local needs in Africa may still rely on imported materials, and would face barriers such as the costs of importation, and an inability to experiment due to lack of easy access to materials.

Only a few African countries have developed regulations on medical devices. Mori, Ravinetto, and Jacobs (2011) argue that there is poor regulatory oversight of medical devices in resource-limited settings, resulting in the proliferation of counterfeit and sub-standard products on the market. South Africa, which is one of the leading countries in medical device development in sub-Saharan Africa, had no dedicated regulations on medical devices until 2015 (Saidi & Douglas, 2018). In the absence of regulations, most African countries do not have checks and balances that guide the selection of materials for medical devices.

Due to limitations in technological development, many African countries face challenges in accessing modern manufacturing techniques for materials. Many novel materials with high strength, light weight, and greater chemical resistance such as nanomaterials and nanotubes have come into existence due to developments in the field of nanotechnology (Ezema, Ogbobe & Omah, 2014). However, most African countries are lagging behind in adopting emerging technologies (Akpan, 2014). Such constraints adversely affect medical device development, since innovators and manufacturers interested in the use of emerging materials such as nanomaterials, and emerging technologies, such as additive manufacturing, do not have access to the required facilities.

In sub-Saharan Africa, South Africa has embraced the potential of 3D printing to revolutionise manufacturing systems, while other countries are following the path of late adopters (Campbell, De Beer & Pei, 2011). In combination with open source designs, 3D printing can improve the ability of low-resource countries to produce medical devices. For instance, researchers at University of Cape Town have developed a 3D printable medical device and released the design as an open source innovation which can be downloaded at no cost (Saidi, Sivarasu & Douglas, 2018). The device, shown in Figure 1, a modular, adjustable ptosis crutch for elevating the upper eyelid in patients with myasthenia gravis, a condition for which treatment options are limited in low-resource settings.

Figure 1: 3D-printed ptosis crutch, described in Saidi, Sivarasu and Douglas, 2018, attached to spectacles.

The way forward

To address the challenges faced by African countries in the development and use of suitable materials for medical devices, there is need to foster a culture of collaboration in the field of biomedical engineering to pool limited resources. The initiative by the African Biomedical Engineering Consortium for capacity building through enhancing biomedical engineering research and teaching capacity at universities in Africa is a good example of how health technology competencies that address the needs of Africa can be developed (Douglas et al., 2017). The development of materials for medical devices in Africa can benefit from pooling of the available physical, human and financial resources on the continent. The development of national systems of innovation such as nanotechnology innovation centres in South Africa (Albuquerque et al., 2015) for research and development of nanostructured materials and their applications by researchers across the continent is an example of how infrastructural challenges can be addressed. The innovation centres provide platforms to develop local materials that are customised to meet the needs of local users.

Regulations to guide the manufacture of, and the selection of materials for, medical devices, are necessary to promote product safety. African countries should invest in developing and reinforcing national regulatory oversight on medical devices. They should embrace new technologies such as 3D printing, which is providing tools for the manufacture of materials that were once the exclusive prerogative of a few companies and has the potential to accelerate the design and manufacture of medical devices in low income settings.

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