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Suitability of developed composite materials for meniscal replacement: Mechanical, friction and wear evaluation

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ABSTRACT

The meniscus is a complex and frequently damaged tissue which requires a substitute capable of reproducing similar biomechanical functions. This study aims to develop a synthetic meniscal substitute that can mimic the function of the native meniscus.

Medical grade silicones reinforced with nylon were fabricated using compression moulding and evaluated for mechanical and tribological properties. The optimal properties were obtained with tensile modulus increased considerably from 10.7 ± 2.9 MPa to 114.6 ± 20.9 MPa while compressive modulus was found to reduce from 2.5 ± 0.6 MPa to 0.7 ± 0.3 MPa. Using a tribometer, the coefficient of friction of 0.08 ± 0.02 was measured at the end of the 100,000 cycles.

The developed composite could be an auspicious substitute for the native meniscus and the knowledge gained from this study is useful as it enhances the understanding of a potentially suitable material for meniscal implants.

1. Introduction

The meniscus of the knee is a C-shaped fibrocartilaginous structure situated between the condyles of the femur and the tibial plateaus. Meniscal injuries are among the most frequent injury at the knee (Fan and Ryu, 2000). Meniscal damage can occur through trauma and tears, for example during sporting activities, accident, or through degeneration of the meniscus cartilage in older people. Although tears originating in the meniscus can be repaired, this cartilaginous tissue does not heal properly due to lack of sufficient blood supply (Athanasiou and Sanchez-Adams, 2009). A meniscal replacement however has a distinguishable benefit in that it will both repair and replace, especially in cases of complex tears (Sweigart and Athanasiou, 2001). Meniscal prostheses are essential as they have a place in restoring functions; they are helpful in increasing the contact area and lowering the contact pressure (McDermott and Amis, 2006; McCann et al., 2009a; Galley et al., 2011a).

One of the reasons for the failure of meniscal implants is the inappropriate material selection which ultimately promotes wear, tear and fracture (Shriram et al., 2017). A wide range of synthetic composites have been investigated for use as meniscal replacements, among them being teflon, carbon fibre-polyurethane-poly(L-lactide), dacron, and polyurethane / PLLA composites (Vrancken et al., 2013; Toyonaga et al., 1983; Wood et al., 1990; Elema et al., 1990; Klompmaker et al., 1996; de Groot et al., 1996). Extensive researches have been conducted on Teflon and Dacron as durable meniscal substitutes (Messner, 1994; Messner et al., 1993). Heijkants et al. Heijkants et al. (2004) studied the application of permeable polyurethane scaffold for meniscal substitutes. Of the properties, the porosity and compression were modified to promote tissue regeneration (Klompmaker et al., 1993; Tienen et al., 2006). A general limitation of these composites is their inability to provide long lasting protection to the articular cartilage and therefore none of these solutions is adequate for young energetic patients. Other problems associated with existing meniscal replacements include inability of the device to replicate the function of the native meniscus, wear of the prosthesis, unavailability, and possible immunological reactions. Other developments that have been investigated involve the use of polyvinyl alcohol (PVA) and polycarbonate-urethane reinforced

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with polyethylene fibres (Holloway et al., 2010; Kon et al., 2012; Elsner et al., 2010). PVA hydrogels have been utilized in the development of meniscal replacements. It has been shown that the inclusion of polyethylene filaments with the hydrogel produced a biomaterial with improved tensile and compressive moduli to resemble that of the local meniscus (Holloway et al., 2010). Likewise, polyethylene reinforced polycarbonate urethane (PCU) has been used for meniscus implant (Kon et al., 2012; Elsner et al., 2010; Linder-Ganz et al., 2010; Zur et al., 2011; Kelly et al., 2006; Vrancken et al., 2015). The natural meniscus is a collagen fibre reinforced composite (Fithian et al., 1990; Mow and Huiskes, 2005) and therefore a composite material, specifically a fibre reinforced polymer composite, could be an ideal material substitute for meniscus prosthesis. Polymeric composite biomaterials are both anisotropic and heterogeneous (Ramakrishna et al., 2001) which are the properties of the natural meniscus (Pangborn and Athanasiou, 2006).

Silicone materials have been widely used in biomedical applications. Their desirable elastic properties, chemical and thermal reliability and excellent biocompatibility have made them acceptable (Gorman and Woolfson, 2002; Colas and Curtis, 2004). The successful outcome of implants made from silicone materials depends on whether the design closely imitates the properties of the parts intended for replacement (Navarro et al., 2008). The incorporation of reinforcements in silicone elastomers has been reported to improve its mechanical properties (Colas and Curtis, 2004; Tiamiyu and Vaughan, 2011). Nylon fibres, on the other hand, have been used for several applications owing to their outstanding physical properties, durability and chemical resistance. They are known for their high strength, low coefficient of friction, good abrasion, and wear resistance and are excellent materials for impact and heat resistance (Hegde et al., 2004; Aharoni, 1997; Kohan, 1995). Nylon reinforced silicone elastomers have been used for various biomedical implants particularly in the area of prosthetic and orthotic applications. They are utilized for making below-knee socket inserts, distal end caps, shoe inserts and for lasting covers that enclose the flexible foam which houses the prosthesis (Sanders et al., 1998; Iftekhar, 2009). Nylon reinforced silicone elastomer sheeting has also been proven to be a suitable temporary material for abdominal closure (Foy et al., 2003).

Due to the important biomechanical functions of the knee meniscus, a replacement for the meniscus should provide mechanical support and stability during load bearing of the knee. Some existing meniscal prostheses were unsuitable as a result of their lower mechanical quality compared to that of the native meniscus (Sweigart and Athanasiou, 2001). Consequently, for a meniscal implant material to sufficiently serve the role of natural meniscus and inhibit destructive changes in the articular cartilage, it should have similar mechanical properties to the native meniscus (Chiari et al., 2006; Kobayashi et al., 2003). Therefore, the mechanical evaluation of an artificial meniscal substitute is crucial since it can give an indication of its behaviour in vivo. Furthermore, it is imperative for a meniscal replacement to have adequate frictional and wear attributes such that it allows the free movement of the device within the meniscal housing. However, the tribological characteristics of meniscal substitutes developed so far have been investigated to a limited extent.

Almost all the meniscal replacement devices are experimental. Only a few have been clinically acceptable for patient's use (Rodkey, 2010; Baynat et al., 2014). Most of the meniscal substitutes to date have failed owing to inability of the device to replicate the function of the native meniscus, susceptibility to wear hindering long term implantation, degeneration of the articular cartilage and inflammatory response leading to destruction of the joint; hence investigation into new materials that will serve to replace the meniscus without the associated shortcomings is the goal of this study. Therefore, we have characterized the mechanical properties, frictional and wear performance of a novel engineered composite material designed for use as a meniscal prosthesis. The developed composites consist of two parts: the polymer matrices are medical grade silicone elastomers while the reinforcing fibres are nylon-6.

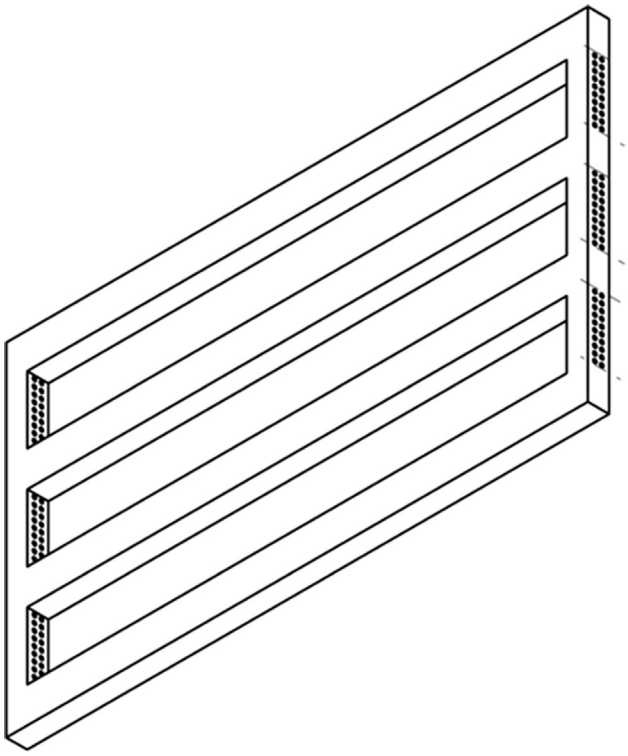

Fig. 1. A sectional view of the assembled mould for the mechanical test samples.

2. Materials and methods

2.1. Mould design

A metal mould was used in the production of the composite samples for the mechanical tests. The fibres were heaved through the mould and kept parallel at same interval distance while being firmly held. A 3D geometric outline was made by utilizing Solidworks (Dassault Systèmes, Vélizy, France). The mould was partitioned into different sections to ease the removal of samples after curing. The schematic layout of the mould is shown in Fig. 1.

2.2. Silicone matrix

Silastic Biomedical grade (Dow Corning Limited, Coventry, UK) enhanced-tear-resistant silicone elastomers (Q7–4720, Q7–4765 and Q7–4780) were utilized as matrix for sample production. Table 1 presents the mechanical properties as specified by the manufacturer.

The elastomers were supplied in two parts, A and B, combined in

Table 1
Material properties of the silicone elastomers and the nylon fibre.

Material property	Q7–4720	Q7- 4765	Q7- 4780	Nylon fibre
Durometer Hardness - Shore A[a]	23	65	77	–
Tear Strength (kN/m)	32	45.1	41.7	–
Tensile Strength (MPa)	9	8	7.8	–
Density (kg/m^3)	1110	1200	1200	1150
Elongation (%)	1310	900	660	–
Elastic Modulus (GPa)	–	–	–	3
Breaking load (kg)	–	–	–	24.9
Melting point (°C)	–	–	–	220

[a] Durometer is generally used as a measure of hardness in elastomers. The Shore A scale is used for 'softer' materials like elastomers.