DEVELOPMENT AND EVALUATION OF POLYCARBONATE-URETHANE COMPOSITE FOR A KNEE MENISCUS REPLACEMENT

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INTRODUCTION
Meniscal injuries are widespread with more than a million meniscal surgeries done yearly in the US and meniscal surgery being reported as the most prevalent of all orthopaedic surgeries [1,2]. The use of polycarbonate urethane (PCU) for a meniscus replacement stemmed from its unique capabilities of weight-bearing forces, ability to withstand intense forces within the knee joint [3] and ease of lubrication due to its hydrophilic nature. Additionally, it proffers low friction properties [4] required by a meniscal replacement to promote movement within the meniscal compartment while withstanding repeated stresses from the femoral condyle during flexion and extension motions.

In order to obtain a meniscal substitute with desirable matching mechanical properties, test pieces were designed, fabricated and tested to check the suitability of the proposed PCU polymeric material as a matrix and its fibre reinforced composites as substitutes that are capable of reproducing as closely as possible the mechanical performance of the human meniscal tissue.

The composite test pieces were designed to consist of longitudinally arranged reinforced fibres modelled after the circumferential collagen fibre orientation of the native meniscus. Our aim therefore is to evaluate the tensile and compressive moduli of the composites and compare the results with available data for the natural meniscus.

METHODS
A custom-built mould was designed for the production of the mechanical test samples. The mould was designed such that the reinforcing fibres could be pulled through the mould and arranged horizontally at equal intervals as well as being held in tension. Bionate 90A PCU pellets (PTG, Berkeley, CA, USA) used as the matrix materials were dried in a vacuum oven at 100°C for 14 h prior to composite preparation while nylon-6 fibres (Fosters of Birmingham, UK) were used as the reinforcing fibres. An equivalent amount of 5% volume fraction fibres were arranged in two layers at 2 mm apart and at 2 mm away from each end of the sample, after which 57g of PCU pellets were used to fill up spaces in the mould. The mould was then placed between two steel plates of a pre-heated hydraulic press and compressed at initial temperature of 190°C for 10 minutes at a pressure of 15 MPa. Thereafter, the mould was removed to add 12 g of the PCU pellets and rectangular cuboid shaped specimens (153 x 19 x 6 mm) were pressed using the hot press at a final temperature of 200°C for another 10 minutes under same pressure. The mould was allowed to cool for a period of 3 hr. before removal of the specimen from the mould. To allow for easy removal of the specimen from the mould after curing a PTFE sheet was placed underneath the mould during composite preparation. The same process was followed for fabricating samples containing 100% polymeric PCU matrix.

Both tensile and compression testing were performed using a Zwick/Roell 1484 material testing machine and three specimens were evaluated for each test. Rectangular cuboid shaped (120 x 19 x 6 mm) specimens were cut such that specimen size 19 mm in width, 6 mm in thickness and 70 mm in gauge length were tested in tension along the fibre orientation at a crosshead speed of 12 mm/min. Compression tests were carried out with cubic (6 x 6 x 6 mm) specimens at a crosshead speed of 5 mm/min, testing was done perpendicular to the orientation of the fibres. The tensile and compressive moduli were calculated from the slope of the linear region of the stress–strain curves recorded.

RESULTS AND DISCUSSION
The graph of tensile stress versus tensile strain was plotted for strains of up to 100% (Figure 1). The curves displayed a linear pattern at low strains. Afterwards, a substantial change occurred in the slope introducing a non-linear behaviour that was sustained until the specimens started to fail. The PCU was not as stiff as its fibre reinforced composites, which indicates that the stiffness of the PCU composite materials are functions of both the stiffness of the PCU matrix and the interspersed fibres. The average values and standard deviation of the tensile moduli, and the compressive moduli of the PCU matrix and its reinforced composite are shown in Table 1. The tensile and compressive moduli of reinforced specimen were higher than the unreinforced counterparts. The tensile moduli of composite increased appreciably with nylon fibres with 603% increase in stiffness. Likewise, nylon fibres were seen to raise the compression modulus of PCU matrix with an increment of 3%.

The menisci perform the role of distributing load uniformly across the tibio-femoral surfaces, thereby shielding the cartilage from extremely high loads which may be deleterious. In carrying out the task of stabilizing the knee joint, the meniscus reduces the joint contact stress by increasing the contact area between the tibio-femoral joint and also provides resistance to the high peak loads. It is therefore paramount that a meniscal substitute is able to perform similarly as these natural weight-bearing structures. Considering the tensile property of the PCU matrix compared to the circumferential tensile modulus of the human meniscus, which is site-dependent, varied between 58 MPa and 295 MPa [5], PCU offers a much lower stiffness. Therefore, it will not appropriately perform the rigorous tasks that the meniscal tissue is subjected to on a routine basis and hence reinforcing the soft polymeric matrix with strong fibres could potentially produce a composite material which is biomechanically capable of substituting the worn out meniscus. The nylon-PCU composite has tensile properties within the values reported for the circumferential tensile modulus of the human meniscus. The aggregate compressive modulus for the human meniscus has been given as 0.22 MPa [5].
compression modulus of the PCU and its composite were considerably higher and are not comparable to that of the human meniscus.

The wide variation in the tensile and compressive properties of the meniscus makes it difficult to exactly reproduce a close match with a synthetic replacement. However, since the functional role of the meniscus is greatly dependent on its unique complex shape and structure, it is therefore expected that the “true” mechanical properties of the developed PCU composites as a meniscal replacement may only be exhibited when the composite prosthesis is constructed to bear close similarities to the geometry and structure of the normal meniscus.

Table 1: Mechanical properties of the fibre reinforced PCU composite compared with its unreinforced matrix.

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<th>Tensile modulus (MPa)</th>
<th>Compression modulus (MPa)</th>
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<tr>
<td>PCU</td>
<td>17.63±0.53</td>
<td>71.22±1.03</td>
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<tr>
<td>PCU-nylon</td>
<td>123.97±1.67</td>
<td>73.39±6.59</td>
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CONCLUSIONS
The result of the tensile modulus determined from this study for the PCU matrix showed it was inadequate and cannot replace nor sufficiently perform the load bearing functions of the meniscus. The effect of the fibre reinforcement was favourable as the tensile modulus was significantly raised to fall within the range of the tensile modulus of human meniscus.

The results from this study suggest that the tensile and compressive properties of PCU could be custom-tailored to that of the meniscal tissue by systematically embedding reinforcement fibres into the PCU matrix such that a composite with desirable mechanical properties is constructed. However, additional studies are required to completely describe the PCU composite as a candidate meniscal substitute capable of gaining its full functionality.

REFERENCES