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What is This?

The bio-tribological characteristics of synthetic tissue grafts

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Abstract: The use of synthetic connective tissue grafts became popular in the mid-1980s, particularly for anterior cruciate ligament reconstruction; however, this trend was soon changed given the high failure rate due to abrasive wear. More than 20 years later, a vast range of grafts are available to the orthopaedic surgeon for augmenting connective tissue following rupture or tissue loss. While the biomechanical properties of these synthetic grafts become ever closer to the natural tissue, there have been no reports of their bio-tribological (i.e. bio-friction) characteristics. In this study, the bio-tribological performance of three clinically available synthetic tissue grafts, and natural tendon, was investigated. It was established that the natural tissue exhibits fluid-film lubrication characteristics and hence is highly efficient when sliding against opposing tissues. Conversely, all the synthetic tissues demonstrated boundary or mixed lubrication regimes, resulting in surface-surface contact, which will subsequently cause third body wear. The tribological performance of the synthetic tissue, however, appeared to be dependent on the macroscopic structure. This study indicates that there is a need for synthetic tissue designs to have improved frictional characteristics or to use a scaffold structure that encourages tissue in-growth. Such a development would optimize the bio-tribological properties of the synthetic tissue and thereby maximize longevity.

Keywords: biotribology, failure, graft, synthetic, connective tissue

1 INTRODUCTION

Almost a century of research into the bio-tribological (i.e. bio-friction) characteristics of the human synovial joint [1, 2] has enabled engineers and surgeons to maximize joint replacement longevity by continually refining the prostheses design. However, despite the use of synthetic (i.e. man-made) connective tissue grafts being reported as early as 1900 [3, 4], relatively few studies have investigated materials for use in replacement or augmentation procedures.

The use of synthetic grafts to replace connective tissues is considered when presented with atypical cases. For example, while the majority of tendon augmentations, following rupture, may be successfully repaired using sutures [5–12], synthetic tendon grafts may be required in cases of tissue loss, or chronic rupture and subsequent retraction of the tendon ends [13, 14]. Historically, the use of synthetic connective tissue grafts was popular during the 1980s, particularly with anterior cruciate ligament reconstruction; however, this was soon associated with a high rate of failure [15–20]. Analysis of the retrieved synthetic implants showed the cause of failure to be their poor bio-tribological performance and subsequent abrasive wear. The generation of wear particles has been reported as causing synovitis [21], including when implanting different anterior cruciate ligament prostheses in to sheep knees [22]. The failure of these, and other synthetic connective tissues, seemed to follow a consistent trend: excellent biomechanical

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results during laboratory tests, followed by enthusiastic preliminary clinical results, which led to a period of over-implantation, complications and recognized clinical failures. Clinicians have since favoured the conventional autologous reconstruction techniques [20].

More than 20 years on and, while new synthetic connective tissues continue to become available to clinicians, there remain scarce data describing their frictional characteristics. However, published anatomical and biomechanical studies have detailed the bio-tribological characteristics of healthy tissue. Investigations have considered the interface between tendon and bone, where tendons 'wrap around' bony pulleys in order to change the line of action of the transmitted contractile force. Fibrocartilage has previously been identified on the deep tendon surface and the opposing surface of the bony pulley, serving to protect the tissues against abrasive wear [23, 24]. Subsequently, a tendon-bone contact is actually a fibrocartilage-fibrocartilage opposition. Previous investigation of tendon-pulley friction reported values ranging from 0.022 to 0.040 [25, 26], which is not dissimilar to that reported within the synovial joint (0.008–0.040) [27]. The efficiency of both contacts has been attributed, in part, to the lubricating properties of lubricin, a surface-bound glycoprotein [28, 29].

Previous bio-mechanical studies refer to the Stribeck curve (Fig. 1) when estimating the lubrication conditions at opposing biological surfaces [30–32]. These studies have determined whether the two tissues are in contact (i.e. boundary lubrication), partially separated (i.e. mixed lubrication), or completely separated by a film of lubricant (i.e. fluid-film

lubrication). The lubrication regime at the interface of two opposing surfaces is dependent on the relative sliding speed of the two contacting surfaces, the load applied normally to the two surfaces, and the lubricant's dynamic viscosity. Given an appreciation of the lubrication regime likely to develop at the conjunction of two materials during typical conditions, an engineer can optimize a design to maximize the beneficial effect of fluid-film lubrication, and thus minimize both abrasive and adhesive wear.

The aim of this study was to investigate the biotribological properties of a range of clinically used synthetic tissue grafts. This enabled estimation of the likely lubrication regimes and thus, by implication, the functional efficiency within the human body. A region of tendon fibrocartilage was also investigated, providing a biological equivalent for comparison. The results of this study will indicate whether wear at synthetic tissue conjunctions can be reduced, and thereby provide information that may allow engineers to increase the longevity of these prostheses.

2 MATERIALS AND METHODS

Twenty bovine legs were obtained from an abattoir following the slaughter of 18 month old animals for the food industry. The metacarpophalangeal joints were aspirated and the synovial fluid pooled; cloudy, bloody, or samples that failed the String test [33] were excluded from the study. The synovial fluid was then refrigerated overnight, before being acclimatized at 37 °C prior to experimentation. A multinational orthopaedic company provided three surgical-grade

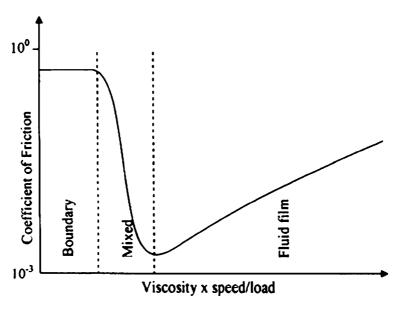


Fig. 1 The Stribeck curve

Table 1 The properties and dimensions of the synthetic tissues

Sample	Description
A B C	5 mm wide densely woven cord of PET fibres 10 mm wide loosely woven cord of PET fibres 5 mm diameter densely woven tube of PET fibres

synthetic tissue grafts (samples A, B, and C). All samples were manufactured from polyethylene terephthalate (PET) fibres, a material which has previously been reported to produce wear particles during *in vivo* investigation of the Leeds Keio ligament prostheses [22]. The study presented here investigates the lubrication regimes generated by the differing structures of the three PET samples (as described in Table 1); a macroscopic image of each graft is presented in Fig. 2.

Each graft was cut to approximately 50 mm in length and both ends were chemically bonded to the apparatus, while ensuring approximately 10 mm of the product was in contact with the counterface. Also investigated was a deep region of tendon that wraps around a bony pulley within the bovine foot (causing the development of a fibrocartilaginous matrix [24]). Bovine tendon has previously been used to draw comparisons with the bio-tribological characteristics of human soft tissue [31]. The coefficient of friction and lubrication regime of both the synthetic and biological tissue samples were investigated using a calibrated pin-on-disc apparatus. The apparatus, shown in Fig. 3, consisted of an aluminium tube (A) (wall thickness 5 mm, outer diameter 25 mm, length 300 mm), pivoted and freely rotating on a pillar with specially modified light bearings and suspended over a glass disc (D). This glass counterface is a previously reported approximation of a fibrocartilaginous opposition ($R_a = 0.297 \,\mu\text{m}$) [31]. The contact was lubricated with excess synovial fluid.

A range of normal loading was applied (0.5, 1.0, 1.5, 2.0, 4.0, 7.0, and 10 N), representing transverse tissue compression. To ascertain the lubrication regime it was necessary to acquire a broad range of data, and hence investigation extended to sliding speeds exceeding those likely *in vivo* (19, 29, 46, 66, and 84 mm/s). The reduced Sommerfeld number – the ratio of sliding speed to load, was then plotted for each combination of the above parameters. The average frictional coefficient was calculated from the arm deflection, with data acquired over a 10 s period immediately following accentuated arm deflection (caused by static friction between the sample and counterface), in recognition of the time-dependant nature of soft tissue friction [34].

3 RESULTS

Results are presented for the three different synthetic tissue grafts (samples A, B, and C) and the fibrocartilaginous region dissected from the deep surface of the bovine flexor tendon. The general trend of the sample A data (Fig. 4) exhibits a high initial friction coefficient (0.2-0.8), which then falls to a lower level (≈ 0.02) as the speed increases or the load decreases. Comparison with the general form of the Stribeck curve suggests a transition from boundary to mixed lubrication at the sample-glass counterface. Further qualification of the lubrication regime is provided by the range of frictional coefficients (0.02–0.80) [32, 35]. A near-horizontal trend-line could be plotted through the data describing sample B (Fig. 5). These data are representative of boundary lubrication with frictional coefficient in the range 0.1–0.3. Sample C (Fig. 6) again reflects boundary lubrication, although it would appear to be developing mixed lubrication at higher values of the reduced Sommerfeld number [32, 35].

Results from the bovine fibrocartilage are presented in Fig. 7. The trend has a distinctly positive gradient and the coefficients of friction (0.006–0.030) were an order of magnitude lower than those for the synthetic tendon data. The results confirm the view that the natural tissue is lubricated in the fluid-film regime.

4 DISCUSSION

The natural fibrocartilaginous tissue appears to have the potential to generate a fluid-film regime when in

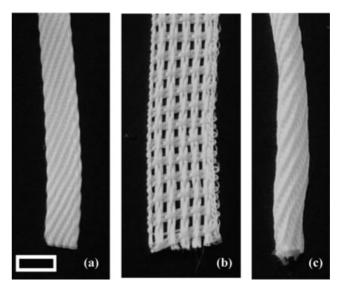


Fig. 2 Macroscopic images of the synthetic tissues, scale bar = 5 mm: (a) sample A, (b) sample B, (c) sample C

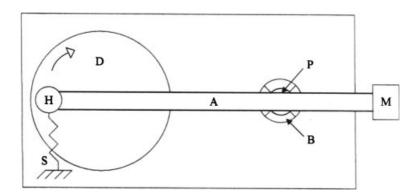


Fig. 3 Schematic representation of the testing apparatus (A, arm; B, bearing; D, rotating disc; H, specimen holder; M, counterbalance mass; P, pillar; S, spring; arrow indicates direction of rotation)

contact with the glass slider, with sliding being resisted by relatively low friction. The existence of this favourable regime is supported further when comparing the frictional coefficients (0.030-0.006) with studies investigating the bio-tribology of other natural tissues [25]. It would appear that the specialized tendon cellular matrix provides significantly superior lubrication properties when compared to the synthetic materials. Direct comparison of these data would indicate that the bio-tribological performance of the fibrocartilage is similar to that previously reported for articular cartilage in the human knee joint (coefficient of friction = 0.008-0.040) [27]. If this fibrocartilaginous region has bi-phasic properties similar to articular cartilage, then this value would likely represent a minimum value [34]. Biochemical similarities are also evident between the superficial surface of the articulating regions (i.e. the articular and fibrocartilaginous regions respectively), as lubricin - the molecule responsible for providing the lubricating properties within the synovial joint – has previously been identified adhered to the tendon bearing surface [28, 29]. Identification of lubricin on only the articulating region of the tendon provides further evidence of the cellular adaptation at the natural tendon–bone opposition, to minimize the effect of friction.

An enhanced understanding of natural connective tissues has enabled incremental improvements of synthetic graft designs [13, 14, 36]. Recently designed grafts are becoming stronger, have a Young's modulus close to that of natural connective tissue (and thus minimize stress shielding), and are biologically inert [3, 37–41]. While the data presented in this study again suggest that PET synthetic grafts are prone to abrasive wear – and thus are susceptible to failure [15–20, 22] – synthetic graft tribology does appear improved when manufactured with a tight weave (i.e. mixed lubrication for the tight-weaved specimens A and C, as opposed to boundary lubrication for specimen B).

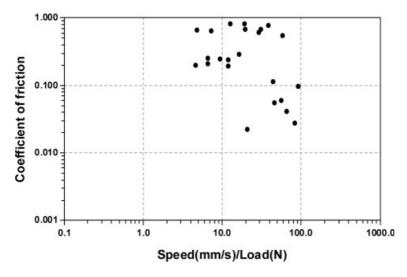


Fig. 4 The results from sample A, tested against a glass counterface

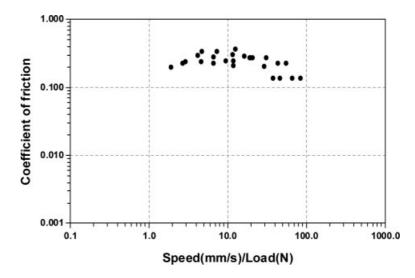


Fig. 5 The results from sample B, tested against a glass counterface

Although the bio-tribology of synthetic tissues may be improved by modifying the surface structure or using alternative materials, only a few materials with the correct properties are readily available as implantable grade fibres. Hence, synthetic tissues on the market today are manufactured from polyester, similar to the material tested in this study. Although there has been recent interest in alternative materials such as poly-L-lactic acid (PLLA) and silk [42], these have yet to be clinically proven. Since neither of these two approaches can currently provide the required characteristics, the alternative is to provide a structure that allows tissue ingrowth, rather than mimicking the natural connective tissue. The synthetic tissue then acts as a scaffold to encourage ingrowth and encapsulation, rather than being a permanent prosthetic linkage. While the new tissue will ultimately act as a barrier to prevent direct

contact between the graft and surrounding structures, the synthetic tissue is still susceptible to wear in the initial postoperative period. The rehabilitation procedure therefore plays an important role in achieving good clinical results, ensuring the tissue does not fail before encapsulation occurs. Synthetic tissues that have used such a scaffold structure can provide good long-term clinical results [43–46].

The viscosity of the lubricant, synovial fluid, is significant in determining the lubrication regime. It is also well known that temperature affects the viscosity of synovial fluid [47], and hence the experiments reported here were conducted in a laboratory at 37 °C. However, little is known about the variation in synovial fluid viscosity with the high shear rates likely to have been encountered in these tests, although it has been found that the viscosity remains reasonably constant at higher shear rates [47]. In this study, it

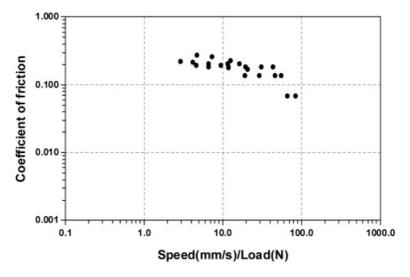


Fig. 6 The results of sample C, tested against a glass counterface

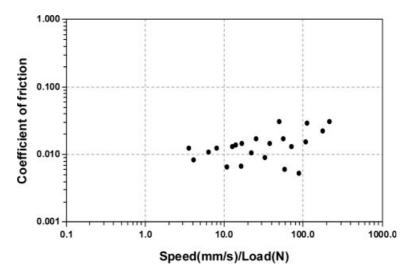


Fig. 7 The results from bovine fibrocartilaginous tendon, tested against a glass counterface

was assumed that the viscosity of the shear thinning lubricant remained constant. Owing to difficulties reported in measuring the synovial fluid viscosity during such experiments [27, 32], it was felt to be inappropriate to include this parameter in Figs 4 to 7.

The experiments in this investigation were carried out under steady rotation of the disc, although the more physiologically correct motion is that of reciprocation. No attempt has been made to introduce oscillation into the disc motion at this stage but, in similar experiments on synovial membrane, the results differed little between steady disc motion and oscillation [32]. Consistent experimental conditions were achieved by controlling the extent of arm deflection, through adjustment of the spring position. The use of the glass counterface to approximate the fibrocartilage bearing surface has been reported previously [31]. The magnitude of loading at the physiological conjuncture is unknown and hence the accuracy of the loading environment applied in the experiments is unclear; a range of sliding speeds was used to allow the lubrication regime to be ascertained.

5 CONCLUSIONS

While the specialized fibrocartilaginous bearing surface of the natural tendon appears to be capable of generating fluid-film lubrication *in vivo*, the synthetic connective tissues appear to operate in less favourable lubrication regimes. This study has, however, identified the importance of design in maximizing the graft's bio-tribological performance. The results of this study also demonstrate the importance of developing grafts that encourage tissue in-growth to gen-

erate optimal lubrication regimes. Achieving such goals will increase the lifespan of synthetic connective tissues.

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