A cadaveric study to compare biomechanical strength of tendon repairs with round-bodied and cutting needles.

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ABSTRACT

This human cadaver study investigated whether flexor tendon repairs performed with round-bodied needles had a higher risk of pull-out compared to cutting needles. Forty human cadaver tendons were repaired (twenty with round-bodied needles, twenty with cutting needles) subjected to tensile traction testing, and evaluated by failure load and mode of failure. The average failure load was 50 N (SD 13 N) for tendons repaired with round-bodied needles, compared to 49 N (SD 16 N) for tendons repaired with cutting needles. Round-bodied needles resulted in more suture pull-out (18 out of 20 tendons) than cutting needles (6 out of 20 tendons). We found no differences in failure load, but significant differences in the mode of failure between round-bodied and cutting needles when used for cadaveric flexor tendon repair

Keywords: Cutting needle, pull-out, round-bodied needle, tendon repair, tensile strength

INTRODUCTION

Cutting needles (conventional, reverse or spatula) have at least two opposing cutting edges and a point that cuts a pathway through tissue. They are designed to penetrate dense tissues with high resistance, such as skin and oral mucosa. Round-bodied needles pass through tissue by stretching rather than cutting and have a sharp tip at the point that flattens to an oval or rectangular shape with no cutting edges. These needles are used for easily penetrated tissues, such as abdominal viscera and most vascular anastomoses. They minimize the potential risk of tearing tissue.

It has been taught for many years that round-bodied needles should be used for tendon repair, as they may be less traumatic (Byrne and Aly, 2019; Strickland, 1999). However, we have not been able to identify studies with human flexor tendons that evaluated the differences in repair strengths of the tendons between round-bodied and cutting needles. The only study directly comparing round-bodied needles to cutting needles in tendon repair was performed with an animal model (Lam et al., 2003). That study reported no significant differences in tensile strength or elasticity of swine tendon repairs performed by either round-bodied needles or cutting needles.

The aim of this study was to evaluate whether the choice of suture needle affected both the load to failure and the mode of failure for flexor tendon repairs in human cadaveric hands. We hypothesized that round-bodied needles may be more prone to suture pull-out as a result of stretching the tendon fibres when passing through rather than cutting them.

METHODS

In this human cadaver study, 40 flexor digitorum profundus (FDP) tendons were tested. The tendons were randomised into either one of two study groups. Twenty tendons were tested following repair with a round-bodied needle, and 20 tendons were tested following repair with a cutting needle. Failure load and mode of failure were evaluated for all tendons.

Tendon specimens

Human samples used in this research project were obtained from the Imperial College Healthcare Tissue Bank (ICTHB). ICTHB is supported by the National Institute for Health Research (NIHR) Biomedical Research Centre based at Imperial College Healthcare NHS Trust and Imperial College London. ICTHB is approved by Wales REC3 to release human material for research (17/WA/0161).

Forty frozen thawed FDP tendons were used. The tendons were harvested from the index, middle, ring and little fingers of 11 cadaveric specimens (six males and five females) (mean age 56 years, range 46 - 68 years). The 11th specimen was used to equate the type of repair for each of the digits. Each tendon was transected with a surgical scalpel at flexor Zone 3 and repaired by a single surgeon (GV). Following randomisation, 20 tendons were repaired with a round-bodied needle (RB-1, 17 mm, 1/2c) and 20 tendons were repaired with a cutting needle (FS-3 CONV, 16 mm, 3/8c). The repair was carried out using a four-stranded Adelaide core suture with a 3-0 synthetic, monofilament, nonabsorbable polypropylene suture (Prolene®, Ethicon Inc., Somerville, NJ, USA). Polypropylene sutures were chosen as they may have superior knot security compared to nylon and polyamide sutures (Choke et al., 2021). No epitendinous repair was done, to avoid unintentional needle-induced damage and subsequent weakening of the core suture (Figure 1). The repaired tendons were kept moist by spraying with normal saline at room temperature during preparation.

Figure 1. (a) A four-strand Adelaide core suture was used with distances of 7mm and 10mm to the repair site, respectively. (b) Time-elongation graph for two index finger flexor digitorum profundus tendons. Specimen A was repaired with a round-bodied needle and shows a suture pull-out force of 51 N. Specimen B was repaired with a cutting needle and shows a more abrupt tendon elongation against no resistance at 62 N. PE: pre-tensioning elongation; 20@500: cyclic elongation with load at 20 N at 500th cycle; 30@500: cyclic elongation with load at 30 N at 500th cycle.

Biomechanical testing

The prepared specimens were subjected to cyclic tensile testing using an Instron 5866 testing machine equipped with a 500 N load cell (Instron Co., High Wycombe, Bucks, UK). Two soft tissue freezing clamps (Pring et al., 1985) were used to fixate both ends of the specimen to the testing machine. The distance between the clamps was set at 50 mm and the tendon was mounted with the repair site midway between the clamps. Moderate pressure was applied to the clamped part of the tendon to ensure that sufficient grip was exerted to hold the specimen in place. During the cyclic tensile test, carbon dioxide (CO₂) gas was used to freeze the clamped part of the tendon to prevent slippage due to the tensile load applied. Application of CO₂ was ceased after the tendon froze to the undeformed zone ($\approx$ 5 mm from the clamp). As a result, the centrally mounted repair site and the respective 20 mm on each side of the repair were evaluated during tensile testing. As tendon lengths were standardised, and the literature would suggest that the cross-sectional area of the tendon does not affect a 4-strand repair (Boyer et al., 2001), it is valid to say that the tendons from each finger were equivalent.

The tendon was preconditioned with a ramp load from 0 N to 10 N at a rate of 200 mm/min. A cyclic loading protocol then was implemented, consisting of sets of 500 cycles, corresponding to five to ten days of active rehabilitation (Linnanmäki et al., 2018). The amplitude of the cyclic loading was increased in 10 N increments each set. Following the 500th cycle of each loading amplitude, the crosshead was fixed for 5 seconds at the displacement reached with the maximum force, to allow the measurement of the gap formation at the repair site. The gap was determined by measuring the largest section of the gap with digital callipers and the distance was determined in millimeters. The largest section was the longest distance between tendon ends. Gap formation measurements were carried out by two observers (GV and WR). The cyclic tensile test was stopped once the repair failed and the mode of failure and failure load were recorded. During cyclic testing, time-elongation graphs were made for each tendon. Failure was defined as no resistance against elongation at the time-elongation graphs, or as a clinical gap formation of more than 2 mm. Failure load was defined as the load value (N) at the failure point. Mode of failure (either suture rupture or suture pull-out) was assessed by both direct observations and time-elongation graphs (Figure 2). Data were collected using the materials testing machine software (Instron Bluehill materials testing software, Instron Co., High Wycombe, Bucks, UK).

Statistical analysis

Statistical analyses were used to evaluate a difference in failure load and mode of failure between tendons repaired with round-bodied and cutting needles. Parameters were assessed by a Kolmogorov-Smirnov test to evaluate whether they were normally distributed. For normally distributed continuous parameters a Student's unpaired t-test was performed. If continuous parameters were not normally distributed, a Mann-Whitney U-test was performed. Discrete parameters were assessed by a Chi-square test. Differences between index, middle, ring and little finger were assessed using an ANOVA test when parameters were normally distributed and a

Kruskal-Wallis test for non-normally distributed parameters. Statistical significance was accepted at the level of $p \leq 0.05$.

RESULTS

Forty FDP tendons were evaluated. Twenty tendons were repaired with round-bodied needles and twenty tendons were repaired with cutting needles. Both groups consisted of tendons from five index fingers, five middle fingers, five ring fingers and five little fingers. All observed failures were due to suture pull-out or suture rupture. A gap formation of more than 2 mm was only seen if the repair failed during the very next cycle.

Failure load

The average failure load was 50 N (SD 13 N) for tendons repaired with round-bodied needles, compared to 49 N (SD 16 N) for tendons repaired with cutting needles. There was no significant difference in the failure load of the two groups ($p = 0.89$). The failure load for each finger is shown in Table 1. There were no significant differences between needle type for each finger.

Table 1. Failure load of the tendons in each finger.

	Mean failure load (N)		
Finger	Round-bodied needle	Cutting needle	P-value
Index	58 (SD 6)	41 (SD 24)	0.25
Middle	50 (SD 10)	46 (SD 15)	0.46
Ring	43 (SD 20)	54 (SD 11)	0.29
Little	43 (SD 11)	54 (SD 13)	0.18

Mode of repair failure

Suture pull-out was observed in 18 out of 20 tendons that were repaired with a round-bodied needle, compared to six out of 20 tendons that were repaired with a cutting needle ($p < 0.01$). Suture rupture was observed in two tendons (10%) that were repaired with a round-bodied needle, compared to 14 tendons that were repaired with a cutting needle ($p < 0.01$). No knot failure was observed.

DISCUSSION

We found no difference in failure load between tendons repaired with round-bodied and cutting needles. However, the mode of failure was different for the needle types. In our study, tendons repaired with a round-bodied needle had a statistically significant higher rate of suture pull-out in the majority of samples compared with only one-third of the samples repaired with cutting needles.

The difference in pull-out incidence can be explained by the cutting mechanism of the different needle types in relation to the tendon fibres. Round-bodied needles separate the tendon fibres when they pass through (Byrne and Aly, 2019), creating a potential passageway for future pull-out when the tendon is put under traction. Cutting needles perforate the tendon with sharp needle edges, cutting the tendon fibres rather than pushing them apart. The risk of tissue cut-out is reduced, as the hole left by the needle leaves a wide wall of tissue that provides resistance to the suture, rather than a potential passageway (Byrne and Aly, 2019). Sahoo et al. (2012) tested the effect of suture needle shape on acellular human dermis patches used for rotator cuff repair. They showed that constructs prepared with reverse-cutting needles reduced the compliance of dermis for rotator cuff repair compared with constructs prepared with round-bodied needles. The reverse-cutting needles moved the penetration hole away from the edge of the graft, reducing the risk of needle cut-out and suture cut-through (Sahoo et al., 2012).

Frick et al. (2001) tested resistance forces acting on a straight 2-0 cutting needle when passing sheep skin and sheep Achilles tendon. When the needle pierced tendon tissue, only one resistance peak was found (when the needle left the tendon). This was in contrast with a needle piercing skin, which showed two resistance peaks (when entering epidermis and when piercing dermis). This suggests that even a cutting needle separates tendon fibres rather than exclusively cutting them. This might explain why one-third of the samples that were repaired with cutting needles in our study had a pull-out mode of failure.

In addition to being less prone to suture pull-out, cutting needles make a suture more prone to rupture. Nduka et al. (2001) demonstrated a core suture that was damaged by a suturing needle on electron micrographs. The likelihood of needle-induced damage is further increased when a suturing technique with multiple passages is performed. With each passage that is made, the risk to the suture increases. This damage weakens the repair and may lead to failure (Nduka et al., 2001). Damage to the core suture from a cutting needle has also been demonstrated as the result of an epitendinous repair (Boyce and Srivastava, 1999). The authors therefore advised to take only epitenon when performing an epitendinous repair, in order to prevent damaging the core suture. As round-bodied needles are considered less likely to damage the core suture, this might explain the higher rupture rate of tendons repaired with a cutting needle in our study.

Our study has a number of limitations. First, a cadaver study is unable to represent the complex physiological processes that occur during tendon healing in living humans. However, the importance of different needle types plays an immediate role at the time of repair and in the first days of healing. Gelberman et al. (1999) showed that biological strengthening only starts after 5 to 10 days of active rehabilitation. Therefore, we expect no major impact of the fact that our study was not conducted in vivo. Second, only 40 human cadaver tendons were used in this study. Third, no epitendinous repair was used in this study. It is known that peripheral sutures tidy up the repair and prevent gapping (Tang et al., 2017). Successful 6-strand core repairs with no peripheral sutures have been described (Giesen et al., 2018; Pan et al., 2019, 2020), however, 4-strand core repairs alone are not considered strong enough (Wu et al., 2021). Caution should therefore be taken in directly extrapolating the study outcomes to clinical practice. Finally, gap formation force was not recorded continuously in this study. Gap formation force is an important and relevant factor in successful clinical outcomes (Wu and Tang, 2021; Wu et al., 2021).

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