LOAD RESPONSE AND GAP FORMATION IN A SINGLE-ROW CRUCIATE SUTURE ROTATOR CUFF REPAIR

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ABSTRACT

Background: Double-row rotator cuff tendon repair techniques may provide superior contact area and strength compared to single row repairs, but are associated with higher material expenses and prolonged operating time. The purpose of this study was to evaluate gap formation, ultimate tensile strength and stiffness of a single-row cruciate suture rotator cuff repair technique, and to compare these results to those of the Mason-Allen and SutureBridge repairs.

Methods: Infraspinatus tendons from twenty-four spring lamb shoulders were harvested and allocated to cruciate suture, Mason-Allen and SutureBridge repair groups. Specimens were loaded cyclically between 10 and 62 N for 200 cycles, and gap formation simultaneously measured using a high-speed digital camera. Specimens were then loaded in uniaxial tension to failure, and construct stiffness and repair strength evaluated.

Results: Gap formation in the cruciate suture repair was significantly lower than that of the Mason-Allen repair (mean difference = 0.6 mm, $p=0.009$) and no different to that of the SutureBridge repair ($p>0.05$). Both the cruciate suture repair (mean difference = 15.7 N/mm, $p=0.002$), and SutureBridge repair (mean difference = 15.8 N/mm, $p=0.034$) were significantly stiffer than that of the Mason-Allen repair; however, no significant differences in ultimate tensile strength between repair groups were discerned ($p>0.05$).

Conclusion: The cruciate suture repair construct, which may represent a simple and cost-effective alternative to double-row and double-row equivalent rotator cuff repairs, has comparable biomechanical strength and integrity to that of the SutureBridge repair, and may

result in improved construct longevity and tendon healing compared to the Mason-Allen repair. Word Count: 250

INTRODUCTION

Surgical repair of full-thickness rotator cuff tear aims to re-establish the fibrovascular interface between the tendon and bone, which is necessary for healing and restoration of the fibrocartilagenous tendon insertion. High biomechanical fixation, as well as reproduction of the native tendon anatomical footprint, has been shown to lead to improved construct performance under loading;⁴ however, recurrent tearing of the repaired has been reported in 20 to 82% of cases.^{8, 11} Causes of rotator cuff repair failure include anchor pull-out, surgical knot loosening, and suture breakage or tendon tear at another location; however, suture pull-out through the tendon has been shown to be the most common construct failure mode in both single- and double-row repairs, and occurs at a load that depends greatly on the given tendon repair technique.³

The ultimate tensile strength and stiffness of a repair construct are frequently used as a surrogate measure of the construct integrity. Since the mean time between primary and revision tendon repair has been shown to be 7.7 weeks, which represents approximately 51-64% of the time required for total tendon healing,²¹ the immediate and short-term biomechanical strength of a repair may be clinically relevant in healing and construct longevity.⁷ The single-row Mason-Allen repair has been shown to exhibit greater ultimate tensile strength compared with simple single row repairs,³ but exhibits a lower ultimate tensile strength than that of double row and double-row equivalent repairs.^{15, 20} Double-row techniques provide superior tensile strength compared to single row repairs due to the increased number of anchors, tendon-suture

perforations and the overall greater tendon footprint available for tendon-suture integration;¹⁶ however, a number of studies have found no difference in the stiffness between the double-row, Mason-Allen, and double-row equivalent SutureBridge repairs immediately after repair.²⁰ These somewhat counterintuitive results suggest the presence residual suture slack in the repair construct prior to loading. Cyclical loading or pre-conditioning of the repaired tendon immediately after surgery has been shown to increase the construct's measured stiffness.¹⁴

Gap formation under cyclic loading has been used as a measure of repair integrity and longevity, since motion at the tendon-bone interface can delay or inhibit tendon-bone healing. It has been shown in a rat model that prolonged repetitive loading at the repaired tendon complex has been associated with significantly increased collagen fiber organization, decreased matrix metalloproteinase expression and less fibrocartilage 21 days postoperatively.¹² The Mason-Allen repair has been shown to exhibit larger gap formation compared with the traditional double row repair¹⁹ and the SutureBridge repair,²² whilst other studies have shown the SutureBridge and double row repairs to exhibit equivalent gap formation. Since double row repairs are associated with higher material expenses, prolonged operating time, and are technically more difficult for the surgeon, greater emphasis has been placed on improving the functional performance and clinical outcome of single-row procedures.

Caldow et al (2015) reported a single-row cruciate suture repair consisting of two bone anchors with four suture perforations through the tendon from each anchor, which are tied off in mattress stitches at 45° to each other. It was shown that the cruciate suture repair exhibited similar footprint contact area and pressure to that of the double row repair.⁶ Despite

these apparent advantages, gap formation has not been evaluated in this construct, and its long-term strength integrity remains largely unknown. The objective of this study was to develop a biomechanical model to evaluate the fixation strength of the cruciate suture repair. The specific aims were twofold. Firstly, to quantify gap formation, ultimate tensile strength and stiffness of the cruciate suture repair, and secondly, to compare these results to those of the single-row Mason-Allen repair and the double-row equivalent SutureBridge repair.

MATERIALS AND METHODS

Specimen preparation

Twenty-four fresh-frozen spring lamb shoulders of six-month age were obtained and all soft tissue from the proximal humerus and scapula of each specimen were removed by sharp dissection. The infraspinatus tendon was detached from the infraspinatus fossa of the scapula and greater tuberosity of the humerus, and its muscle resected. Anatomical measurements of all specimens were performed with digital callipers (Absolute Digital Caliper 500 Series, Mitutoyo, USA) including infraspinatus tendon thickness at origin and insertion, tendon width at insertion and origin, tendon length, humeral thickness at nutrient artery level, humeral head width and humerus length. All specimens were screened for macroscopic signs of degeneration. Specimens were stored at -20 °C following dissection and were thawed for 24 hours prior to experimentation.

Surgical repair technique

Specimens were randomly assigned to three repair groups: (1) single-row cruciate suture repair consisting of two overlapping stitches oriented 45° to the tendon (Fig. 1A),⁶ (2) single-row

Mason-Allen repair consisting of a mattress stitch and overlapping simple stitch (Fig. 1B) and (3) double-row equivalent knotless SutureBridge repair consisting of two medial row mattress stitches with the free suture limbs passing to two lateral row anchors (Fig. 1C). All surgeries were performed with non-absorbable suture anchors (Smith & Nephew Inc, London, UK) and No. 2 Fiberwire suture. In the case of the SutureBridge repair, knotless absorbable SwiveLock[®] anchors were used in the lateral row (Arthrex, Naples, Florida, USA). The initial knot tied for each stitch was a sliding half-hitch knot, followed by four half-hitch knots in alternating posts. All surgeries were performed by two qualified orthopaedic surgeons at one practice using a standardised technique.

Experimental protocol

All repair constructs underwent cyclic loading followed immediately by load-to-failure testing using an Instron materials testing system (Instron, Model 3521, Parker Hydraulics) instrumented with a 10kN uni-axial load cell (Instron 67918, Instron, UK) sampling at 50 Hz. The medial end of the tendon was fixed in a customised sinusoidal grip clamp, which was attached to the load cell and upper crosshead of the Instron system (Fig. 2A). The proximal humerus was embedded in a cylindrical potting block with Plaster of Paris. An adjustable alignment bracket was used to orient the humerus to ensure that tension applied to the infraspinatus tendon was in the direction of the muscle line of action.

A 10 N pre-tension was initially applied to the repaired tendon for approximately 10 seconds to remove residual tendon slack and backlash in the fixtures. The tendon was then loaded to 62 N, which represents the approximate force generated in the supraspinatus during elevation of the upper limb to 90 degrees.¹ The tendon was then unloaded to 10 N, and this load cycle repeated at a frequency of 0.25 Hz for 200 cycles, simulating the initial conditioning

loading of the construct post-operatively.^{13, 14} The position of pairs of fiducial markers placed on the greater tuberosity of the humerus, 10 mm lateral to the tendon edge, and superficial lateral tendon, 5 mm medial to the edge of the repair, was recorded with a high definition digital video camera (Canon EOS 7D, Tokyo, Japan) at a sampling frequency of 50 Hz. During testing, specimens were kept moist by irrigation with saline solution.

Tendon displacement was quantified from the change in position of the two tendon markers relative to the two humeral markers using digital image analysis (Fig. 2B and 2C).¹⁵ Gap formation at a given load cycle was defined as the peak-to-peak difference in tendon displacement relative to bone between that load cycle and the initial load cycle¹⁵. Gap formation was calculated as the average tendon marker displacement measured from the two adjacent tendon-bone markers. Following cyclic loading, each repaired tendon was then loaded in tension to failure by displacing the tendon at a constant rate of 1 mm/s⁶ whilst simultaneously sampling applied force and displacement at 50 Hz. Ultimate tensile strength was defined as the maximum tensile load that occurred just prior to complete disruption of the repair construct.^{6, 15} Repair construct stiffness was calculated from the gradient of the line of best fit applied to the resultant load-displacement curve.^{6, 19}

Statistical analysis

A Kruskal-Wallis single-way analysis of variance (ANOVA) for non-parametric data was used to analyse differences in gap formation, ultimate tensile strength and stiffness of the three repair groups. Tukey HSP post hoc testing was used to evaluate mean differences between groups and calculate 95% confidence intervals. Based on an expected gap formation of 2.5 mm, 1.7 mm and 1.7 mm in the Mason-Allen, SutureBridge and cruciate suture repairs groups,

respectively,^{14, 16, 19} a sample size of $n=24$ ($n=8$ in each group) was determined.⁴ This equates to an effect size of 0.754, and a study power of 0.817. Standard deviation and standard error of the mean were calculated and used as a measure of the dispersion of the measured data. Significance level was set at $p<0.05$. Statistical analysis were performed using the statistical package for Social Science (PASW Statistics 18, SPSS Inc., IL)

RESULTS

Ultimate tensile strength and stiffness

No statistically significant differences in ultimate tensile strength were observed between the cruciate suture, Mason-Allen and SutureBridge repairs ($p<0.05$); however, the cruciate suture repair exhibited a larger ultimate tensile strength (240.7 ± 23.1 N) compared to that of the Mason-Allen (172.0 ± 15.3 N) and SutureBridge repair (184.1 ± 15.7 N). The cruciate suture repair exhibited significantly greater stiffness compared to that of the Mason-Allen repair (mean difference = 15.7 N/mm, 95% CI [1.3, 30.1], $p = 0.020$) (Table 1). The SutureBridge also exhibited significantly greater stiffness compared to that of the Mason-Allen repair (mean difference = 15.8 N/mm, 95% CI [1.4, 30.2], $p = 0.034$). No significant differences in stiffness were observed between the cruciate suture repair and SutureBridge repair ($p<0.05$), which were 61.6 ± 4.6 N/mm and 61.7 ± 4.4 N/mm, respectively. Mean Pearson coefficient of regression values, R^2 , for stiffness regression calculations were not-significantly different between groups.

Gap Formation

The Mason-Allen repair exhibited significantly greater gap formation compared with that of the SutureBridge repair and cruciate suture repair after 50, 100, 150 and 200 load cycles ($p < 0.01$) (see Table 1). After 50 cycles of loading, the gap formation in the Mason-Allen repair was 0.6 mm larger than that of the SutureBridge repair (95% CI [0.2, 1.0], $p = 0.002$) and 0.5 mm larger than that of the cruciate suture repair (95% CI [0.1, 0.9], $p = 0.001$) (Supplementary Material). After 200 cycles, the gap formation in the Mason-Allen repair was 0.6 mm larger than that of the SutureBridge repair (95% CI [0.2, 1.1], $p = 0.002$) and 0.6 mm larger than that of the cruciate suture repair (95% CI [0.2, 1.0], $p = 0.009$). The cruciate suture repair demonstrated a slightly greater mean gap formation compared with that of the SutureBridge, however, this trend was non-significant ($p > 0.05$).

DISCUSSION

The present study found gap formation in the SutureBridge (1.1 ± 0.1 mm) and cruciate suture repairs (1.1 ± 0.1 mm) to be significantly less than that of the Mason-Allen repair (1.7 ± 0.2 mm) at 200 load cycles. The difference in gap formation between these repairs is in reasonable agreement with previous studies.^{2, 22} For example, Wellman et al (2009), using a bovine subscapularis tendon model, reported 41% smaller gap formation in a SutureBridge repair compared with that of the Mason-Allen repair²² – a finding similar to that reported in the present study (37%). Furthermore, a bovine infraspinatus model reported gap formation in the SutureBridge construct to be significantly less than that of the Mason-Allen repair at 1, 200 and 500 cycles.² The finding that the cruciate suture repair exhibits less gap formation than that of the Mason-Allen repair may be due to the differing suture configurations. The increased number of tendon perforations and the crossed nature of the cruciate sutures orients suture passes at 45° to

the tendon line of action, which been shown to increase tendon-bone contact area and pressure compared with that of the Mason-Allen repair.⁶ This suture configuration may increase the frictional force between tendon and bone through increased contact pressure, and contribute to reduced dynamic tendon slippage under tractional forces. Ultimately, this may result in lower gap formation compared to that in constructs where suture passes are oriented parallel to the tendon collagen fibre direction, or in cases where suture passes create low contact pressure.

Previous studies have suggested that high gap formation is linked to impaired biological tendon-bone healing¹⁸ and increased re-tear rates following rotator cuff tendon repair⁹. Therefore, a repaired tendon should exhibit sufficient fixation strength to prevent gap formation and re-tear through pull-out. The results of the present study show that the cruciate suture repair exhibits similar gap formation, stiffness and ultimate tensile strength to the double-row equivalent SutureBridge repair, and improved strength and gap formation relative to the Mason-Allen repair. The biomechanical performance demonstrated in the present study, in conjunction with the contact area and pressure outcomes reported in a previous study,⁶ suggest that the cruciate suture and SutureBridge repairs may result in similar short-term clinical performance. The SutureBridge may be more time consuming and costly than the cruciate suture repair, as four anchors must be placed, as is the case with other double-row constructs.^{5, 15} While the faster ‘SpeedBridge’ repair may provide speed advantages over the SutureBridge repair, since it is knotless, the cruciate suture repair involves placement of only a single row of bone anchors, and thus, may represent a quicker, easier and more cost effective alternative to double-row and some double-row equivalent repair techniques.

In the present study, the stiffness of the cruciate suture (61.6 ± 4.6 N/mm) and SutureBridge repairs (61.7 ± 4.4 N/mm) were significantly greater than that of the Mason-Allen

repair (45.8 ± 4.4 N/mm). These reported stiffness values, however, are notably larger than those reported in other studies.^{6, 19} For example, Caldow et al (2015) reported a cruciate suture repair construct stiffness of 10.9 ± 4.1 N/mm, which is 18% of the value reported in the present study.⁶ This observation was also reported in a study by Kim et al (2006), which compared stiffness in double-row and single-rows repairs after a cyclic loading regiment.¹⁴ Kim et al (2006) showed there was a 100.3% and 191.4% increase in linear stiffness between the first and 200th cycles, respectively. The greater repair construct stiffness reported in the present study may be a consequence of suture movement during the cyclic loading that was applied prior to the final tendon pull out and stiffness measurement. Tendon cyclic pre-loading is likely to eliminate residual slack in the sutures resulting in an overall less compliant repair construct and a more stable suture fixation within the collagen network of the tendon; however, this would only occur if the tendon-bone motion threshold for healing is not exceeded, which in a previous study has been identified as a gap formation of greater than 4 mm.¹⁷ The results suggest that early passive mobilisation of the upper limb to preload the construct may improve its stiffness and stability characteristics, and in the absence of excessive muscle and joint loading, contribute to improved healing.

There are a number of limitations of the present study. First, the young ovine infraspinatus tendon used in the present study may not be representative of human rotator cuff tendon anatomy, and do not model the degenerative tendon state observed clinically in many patients that present for reconstruction. However, the ovine infraspinatus is a frequently used model of the human supraspinatus due to macroscopic similarities in tendon morphology and histology,¹⁰ and provides a sound model for evaluating *relative* differences between surgical repair groups. As such, no significant between-group differences were found in tendon or

humeral anatomy (Supplementary Material). Second, the present study examined the immediate and short-term biomechanical behaviour of rotator cuff repairs and the results do not necessarily reflect the influence of tendon quality and healing on construct longevity.¹⁵ Third, the sample size used in this study may have underpowered some experimental measures. For example, there appeared to be trends in ultimate tensile strength that did not reach significance. Thus, a greater sample size may have offered greater statistical power with respect to ultimate tensile strength. Finally, while the two senior surgeons performing the procedures in this study were trained to carry out the repairs in an identical manner with the use of a suture-hole template and standardised Fiberwire lengths, there may have been some variations in the reconstructions, including those associated with suture tension, and this may have increased the dispersion of the data and influenced the statistical outcomes.

CONCLUSION

The present study demonstrated that the single-row cruciate suture repair exhibits less gap formation under loading than the Mason-Allen repair, and equivalent gap formation to the double-row equivalent SutureBridge repair. In addition, the cruciate suture repair construct was found to be of similar stiffness to the SutureBridge repair, and significantly stiffer than the Mason-Allen repair construct. Since the cruciate suture repair may ultimately be a faster, easier and more cost effective alternative to the double-row and double-row equivalent repairs, it may represent a more effective alternative to conventional single-row rotator cuff repairs.

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FIGURE LEGENDS

Figure 1: Diagram illustrating the (A) cruciate suture, (B) Mason-Allen and (C) SutureBridge repair techniques.

Figure 2: The Instron Material Test system used for load application (A), tendon repair construct (B), and gap formation calculation (C). Humerus specimens were embedded in cylindrical potting block using Plaster of Paris and the tendon repair constructs clamped using a customised sinusoidal grip clamps. A specimen alignment bracket was used to orient the specimen to ensure that the tendon was pulled in the direction of the muscle line of action. The upper cross-head was displaced upward at a constant rate while a load cell measured the force applied directly to the tendon. The locations of pairs of markers placed on the tendon and bone were measured using a high-speed camera and used to calculate gap formation. Gap formation at the n^{th} load cycle was calculated by subtracting the average distance between two tendon markers (blue dots) with respect to two humeral-fixed markers (black dots) at the first load cycle from the average distance between the two tendon markers at the n^{th} load cycle (red dots) with respect to the two humeral-fixed markers.

TABLES

Table 1: Gap formation (mm) at 50, 100, 150 and 200 load cycles, ultimate tensile strength (N) and stiffness (N/mm) data for the cruciate suture, Mason-Allen and SutureBridge repair constructs. Mean and standard error of mean (SEM) data are provided.

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Repair	Gap Formation										Ultimate tensile Strength	
	50 cycles		100 cycles		150 cycles		200 cycles		Stiffness		Mean	SEM
	Mean	SEM	Mean	SEM	Mean	SEM	Mean	SEM	Mean	SEM		
Cruciate suture	0.7	0.1	0.9	0.1	1.0	0.1	1.1	0.1	61.6	4.6	240.7	23.1
Mason-Allen	1.2	0.2	1.4	0.2	1.6	0.2	1.7	0.2	45.8	4.4	184.1	15.7
SutureBridge	0.6	0.1	0.8	0.1	1.0	0.1	1.1	0.1	61.7	4.4	172.0	15.3

Table 1: Gap formation (mm) at 50, 100, 150 and 200 load cycles, ultimate tensile strength (N) and stiffness (N/mm) data for the cruciate suture, Mason-Allen and SutureBridge repair constructs. Mean and standard error of mean (SEM) data are provided.

figure1

Figure2_combined.tif

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