Pectoralis Major Tendon Repair:

A Biomechanical Study of Suture Button versus Transosseous Suture Techniques

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Abstract

Purpose: Pectoralis major tendon avulsion injury benefits from surgical repair. The technique used and speed of rehabilitation in this demanding population remains subject to debate. We performed a biomechanical study comparing suture button (Pec Button™, Arthrex, Naples, FL) with a transosseous suture technique (FibreWire, Arthrex, Naples, FL).

Methods: Freshly slaughtered porcine humeri were prepared to model a single transosseous suture or suture button repair. A static, tensile load to failure experiment and a cyclic, tensile load experiment to model standard (10,000 cycles) and accelerated rehabilitation (20,000 cycles) philosophies were tested. The mode of failure, yield and ultimate failure load, extension (clinical failure >10mm) and the resistance to cyclic loading was measured.

Results: The mode of failure was suture fracture in all the static load experiments with 10/11 occurring as the suture passed through the button and 7/11 as the suture passed through the bone tunnels. There was a significant difference in yield load, favoring transosseous suture (p=0.009, SB 673.0N (647.2-691.7N), TOS 855.0N (750.0-891.4N)) and median extension, favoring suture button (p=0.009, SB 8.8mm (5.0-12.4mm), TOS 15.2mm (13.2-17.1mm)).

2/3 transosseous suture and 0/3 suture buttons failed before completing 20,000 cycles. The difference in mean number of cycles completed was non-significant. The difference in mean extension was 5.1mm (SB 6.7mm, TOS 11.7mm).

Conclusions: Both techniques show advantages. The difference in extension is likely to be more clinically relevant than load tolerated at failure, which is well above physiological levels. The findings do not support an accelerated rehabilitation model.

Key Words: Pectoralis Major Repair, Transosseous Suture, Pec Button, Rehabilitation

Introduction

Pectoralis major tendon rupture is an unusual yet increasingly common injury, particularly in young, typically weight lifting athletes [3]. In a meta-analysis, the median age at injury was 28 years, complete ruptures were more common than partial ruptures and occurred most frequently at the tendon-bone interface (70%), less frequently at the musculotendinous junction (27%), and rarely within the tendon substance and muscle belly (1% each) [3]. Surgical repair restores strength, function and cosmetic appearance more predictably than non-surgical management and is recommended [1, 3, 12, 13, 16, 17, 19, 27] in all but the most unfit and elderly patient [4, 5]. A number of techniques for reconstructing the tendon-bone interface have been advocated, including transosseous sutures [12]; barbed staples [6]; suture anchors [12]; and more recently, suture buttons [26]. Reports of failure following surgical reconstruction are rare but include failure at tendon-suture interface and humeral fracture [10, 23].

During postoperative rehabilitation, prolonged periods of shoulder immobilisation are routinely practiced with concurrent risk of shoulder and elbow stiffness. Accelerated and graded rehabilitation programmes [10, 15] have emerged to reduce these risks and reduce the total morbid period. To facilitate this rehabilitation philosophy, the most reliable construct for the repair must be employed. There is a paucity of biomechanical studies [8, 18] in the peer-reviewed literature to help choose between surgical techniques. Of the two published studies, neither has been able to convincingly show an advantage of other techniques over the transosseous repair [21].

In order to help determine the optimal method of tendon reattachment, we performed a biomechanical study comparing a suture button technique (Pec Button™, Arthrex, Naples, FL) with the gold standard transosseous suture repair technique. We have used a model that accurately represents our study population and clinically derived data to detect clinically relevant differences. The null hypothesis was that there would be no difference in the mode of construct failure, the ultimate load to failure and the resistance to cyclic loading failure between the two models.

Materials and Methods

Specimen Preparation

A freshly slaughtered, porcine humerus model was selected to reproduce the strong and hard bone of young, weightlifting athletes. The bone density of 8 month old porcine humeri is comparable to middle aged humans [14] with cortical diameters comparable to that of adult, Caucasian, human bone at the level of the pectoralis major footprint (Figure 1a & 1b**)** [9]. The specimens were stripped of soft tissue and surgically prepared as detailed below. The specimens were then wrapped in Ringers Lactate soaked swabs and double bagged to prevent drying. The specimens for the ultimate load to failure experiment were tested immediately. The cyclic loading specimens were frozen at -20˚C and thawed overnight before testing.

The models were randomly assigned in equal numbers to either a suture-button (SB) or transosseous suture (TOS) group and then to one of two experiments, static tensile load to failure or cyclical tensile load for testing.

Surgical Technique

The SB model was prepared as described by Schnaser et al [22]. The technique employs a unicortical drill hole, a suture button (Pec Button, Arthrex, Naples, FL) that lies within the medullary canal and light decortication [of the pectoralis major tendon footprint] to bleeding bone. A 10x20x2mm trough in the tendon footprint was created before passing a 3.2mm drill to facilitate passage of the suture button. A suture button (Pec Button™, Arthrex, Naples, FL) with two suture loops (#2 Fibrewire™, Arthrex, Naples, FL) were passed intramedullarily and adjusted to sit snugly against the medullary cortex, with four suture ends protruding (Figure 2).

The TOS model was prepared with an identical footprint trough, two 3.2mm drill holes 1cm apart and two corresponding drill holes in the lateral cortex. Two sutures (#2 FibreWire™, Arthrex, Naples, FL) were passed creating two suture loops lying over the lateral, 1cm bone bridge. Two suture ends were left protruding through each trough drill hole (four suture ends in total) (Figure 3).

Biomechanical Test

Testing was performed on a screw driven-materials testing machine (Model 3365, Instron Corporation, Norwood, MA, USA) with a 5KN load cell (accuracy ±0.5% down to 1/100th of load cell capacity and ±0.5% of displacement reading) in a controlled environment of 20 degrees Celsius, 50% humidity and atmospheric pressure. The testing machine was driven either in load or position control, depending on the nature of the experiment, by Bluehill® 3 testing software (Instron Corporation, Norwood, MA, USA), data acquisition was performed using the same package. The sutures were attached by tying the free ends over a smooth T-bar with five consecutive reef knots, creating two independent suture loops (Figure 4a & 4b).

FiberWire^{TM} (Arthrex, Naples, FL) is a contemporary, surgical suture material. The biomechanical characteristics of the material have been well described [20]. Failure under tensile load is typically via a bimodal sequence, with initial failure of the core fibers (**Figure 5**). Abrasion failure is typically by disruption of the outer fibers first. In this study, the initial failure is referred to as the first peak and the ultimate failure is the second peak, with corresponding load and extension measurements. Either may denote clinical failure, depending on the clinical scenario.

Experiment 1 – Static, Tensile Load to Ultimate Failure:

The experiment replicates a single catastrophic event resulting in the re-disruption of the suture-bone interface. Each bone was clamped onto the baseplate of the materials testing machine ensuring the sutures were perpendicular to the surface of the bone and to the horizontal bar of the loading jig. The model is prepared with a 45mm gauge length and a 20N preload before tensioning at a 4mm/sec displacement rate. Mode of failure (bone, suture at bone interface or intra-substance suture and if failure has typical abraded appearance), load and extension at first and second peaks are recorded. Extension is a surrogate measure of gapping at the tendon-bone interface. We use 10mm of extension as a clinically important amount, over which clinical failure by gapping would occur.

Experiment 2 - Cyclical Tensile Load:

The experiment replicates the early period after reconstruction, where the tensile load is born solely by the repair. Our locally devised (but not yet clinically implemented) accelerated rehabilitation model includes 10 cycles of active adduction and 10 cycles of active internal rotation, every hour for 12 hours a day. Over a twelve-week programme, this totals 20,000 cycles. By twelve weeks, healing is sufficient to at least share the load with the repair [24].

There is no literature directly assessing the force transmitted by a human pectoralis major tendon. An isokinetic dynamometer experiment of horizontal adduction in the plane of the scapula in young, athletic patients' shoulders following pectoralis major repair (mean 21 months following surgery) recorded maximum torque of 89-92Nm at 60 degrees per second and 86-95Nm at 120 degrees per second [7]. By estimating the mid point of the tendon insertion to lie 9cm distal to the centre of rotation of the humeral head, a range of maximum possible force generated of between 956N and 1056N is calculated. Pectoralis major is not the only adductor of the shoulder and the model reproduces at most 50% of the repair (typically two or three suture buttons are recommended or six to eight suture ends in a transosseous repair). A cyclic tensile force of one third of the maximum calculated load, 350N, is used.

The prepared models are secured in the jig as above and sequentially cycled between 20N and 350N of load with a displacement rate of 10mm/s, corresponding to a cycling frequency of 0.5Hz, until either failure or 20,000 cycles completed. In the event of failure, the mode of failure (bone, suture at bone interface or intra-substance suture) and the number of cycles completed are recorded. Maximum change in extension is recorded and 10mm used to represent clinical failure by gapping.

Statistical Analysis

There is no data to help determine what constitutes a single, catastrophic load. Having calculated that during maximal, active contraction 350N is passed through each reconstructed tendon-bone interface, an assumption is made that a catastrophic load would be 50% greater or more (350N + 175N = 525N). In a similar study of pectoralis major tendon repairs in a cadaveric model [8], the standard deviation of the ultimate failure load of both a transosseous suture and suture anchor techniques was 110N. To determine the sample size a power calculation was performed, assuming alpha 0.05 and beta 0.8. To detect this difference (175N), 4 experiments in each arm are required. To compensate for the compounding assumptions in this calculation, 11 experiments in each arm were planned.

The standard rehabilitation programme practiced at the Avon Orthopaedic Centre, Bristol is identical to the proposed accelerated programme except that in the standard programme the patient is rested in a sling for the first 6 weeks. Standard rehabilitation patients therefore complete 10,000 cycles in the first 12 weeks, half of that of the accelerated programme. During testing therefore, a difference of 10,000 cycles between the groups is considered clinically significant. A further power calculation, assuming alpha 0.05 and beta 0.8, predicted that to detect this difference (50%), 3 specimens in each arm are required, hence 4 experiments in each arm were performed.

Data was analysed using a custom-developed algorithm written with Matlab R2011b (Mathworks, MA, USA). SPSS 12 (IBM, NY, USA) was use to perform statistical analysis. Kolmogorov-Smirnov test of normality of data distribution is used in the static tensile load experiments. Continuous, parametric data are tested with an Independent Samples Median Test with 2-tails and presented as median, 95% confidence intervals. $P<0.05$ is chosen as significant.

Results

Experiment 1 – Tensile Load to Ultimate Failure:

Eleven tests in each group were performed. The mode of failure was at the suture in all cases with no failure of the bone and no clear evidence of failure by suture abrasion. In the SB group, 10 of the 11 sutures failed as the suture passed through the button and one suture failed at the jig. In the TOS group, 7 sutures failed within the bone and 4 sutures failed in their mid-substance.

Tests of normality revealed a parametric distribution of load and extension. There was a significant difference in extension between the two groups at the first peak (p=0.009) (SB 8.8mm (95% confidence interval; 5.0-12.4mm), TOS 15.2mm (13.1-17.0mm)) (**Figure 6**). The difference between the extensions at the second peak approached but did not reach significance (p=0.086) (SB 14.8 (13.7-17.4), TOS 19.6 (17.4-22.0)) (**Figure 6**). The median load at first peak approached but did not reach significance (p=0.086) (SB 525.0N (199.7-586.5N), TOS 694.0N (562.3-759.0N)) (**Figure 7**). The median load at second peak was significantly different (p=0.009) (SB 673.0N (647.2-691.7N), TOS 855.0N (750.0-891.4N)) (**Figure 7**).

Experiment 2 - Cyclic Tensile Load:

Three tests were successfully performed in the each group. In one SB test, the suture slipped off the t-bar and in one TOS test, the knot failed.

Two of the three tests in the TOS group failed before completing 20,000 cycles. The mode of failure was suture fracture in both cases, one at the knot and one in the sutures mid substance. Neither had typical features of suture abrasion failure.

The numbers of cycles before failure and mean number of cycles completed are shown in **Table 1**. The difference between the means was not significant. The change in extension between cycle one and final cycle is shown in **Table 2**.

Discussion

The most important findings from the present study are that the suture button technique has shown parity with the transosseous suture technique for pecotoralis major tendon reconstruction, with neither technique being clearly superior. There are specific advantages to each technique that the surgeon should consider. Although TOS has a superior resistance to tensile load, both techniques fail well above normal physiological loads. The SB has superior resistance to tendon-bone gapping, which is likely to be more clinically relevant. The study does not support an accelerated rehabilitation philosophy.

In the published studies of pectoralis major tendon reconstruction, no clear advantage of contemporary techniques over the classical TOS have been shown [2] and suture anchor repairs appear inferior [8, 18]. Interestingly, this is not the case in a study of distal biceps repair where SB showed an advantage over TOS [11]. In each published biomechanical pectoralis major experiment, a suture-tendon repair interface has been included (41 individual tests in total). In no cases has this interface been the site of failure. The TOS was therefore considered to be the gold standard with which to test the SB against and the suture tendon interface was removed.

Clinically relevant differences rather than arbitrary statistical percentages are used to detect differences between the two groups in this fully powered study. The loads used and cycles tested are calculated from clinical data derived from post operative patients [7] and rehabilitation regimes. The calculations purposefully err to reduce the risk of false negative and false positive results.

The study aims to inform surgeon's choice. It is the first biomechanical experiment testing pectoralis major rehabilitation strategies. Further findings that may assist in surgical decision making are as follows:

- SB is a simpler technique. The unicortical position ensures visual confirmation that the button has been engaged and avoids exposure of the posterior-lateral aspect of the humerus. It requires with less dissection, less risk to the axillary nerve and shorter surgical time.

- TOS materials are financially more efficient. The Pec Button is sold as part of an implant delivery system (£554), which contains 4x buttons preloaded on FiberWire sutures with needles and a disposable drill pin and introducer. An equivalent 8x suture FiberWire TOS repair would cost £232 plus the price of a disposable drill pin.

- The cyclical study was unable to show a difference of 10,000 cycles, which is considered the difference between rehabilitation philosophies and our data does not support accelerated rehabilitation.

- The mean extension at the end of the cyclic experiment in the TOS group was nearly double the SB group. This suggests that TOS repairs have a greater risk of failing by tendon-bone gapping than those repaired with SB.
- The mode of failure appears to be different between repair techniques. FibreWire has a greater tensile strength than other contemporary polybraided sutures but it is more sensitive to failure by abrasion [20]. In the TOS technique, the suture passes through two 90 degree turns over the bone bridge. In the SB technique, there is just a single 180 degree turn. This may help explain why 7/11 TOS failed at the bone suture interface compared with 10/11 failures at the button. Interestingly, there was no evidence of abrasion failure in this study.

Transferring biomechanical results to a clinical setting should be performed with care. Any biological model is subject to inter-specimen biomechanical variation. Porcine humeri were chosen as a better model of our study population [14] than osteoporotic cadaveric bone or other synthetic models. Cadaveric bone suffers from age related osteoporosis [25] and therefore is prone to early failure under tensile loads by brittle fracture as seen in previous studies [8, 18]. Even the relatively youthful cadavers used by *Rabuck* et al. [18] (mean age 54.4 years) are well beyond the typical age of the population under investigation [3]. Modeling a rehabilitation regime in the laboratory is an imprecise representation of a clinical programme. Few if any patients are motivated enough to comply with their instructions with such discipline as the study models.

This study is relevant to surgeons deciding which techniques to employ when faced with this injury and builds on the published material already available.

Conclusion

The suture button technique has shown parity with the transosseous suture technique of pecotoralis major tendon reconstruction and has superior resistance to clinical failure by tendon-bone gapping. The study does not support an accelerated rehabilitation philosophy.

The authors declare that they have no conflict of interest.

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Table 1 – Number of cycles completed before failure or end of test.

Sample	TOS (number of cycles)	SB (number of cycles)
1	5,615	20,000
2	13,822	20,000
3	20,000	20,000
Mean	13,146	20,000

Table 2 – Change in extension between cycle one and end of test.

Sample	TOS Extension(mm)	SB Extension(mm)
1	12.6	6.8
2	13.0	6.3
3	9.6	7.0
Mean	11.7	6.7

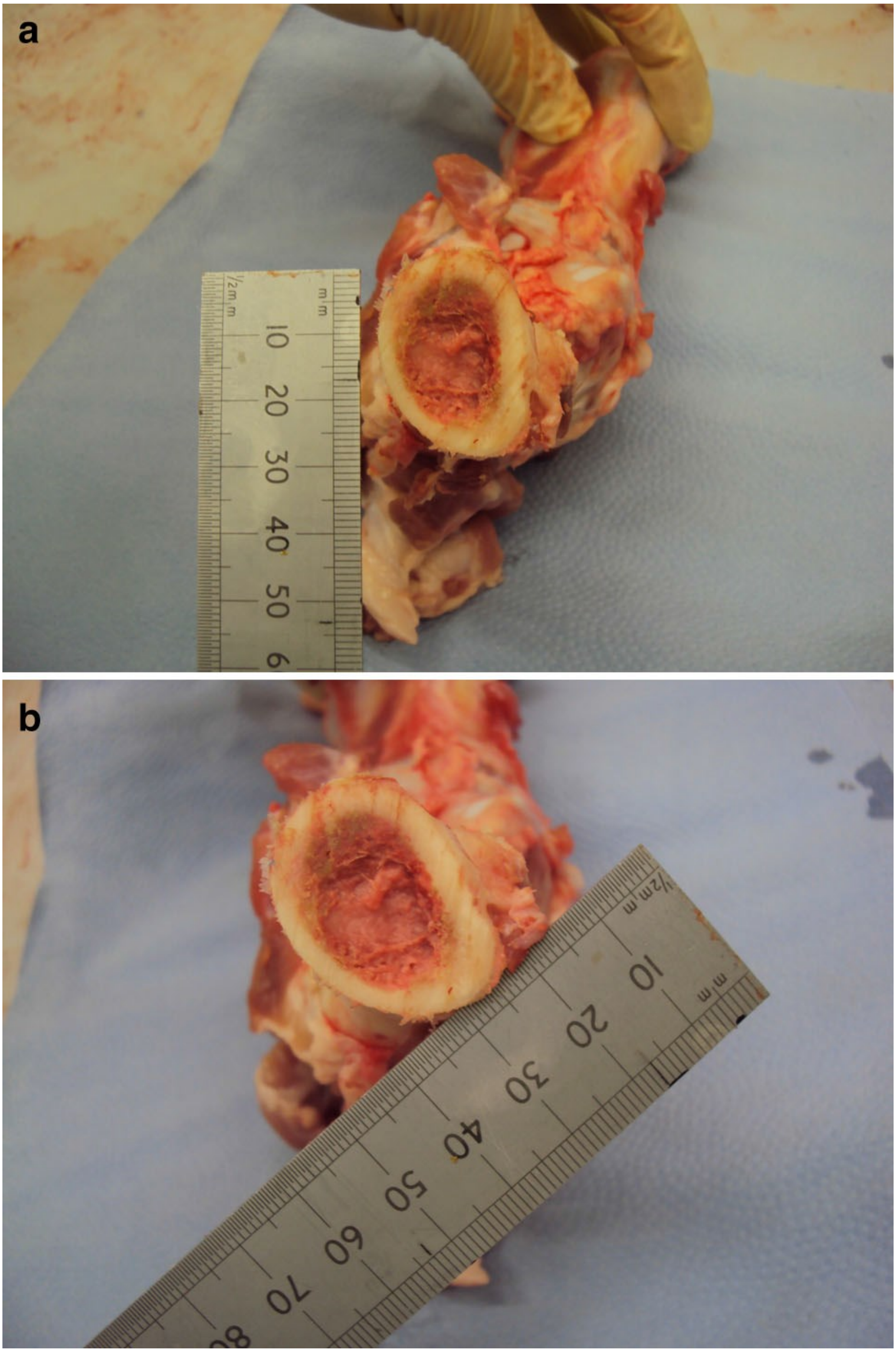

Figure 1a & 1b Cortical dimensions of porcine humerus

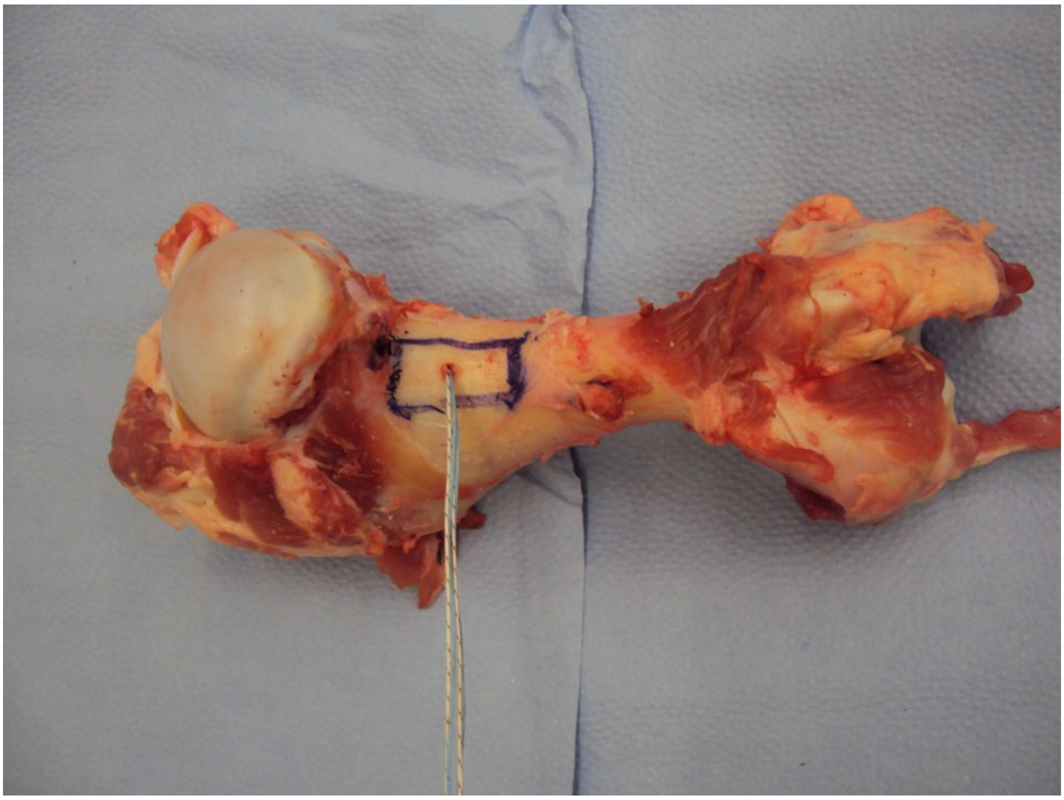

Figure 2 Porcine humerus prepared with unicortical suture button

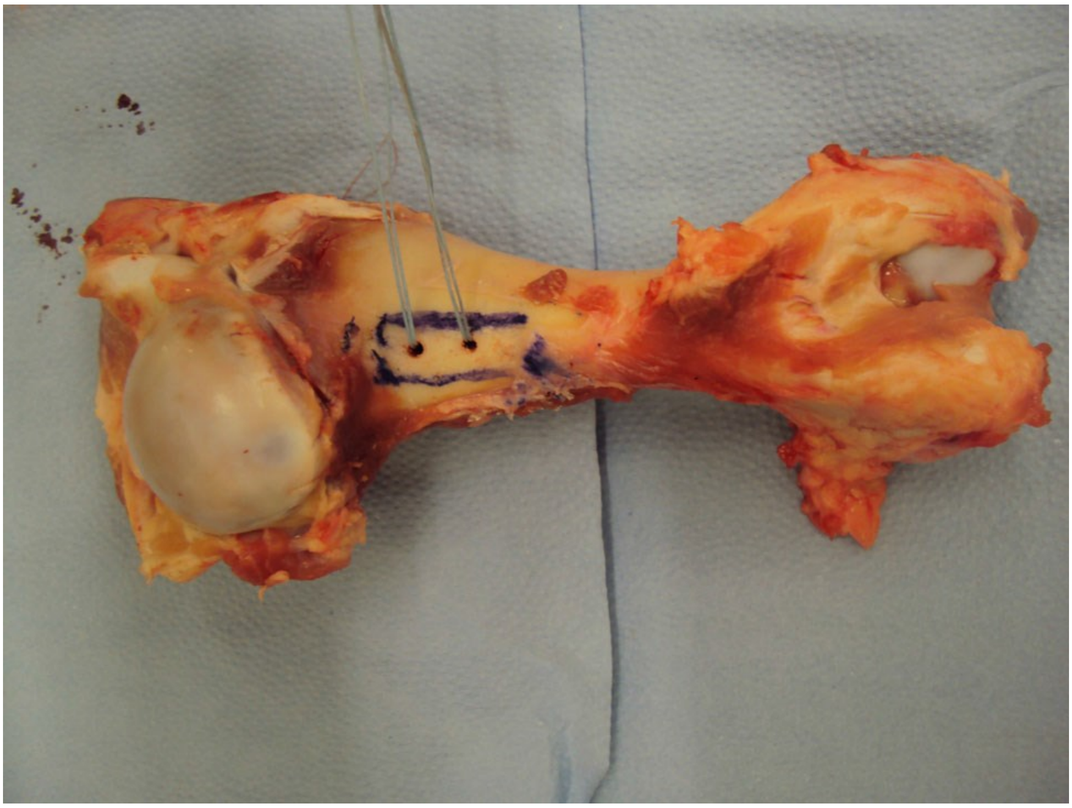

Figure 3 Porcine humerus prepared with bicortical transosseous sutures

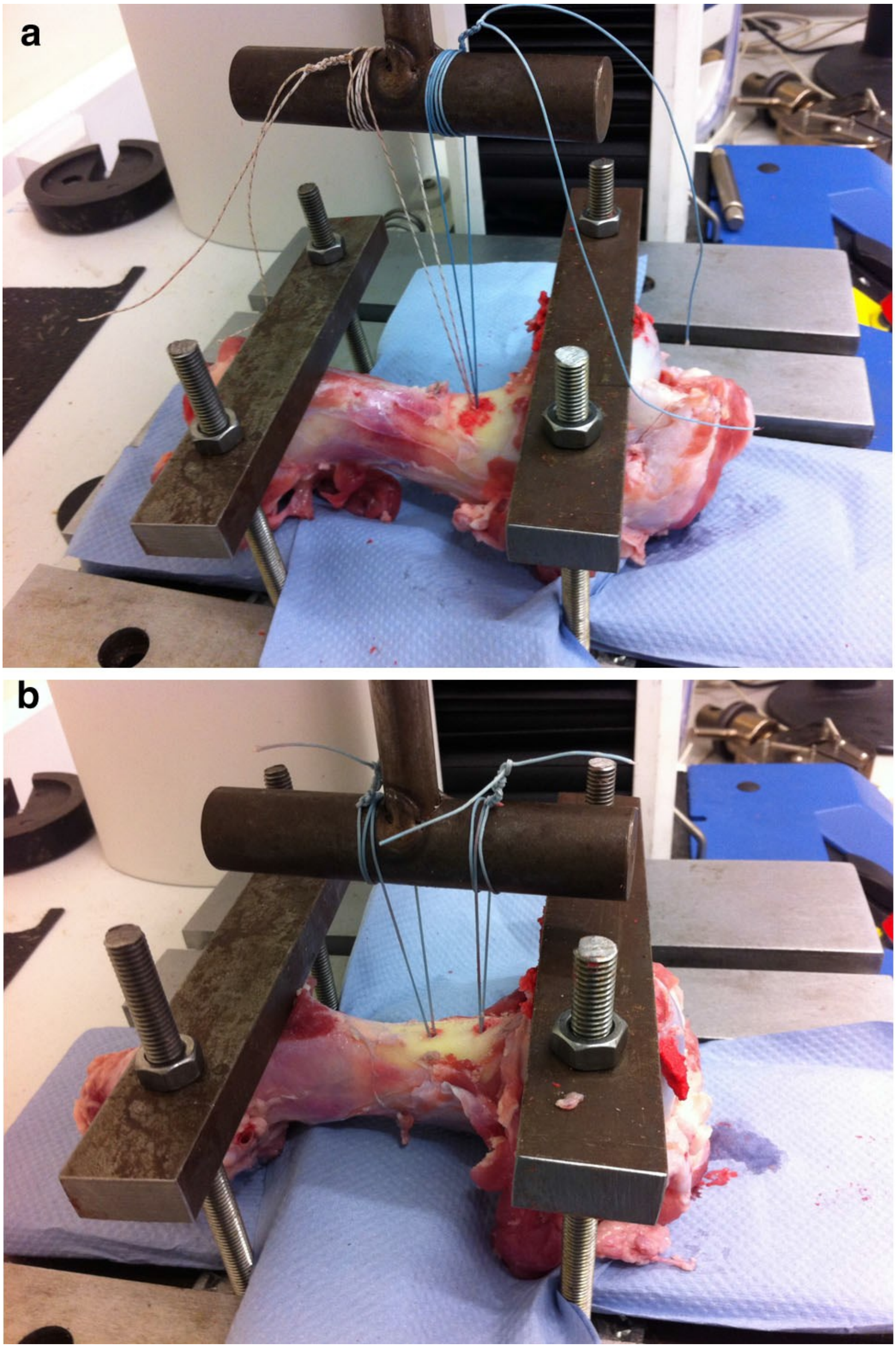

Figure 4a & 4b Prepared porcine humerus mounted in marterial testing machine

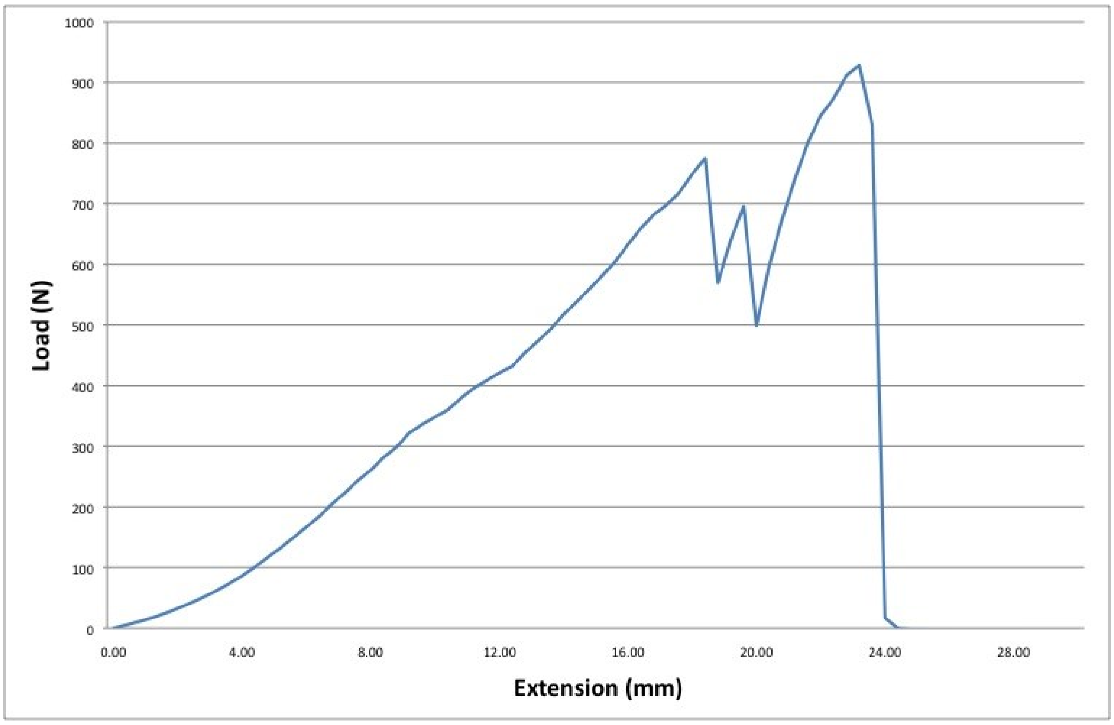

Figure 5 Typical, bimodal failure of FibreWire suture under tension

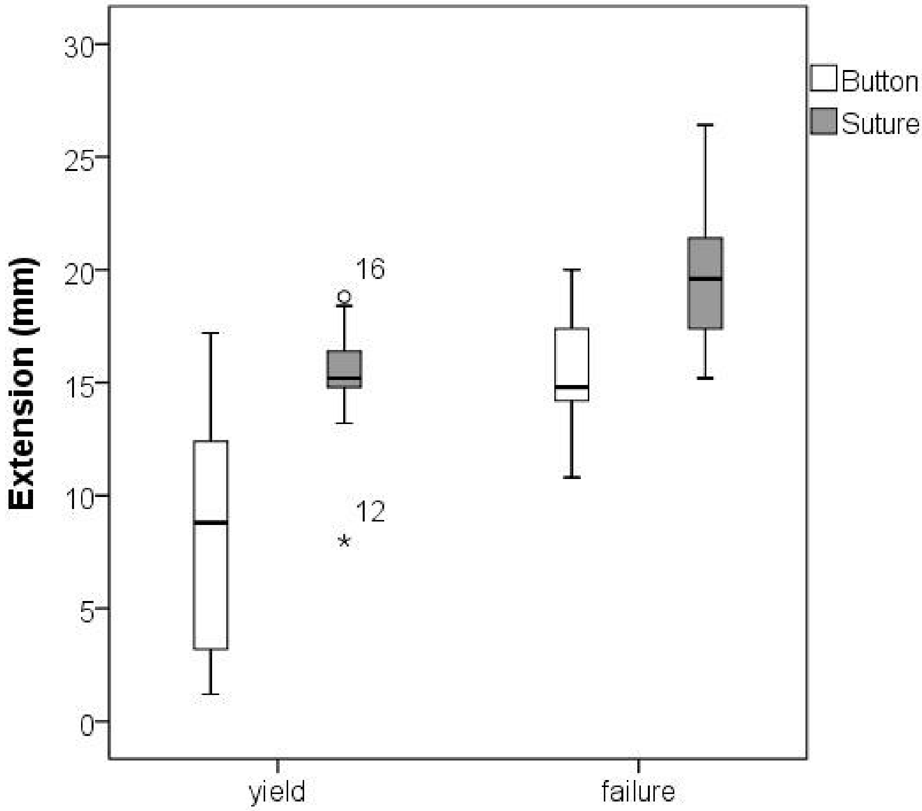

Figure 6 Extension at yield failure and ultimate failure

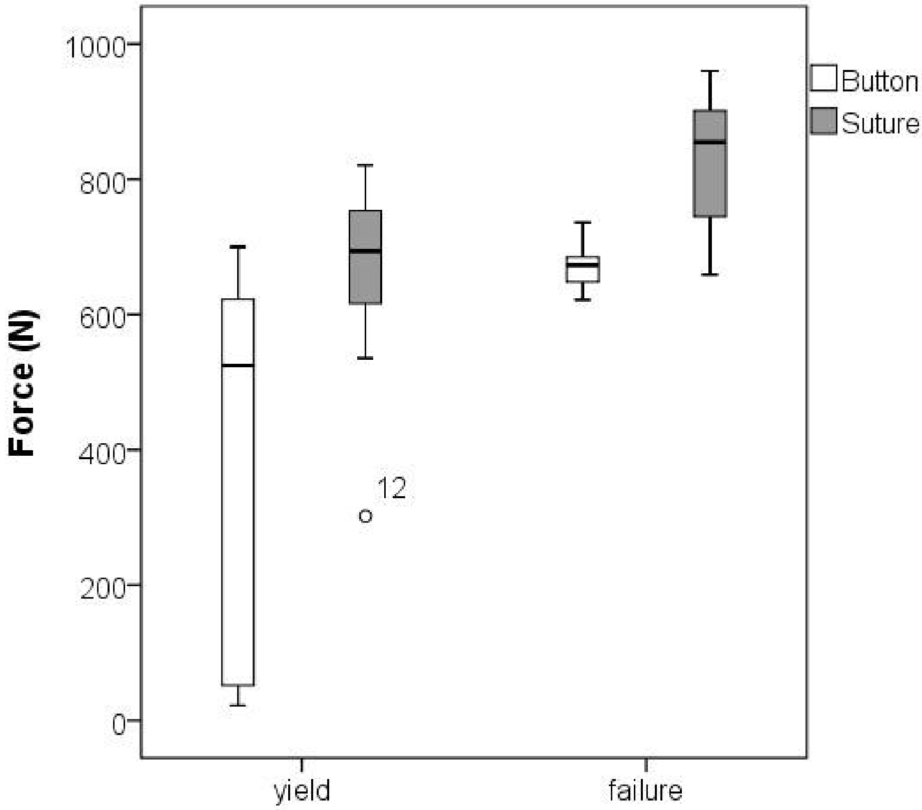

Figure 7 Median load at yield failure and ultimate failure