An Analysis of the Biomechanics of Interference Screw Fixation and Sheathed Devices for Biceps Tenodesis

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Abstract

Background
This study aimed to evaluate the differences in biomechanical properties of biceps tenodesis when performed with sheathed versus unsheathed screws and also to investigate the effect of altering the pre-tension.

Methods
Tenodesis was performed in an *in vitro* model using biomechanical test blocks and ovine tendons. Blocks were allocated to 1 of 5 groups which varied by method of tenodesis and cyclical loading protocol: Group A, Biosure PK screw (10-100N), Group B: 7-8mm Biosure Sync and Biosure PK screw (10-100N), Group C : Biosure PK screw (10-70N), Group D: Biosure PK (20-100N), Group E: Custom sheath and Biosure PK screw (10-100N). If tenodeses remained intact after 500 cycles maximum load to failure testing was performed.

Findings
30% of tenodeses in Group A failed prior to 500 cycles whereas none failed in the sheathed device groups (p=0.02). Using a sheathed device prevented mal-rotation. However, tenodeses in Group B were more likely to fail immediately distal to the tenodesis at a load below the anticipated maximum load to failure suggesting tendon damage during fixation. Using the custom sheath, which did not have sharp edges, resulted in a statistically significant increased maximum load to failure in Group E (348N) when compared to Group A (228N, mean difference 120N, p=0.01) and Group B (253N, mean difference 95N, p=0.0007).

Interpretation
Sheathed devices prevent mal-rotation and increase stiffness and maximum load to failure. This is further improved by reducing tendon damage at the time of tenodesis.

1. Introduction

The long head of biceps (LHB) tendon can be a significant source of shoulder pain. Tenotomy or tenodesis are surgical options that are indicated when non-operative management has been exhausted. Both techniques have been reported to demonstrate good outcomes but controversy exists as to which option is best. In part, this is due to a lack of high quality evidence and wide variations in study criteria and subsequent outcomes [1]. Recent systematic reviews have shown both procedures have similar clinical outcomes with the only major difference being a higher incidence of cosmetic deformity with tenotomy [1,2]. However, other authors have also reported that tenotomy is generally associated with higher rates of distal migration, muscle spasm and weakness of elbow supination [3,4,5]. These issues are often cited as reasons to select a tenodesis procedure over a simple tenotomy in young patients, muscular patients of any age and those with high functional demands, as well as those with a low body fat percentage where a cosmetic deformity is less likely to be acceptable.

There are a large number of different techniques for performing biceps tenodesis and many of these have been evaluated with respect to their biomechanics. Numerous laboratory studies have shown that the use of interference screws compares favourably to other arthroscopic techniques because of higher ultimate loads to failure and improved stiffness [6,7] but clinical results have been less promising with revision rates as high as 36-45% being reported in some series [8,9]. However, in general terms the failure rate for this procedure is not clearly defined in the literature and cosmetic deformity, or the "Popeye sign" has also been reported with similar frequency to that seen after tenotomy [10]. Failure can occur in a number of ways and is dependent on the technique and implant design. For example with suture anchors, Ozalay, et al. reported that the most common mode of failure is cut out at the eyelet [6]. With interference screws failure tends to occur most commonly by rupture at the tendon-screw interface [11] or slippage [6,12]. Some of these failures may in part be due to direct trauma to the tendon during fixation or from abrasion to the tendon by the edges of the implant or bone tunnel [11,13]. Another potential reason, highlighted by studies investigating ACL graft fixation with interference screws, is that screw insertion can cause rotation of the graft resulting in an eccentric position relative to the screw with subsequent reduced load to failure [13,14,15]. The use of a screw with a sheath may minimise these rotational forces, reduce the tendon damage caused by screw insertion and also offer improved mechanical properties secondary to the greater compression achieved by expansion of the sheath [16]. This study aims to evaluate the biomechanics of interference screw fixation for biceps tenodesis and compare this to the biomechanics of sheathed devices. This study also aims to assess the effect of pre-tensioning on the biomechanics of tenodesis. One of the technical challenges with using a screw for tenodesis compared to some of the other commonly used implants (e.g. cortical button) is that screw insertion can cause an uncontrolled and variable degree of tendon rotation and entrainment thus making accurate restoration of normal tension difficult. This failure to adequately restore the physiologic length-tension relationship of the biceps has been suggested as an important contributing factor to the high rates of revision surgery reported in some series but the influence on the biomechanics of fixation has not been studied [17].

2. Method

An in vitro model was used for biceps tenodesis. In order to eliminate variation due to differences in the quality of individual specimens of cadaveric bone we used cellular rigid polyurethane biomechanical test blocks that replicate the properties of cancellous bone (Sawbones, Malmo, Sweden). A number of different densities are available. Poukalova, et al. correlated mechanical properties of the proximal humerus with Sawbones biomechanical test blocks [18] and on the basis of this work we postulated that either the 15 or 20 pcf (pounds per cubic foot) density would be the most representative of the in vivo situation. In pre-trial studies it was noted empirically that the insertion torque for an interference screw into a 20 pcf test block was considerably higher than the in vivo situation. Conversely, we found that the 15 pcf density was a good approximation and selected that for the remainder of the study.

Flexor tendons from cow hind limbs were used to represent the biceps tendon. These were trimmed to replicate the dimensions of the human long head of biceps tendon. (Fig 1). All tendons were prepared by a single surgeon (GM) to minimise variability in technique. Uniformity was confirmed by subsequently ensuring that prepared tendons would pass with a snug fit, when doubled, through a 6mm graft sizer. A diameter of 6mm was chosen, which is 1mm less than the average 7mm diameter of a biceps tendon, because the cow flexor tendons were significantly stronger and less deformable than a human biceps tendon. By using 6mm it allowed easy insertion of the screw replicating the clinical situation. After preparation, tendons were stored frozen at -20^{o}C and then fully defrosted in a water bath at room temperature when required.

Fig 1. Showing preparation of tendons to a standardised size

Tenodesis of the biceps tendon was performed by a single surgeon (AS) using either Biceptor and/or Biosure instrumentation and either a 7x25mm Biosure PK screw alone or in combination with a Bisoure Sync sheath (all Smith and Nephew, Memphis, USA) or a custom sheath. Fifty tendons and blocks were prepared and randomly allocated to one of five groups with 10 specimens in each. Allocation to tenodesis technique and loading protocols were as follows: Group A, Biosure PK screw (10-100N), Group B: 7-8mm Biosure Sync and Biosure PK screw (10-100N), Group C : Biosure PK screw (10-70N), Group D: Biosure PK (20-100N), Group E: Custom sheath and Biosure PK screw (10-100N). The upper limit of cyclical loading of 100N was selected in these groups based on the previous work of Mazzocca et al. who demonstrated this to be 50% of the average failure load for biceps tenodesis and the fact that other authors have also used this figure in their studies [19,20]. Groups C and D were tested to evaluate whether decreasing the maximum load (i.e. effectively lengthening intra-operatively) and increasing the pre-tension (i.e. effectively over tensioning) affected the biomechanics of the construct. We used an upper figure of 70N as we felt a 30% decrease in loading compared to our standard testing regime represented a significant reduction and in fact this figure has been used by other authors thus offering some degree of uniformity for comparison between studies [12,17]. As there are no figures available to guide a study of pre-tensioning we increased the lower limit of our cyclical loading by 100% to 20N as we felt this represented a significant increase that would be realistically achieved by the surgeon in vivo at the time of tenodesis.

The surgical technique used for the Biosure PK screw and Biosure Sync implants was as described by the manufacturer [21,22]. For the Interference screw technique, a 2.4mm guide wire was inserted into the centre of a biomechanical test block, this was then over-reamed with a 7mm drill to a depth of 30mm. The hole was then tapped with the Biceptor 7mm tap. The small Biceptor tendon tuning fork was then used to insert the tendon to the base of the hole. The guide pin was then hammered into the base of the hole to temporarily hold the tendon in place. The tuning fork was removed and the interference screw inserted. The technique for tenodesis using the sheathed device differed after the insertion of the initial guide pin. An 8mm tunnel was drilled to a depth of 30mm, the 7-8mm Biosure Sync Dilator was then used in preparation for sheath insertion. The tendon was inserted as described previously and the Biosure Sync sheath was hammered into place using the insertion device taking care to ensure that the limbs of the tendon sat between the wings of the implant during this process as per the manufacturers recommended technique.

The surgical technique differed in Group E from the Biosure Sync technique in that a custom made sheath was used and that the dilator was not required. This custom sheath was made from a 0.6 mm thick, high density polyethylene sheet (Arla, Leeds, UK), which was folded and secured using a clear, polypropylene, pressure-sensitive adhesive based stationery tape (Scotch 3M, Bracknell, UK) (Fig 2). The sheath approximated the length and core diameter of the Biosure PK screw. The concept was to provide a device that minimised

damage to the tendon on insertion by removing all sharp edges but still retaining the biomechanical advantages of a sheathed implant.

Fig 2. Showing custom made sheath being folded and secured with tape

The custom made sheath was inserted using the tuning fork at the same time as the tendon was inserted into the tunnel and the tenodesis was then fixed with a 25 x 7mm Biosure PK screw as shown in Fig 3.

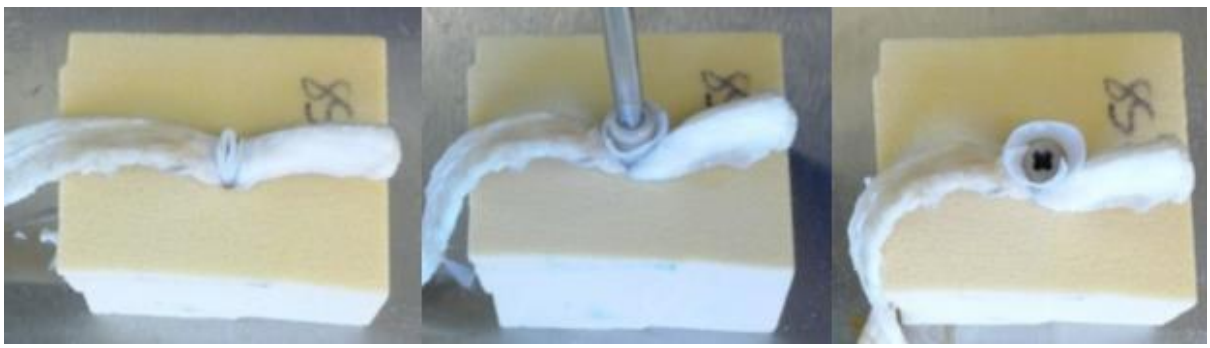

Fig 3. Showing the insertion technique for the custom made sheath and Biosure PK screw

Once the tenodesis was performed, specimens were mounted in the mechanical testing rig (Fig 4). This consisted of a custom designed jig to hold the biomechanical test block. The free end of the tendon was dually secured within the testing rig. In the first instance the tendon was whip-stitched using Number 2 Ultrabraid suture (Smith and Nephew, UK). The suture was then tied to a pin within a zigzag-clamp, which was also tightened thus providing a very secure fixation.

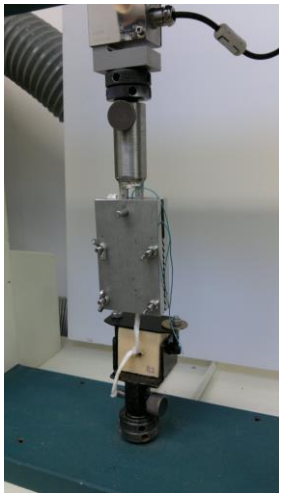

Fig 4. Specimen mounted in mechanical testing rig

Testing was performed at room temperature and specimens were kept moist by frequent application of saline spray. After preloading, vertical tensile testing was performed with a loading rate of 5mm/min for 500 cycles. If specimens remained intact after 500 cycles, then they were tested to maximum load to failure. All mechanical testing was video recorded so that mode and location of failure could be easily assessed. Failure was defined as elongation greater than 30mm or complete rupture of the tendon.

Statistical analyses was performed using GraphPad statistics software [23]. The Fishers Exact test was used to compare categorical data. The unpaired t-test was used to compare mean values obtained from the biomechanical analyses. Statistical significance was set at $p<0.05$.

3. Results

Table 1. Shows a summary of the results of biomechanical testing within each group.

Table 1 provides a summary of the results.

3.1 Tendon mal-rotation on screw insertion

Mal-rotation was common. Although all tendons in the sheathed groups remained in the intended 6 o'clock position on fixation, this contrasted to only 4 remaining in position in Group A. This difference was statistically significant ($p=0.0004$).

3.2 Cyclic elongation and failure on cyclical loading

In Group A, 3/10 specimens failed before 500 cycles (mean number of cycles 381, range 24-500). In contrast, in Group B and E, there were no failures prior to 500 cycles and this difference was statistically significant (mean difference 118.8 cycles (95% CI 28 to 209.6), $p=0.02$), There were no significant differences in mean cyclic elongation at 500 cycles in Groups A (6.9mm), B (14.8mm) or E (11.4mm).

3.3 Maximum load to failure

There was a statistically significant increased maximum load to failure in Group E (348N) when compared to Group A (228N, mean difference 120N, (95% CI 32.2 to 207.1) $p=0.01$) and Group B (253N, mean difference 95N, (95% CI 46.1 to 143.7), $p=0.0007$). There was no difference between Group A and B with respect to maximum load to failure (mean difference 25N, (95% CI -117.2 to 67.7), $p= 0.5$).

3.4 Stiffness of tenodesis

There were significant differences in the mean stiffness of the tenodeses between groups A (16.25 N/mm), B (8.31 N/mm) and E (15.87 N/mm). Both Groups A and E were significantly stiffer than Group B (A vs. B; Mean diff 7.94 N/mm, (95% CI 2.0 to 13.8), p=0.0113, E vs. B; mean difference 8.05, (95% CI 4.8 to 11.3), p=0.0001). Groups A and E were not significantly different with regards to stiffness.

3.5 Pre-tensioning

There were no significant differences between Groups A and either Groups C or D in any regard.

3.6 Mode of failure

There was a significant difference in the mode of failure between sheathed and unsheathed groups. In Group A, on maximum load to failure, 6/10 constructs failed at the tendon/implant interface, the remainder failed in the tendon substance. In Group B all constructs failed within the substance of the tendon itself. This was statistically significant (Fishers exact test, two-tailed p=0.01). In Group E the mode of failure was similar to B with 7/10 failing within the substance of the tendon though at significantly higher load. Despite this trend there was no statistically significant differences between Group E and either Group A or B in regard to mode of failure.

4. Discussion

This study demonstrates that using a sheathed device reduces the risk of mal-rotation of tendons on screw insertion. This is important because previous studies have demonstrated that mal-rotation can result in eccentric graft positions, unequal loading of tendon fibres and a pre-disposition to early failure. A sheath providing 360 degrees of protection to the tendon may also contribute to increased ultimate failure strength. In this study, using a sheathed device significantly reduced the risk of premature failure on cyclical loading (i.e. before 500 cycles).

It is previously reported that sheathed devices confer an increased maximum load to failure [16]. There was certainly a trend towards this in Groups B and E, and in the latter this was statistically significant. Analysis of the mode of failure was performed for all groups but the difference was most obvious and statistically significant between Groups A and B. In Group A, 6 failures occurred at the tendon/implant interface. This slippage had been anticipated at maximum loads. However, 4 tenodeses failed within the tendon substance at loads lower than one would expect ovine flexor tendon to fail. Potential reasons for this include damage to the tendon on insertion and rotation of the tendon on screw insertion resulting in differential loading of tendon fibres. We were particularly careful to try and avoid these issues and one can argue that it was perhaps easier for us to do so in an in vitro setting as compared to attempting the same procedure arthroscopically. Fig 5 demonstrates how tendon mal-rotation can occur even when tension is applied to both ends of the tendon which is arguably more difficult to achieve *in vivo*.

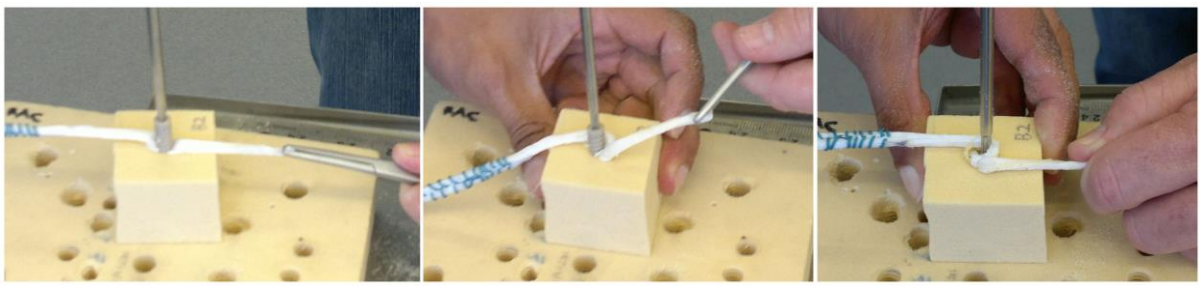

Fig 5. Tendon rotation on insertion of an interference screw alone.

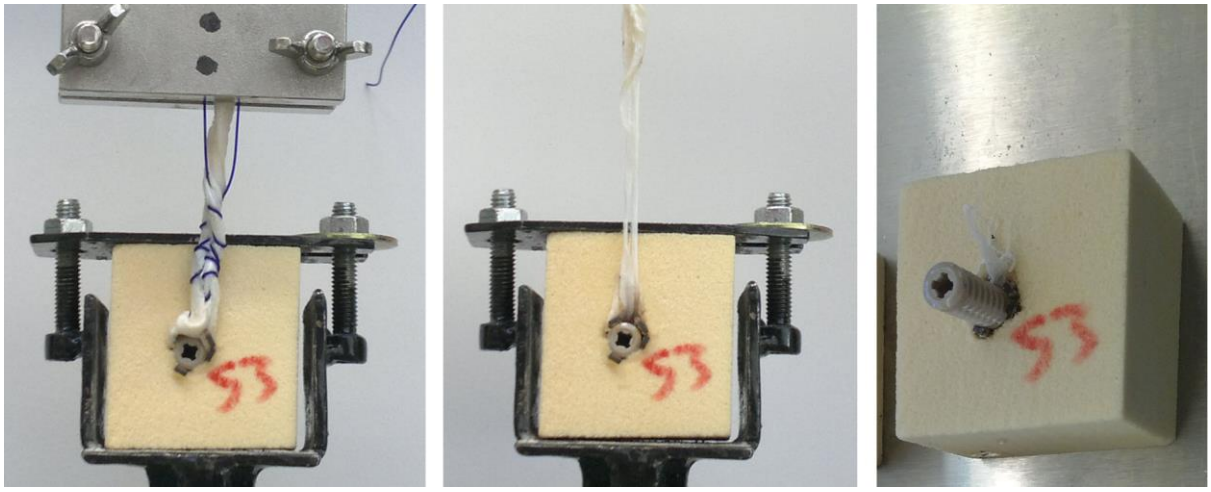

Fig 6. Stages a typical sample in Group B.

In Group B, failures tended to occur within the substance of the tendon just distal to the implant but the tendon tissue inside the drill hole remained firmly fixed by the implant. The location of failure, and the fact that this also occurred at loads much lower than one would expect ovine flexor tendon to fail again suggests that the tendon tissue was damaged, either by insertion of the sheath, or by rubbing against either the edge of the implant or the bone tunnel, thus predisposing it to premature failure. However, it should be noted that the Biosure Sync device is not intended for biceps tenodesis and is marketed for tibial fixation of 4 strand ACL grafts. This is an important point as tibial fixation of an ACL graft is loaded in an entirely different manner biomechanically and hamstring tendons are different in size and quality to the biceps. In Group E there was no rotation of the tendon, similar to Group B yet with significantly higher failure loads. It is likely that the 360 degrees of protection provided by the custom sheath prevented tendon damage more effectively than the more open sheath design of the Biosure Sync device.

The custom sheath was constructed specifically to test the hypothesis that reducing tendon rotation and damage would provide significant improvements in the mechanical properties of biceps fixation. This indeed seems to be the case as the mean maximum load to failure and stiffness were significantly higher with this device than with the Biosure Sync device. The custom sheath had a smooth outer covering offering no frictional resistance to tendon pull-out, this is in contradiction to all other sheath devices currently on the market for tendon fixation. This was done on purpose in order to try and isolate the issues of mal-rotation and tendon damage from any particular fixation design, which could have improved the ultimate failure strength. Tendon damage on screw insertion is a greater issue in biceps tenodesis as opposed to ACL fixation due the physiological stresses placed on the tendon. Unlike tibial ACL fixation the tensile load on the tendon is distal to the fixation, thus any damage caused by the screw or bone at the cortex of the tunnel (which is the most likely location of tendon damage) will determine the ultimate load to failure rather than the fixation itself. Thus there is potential for further improvements in the fixation strength by altering surface geometry.

A further interesting point to note is that the range of values, particularly of maximum load to failure and extension at 500 cycles are fairly broad even within individual groups. This occurred despite trying to standardise our protocol as much as possible by adopting measures such as using ovine flexor tendons of a similar age and size, standardised biomechanical test blocks, a single surgeon preparing all the tendons and another performing all the tenodeses. This variability therefore suggests that mal-rotation and damage to the tendon are serious considerations with this technique and that avoiding them can improve the biomechanics of fixation. The custom sheath device reduced the risk of mal-rotation and protected the tendon on screw insertion. It is therefore unsurprising that the range of maximum loads to failure in this group were very much smaller than any other group.

Groups C and D were tested to evaluate whether decreasing the maximum load on cyclical testing (under-tensioning or lengthening the tendon) and pre-tensioning (over-tightening or shortening the tendon) affected the biomechanics of the construct. Unfortunately, this aspect of our study had some significant limitations. The first is that physiological loads and resting tension in the LHB tendon in vivo are not known. It is therefore

difficult to know what figures to use when designing a biomechanical study. We used a figure of 70N as we felt a 30% decrease in loading compared to our standard testing regime represented a significant reduction in load and in fact this figure has been used in previous studies [12,17]. However, we did not find any significant difference when comparing Groups A and C in any regard. Similarly, little is known about the effect of over-tensioning on biceps tenodesis. As there are no figures available to guide a study of pre-tensioning we increased the lower limit of our cyclical loading by 100% to 20N as we felt this represented a significant increase that would be appreciated by the surgeon in vivo at the time of tenodesis. Both over and under-tensioning are suggested as reasons for ongoing pain after tenodesis but there is no reliable way to precisely restore the normal length at the time of fixation if using an interference screw technique. Although anatomical landmarks can be used to assist in guiding the restoration of length [24] but the actual process of inserting the screw or a sheath can entrain tendon tissue or rotate it such that the intended length, and thus tension is changed. Despite this we did not see any significant differences between Groups A and D on biomechanical testing and so this issue may contribute to persistent physical symptoms it appears not to significantly affect the strength of fixation.

This study highlights some of the issues with biceps tenodesis performed with a sheathed device or a screw alone. These include failure of fixation, damage to the tendon or mal-rotation on insertion of the implant, and entrainment of the tendon making it difficult to accurately restore length and tension. An alternative technique for biceps tenodesis using a cortical button has recently been investigated. The use of suture fixation and a button has been shown to be biomechanically superior to an interference screw technique, with higher maximum load to failure and greater stiffness [25,26]. The use of a cortical button technique potentially reduces the risk of tendon damage and may explain these findings considering the techniques reliance on suture fixation which is generally considered inferior. However, further clinical studies are required to establish long term results.

5. Conclusions

Concerns with current implants for biceps tenodesis include damage to the tendon on insertion, mal-rotation, and entrainment, leading to potential early failure and difficulty in restoring tension accurately. We experienced some of these issues during the study and this in part explains the wide range of maximum loads to failure and extension even within groups. However, using a custom made sheath device that minimised damage to the tendon on insertion and reduced mal-rotation we demonstrated more uniform outcomes, higher maximum loads to failure and increased stiffness of the construct. This study serves to highlight some of the technical pitfalls of biceps tenodesis but also has implications for biomechanical considerations of future implant design.

We did not demonstrate any affect on the properties of fixation by increasing the pre-tension in an attempt to simulate over-tensioning, but our study was limited by the lack of good data regarding the normal tension in the LHB and therefore this is an area for further study.

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