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

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2	Biceps Tenodesis		
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38 Abstract

39 Background

40 This study aimed to evaluate the differences in biomechanical properties of biceps tenodesis when performed

- 41 with sheathed versus unsheathed screws and also to investigate the effect of altering the pre-tension.
- 42 43 *Methods*
- 44 Tenodesis was performed in an *in vitro* model using biomechanical test blocks and ovine tendons. Blocks were
- 45 allocated to 1 of 5 groups which varied by method of tenodesis and cyclical loading protocol: Group A, Biosure
- 46 PK screw (10-100N), Group B: 7-8mm Biosure Sync and Biosure PK screw (10-100N), Group C : Biosure PK
- 47 screw (10-70N), Group D: Biosure PK (20-100N), Group E: Custom sheath and Biosure PK screw (10-100N). If
- 48 tenodeses remained intact after 500 cycles maximum load to failure testing was performed.49
- 50 Findings
- 51 30% of tenodeses in Group A failed prior to 500 cycles whereas none failed in the sheathed device groups
- 52 (p=0.02). Using a sheathed device prevented mal-rotation. However, tenodeses in Group B were more likely to
- 53 fail immediately distal to the tenodesis at a load below the anticipated maximum load to failure suggesting
- 54 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).
- 58 Interpretation
- 59 Sheathed devices prevent mal-rotation and increase stiffness and maximum load to failure. This is further
- 60 improved by reducing tendon damage at the time of tenodesis.
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79 1. Introduction

80 The long head of biceps (LHB) tendon can be a significant source of shoulder pain. Tenotomy or tenodesis are 81 surgical options that are indicated when non-operative management has been exhausted. Both techniques 82 have been reported to demonstrate good outcomes but controversy exists as to which option is best. In part, 83 this is due to a lack of high quality evidence and wide variations in study criteria and subsequent outcomes [1]. 84 Recent systematic reviews have shown both procedures have similar clinical outcomes with the only major 85 difference being a higher incidence of cosmetic deformity with tenotomy [1,2]. However, other authors have 86 also reported that tenotomy is generally associated with higher rates of distal migration, muscle spasm and 87 weakness of elbow supination [3,4,5]. These issues are often cited as reasons to select a tenodesis procedure 88 over a simple tenotomy in young patients, muscular patients of any age and those with high functional 89 demands, as well as those with a low body fat percentage where a cosmetic deformity is less likely to be 90 acceptable.

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92 There are a large number of different techniques for performing biceps tenodesis and many of these have 93 been evaluated with respect to their biomechanics. Numerous laboratory studies have shown that the use of 94 interference screws compares favourably to other arthroscopic techniques because of higher ultimate loads to 95 failure and improved stiffness [6,7] but clinical results have been less promising with revision rates as high as 96 36-45% being reported in some series [8,9]. However, in general terms the failure rate for this procedure is not 97 clearly defined in the literature and cosmetic deformity, or the "Popeye sign" has also been reported with 98 similar frequency to that seen after tenotomy [10]. Failure can occur in a number of ways and is dependent on 99 the technique and implant design. For example with suture anchors, Ozalay, et al. reported that the most 100 common mode of failure is cut out at the eyelet [6]. With interference screws failure tends to occur most 101 commonly by rupture at the tendon-screw interface [11] or slippage [6,12]. Some of these failures may in part 102 be due to direct trauma to the tendon during fixation or from abrasion to the tendon by the edges of the 103 implant or bone tunnel [11,13]. Another potential reason, highlighted by studies investigating ACL graft 104 fixation with interference screws, is that screw insertion can cause rotation of the graft resulting in an 105 eccentric position relative to the screw with subsequent reduced load to failure [13,14,15]. The use of a screw 106 with a sheath may minimise these rotational forces, reduce the tendon damage caused by screw insertion and 107 also offer improved mechanical properties secondary to the greater compression achieved by expansion of the 108 sheath [16]. This study aims to evaluate the biomechanics of interference screw fixation for biceps tenodesis 109 and compare this to the biomechanics of sheathed devices. This study also aims to assess the effect of pre-110 tensioning on the biomechanics of tenodesis. One of the technical challenges with using a screw for tenodesis 111 compared to some of the other commonly used implants (e.g. cortical button) is that screw insertion can cause 112 an uncontrolled and variable degree of tendon rotation and entrainment thus making accurate restoration of 113 normal tension difficult. This failure to adequately restore the physiologic length-tension relationship of the 114 biceps has been suggested as an important contributing factor to the high rates of revision surgery reported in 115 some series but the influence on the biomechanics of fixation has not been studied [17].

116117 2. Method

118 An in vitro model was used for biceps tenodesis. In order to eliminate variation due to differences in the 119 quality of individual specimens of cadaveric bone we used cellular rigid polyurethane biomechanical test 120 blocks that replicate the properties of cancellous bone (Sawbones, Malmo, Sweden). A number of different 121 densities are available. Poukalova, et al. correlated mechanical properties of the proximal humerus with 122 Sawbones biomechanical test blocks [18] and on the basis of this work we postulated that either the 15 or 20 123 pcf (pounds per cubic foot) density would be the most representative of the in vivo situation. In pre-trial 124 studies it was noted empirically that the insertion torque for an interference screw into a 20 pcf test block was 125 considerably higher than the in vivo situation. Conversely, we found that the 15 pcf density was a good 126 approximation and selected that for the remainder of the study.

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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

135 frozen at -20° C and then fully defrosted in a water bath at room temperature when required.



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Fig 1. Showing preparation of tendons to a standardised size

140 141 Tenodesis of the biceps tendon was performed by a single surgeon (AS) using either Biceptor and/or Biosure 142 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 143 144 randomly allocated to one of five groups with 10 specimens in each. Allocation to tenodesis technique and 145 loading protocols were as follows: Group A, Biosure PK screw (10-100N), Group B: 7-8mm Biosure Sync and 146 Biosure PK screw (10-100N), Group C : Biosure PK screw (10-70N), Group D: Biosure PK (20-100N), Group E: 147 Custom sheath and Biosure PK screw (10-100N). The upper limit of cyclical loading of 100N was selected in 148 these groups based on the previous work of Mazzocca et al. who demonstrated this to be 50% of the average 149 failure load for biceps tenodesis and the fact that other authors have also used this figure in their studies 150 [19,20]. Groups C and D were tested to evaluate whether decreasing the maximum load (i.e. effectively 151 lengthening intra-operatively) and increasing the pre-tension (i.e. effectively over tensioning) affected the 152 biomechanics of the construct. We used an upper figure of 70N as we felt a 30% decrease in loading compared 153 to our standard testing regime represented a significant reduction and in fact this figure has been used by 154 other authors thus offering some degree of uniformity for comparison between studies [12,17]. As there are 155 no figures available to guide a study of pre-tensioning we increased the lower limit of our cyclical loading by 156 100% to 20N as we felt this represented a significant increase that would be realistically achieved by the 157 surgeon in vivo at the time of tenodesis.

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159 The surgical technique used for the Biosure PK screw and Biosure Sync implants was as described by the 160 manufacturer [21,22]. For the Interference screw technique, a 2.4mm guide wire was inserted into the centre 161 of a biomechanical test block, this was then over-reamed with a 7mm drill to a depth of 30mm. The hole was 162 then tapped with the Biceptor 7mm tap. The small Biceptor tendon tuning fork was then used to insert the 163 tendon to the base of the hole. The guide pin was then hammered into the base of the hole to temporarily 164 hold the tendon in place. The tuning fork was removed and the interference screw inserted. The technique for 165 tenodesis using the sheathed device differed after the insertion of the initial guide pin. An 8mm tunnel was 166 drilled to a depth of 30mm, the 7-8mm Biosure Sync Dilator was then used in preparation for sheath insertion. 167 The tendon was inserted as described previously and the Biosure Sync sheath was hammered into place using 168 the insertion device taking care to ensure that the limbs of the tendon sat between the wings of the implant 169 during this process as per the manufacturers recommended technique.

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171 The surgical technique differed in Group E from the Biosure Sync technique in that a custom made sheath was172 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
- 175 length and core diameter of the Biosure PK screw. The concept was to provide a device that minimised

- 176 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). Thisconsisted 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
- 197 tightened thus providing a very secure fixation.



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

Fig 4. Specimen mounted in mechanical testing rig

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.

Testing was performed at room temperature and specimens were kept moist by frequent application of saline

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).

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242 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.

250 3.5 Pre-tensioning

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

256 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.

265266 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).

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274 It is previously reported that sheathed devices confer an increased maximum load to failure [16]. There was 275 certainly a trend towards this in Groups B and E, and in the latter this was statistically significant. Analysis of 276 the mode of failure was performed for all groups but the difference was most obvious and statistically 277 significant between Groups A and B. In Group A, 6 failures occurred at the tendon/implant interface. This 278 slippage had been anticipated at maximum loads. However, 4 tenodeses failed within the tendon substance at 279 loads lower than one would expect ovine flexor tendon to fail. Potential reasons for this include damage to the 280 tendon on insertion and rotation of the tendon on screw insertion resulting in differential loading of tendon 281 fibres. We were particularly careful to try and avoid these issues and one can argue that it was perhaps easier 282 for us to do so in an in vitro setting as compared to attempting the same procedure arthroscopically. Fig 5 283 demonstrates how tendon mal-rotation can occur even when tension is applied to both ends of the tendon 284 which is arguably more difficult to achieve in vivo.

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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 300 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 360 303 degrees of protection provided by the custom sheath prevented tendon damage more effectively than the more open sheath design of the Biosure Sync device.

306 The custom sheath was constructed specifically to test the hypothesis that reducing tendon rotation and 307 damage would provide significant improvements in the mechanical properties of biceps fixation. This indeed 308 seems to be the case as the mean maximum load to failure and stiffness were significantly higher with this 309 device than with the Biosure Sync device. The custom sheath had a smooth outer covering offering no 310 frictional resistance to tendon pull-out, this is in contradiction to all other sheath devices currently on the 311 market for tendon fixation. This was done on purpose in order to try and isolate the issues of mal-rotation and 312 tendon damage from any particular fixation design, which could have improved the ultimate failure strength. 313 Tendon damage on screw insertion is a greater issue in biceps tenodesis as opposed to ACL fixation due the 314 physiological stresses placed on the tendon. Unlike tibial ACL fixation the tensile load on the tendon is distal to 315 the fixation, thus any damage caused by the screw or bone at the cortex of the tunnel (which is the most likely 316 location of tendon damage) will determine the ultimate load to failure rather than the fixation itself. Thus 317 there is potential for further improvements in the fixation strength by altering surface geometry. 318

319 A further interesting point to note is that the range of values, particularly of maximum load to failure and 320 extension at 500 cycles are fairly broad even within individual groups. This occurred despite trying to 321 standardise our protocol as much as possible by adopting measures such as using ovine flexor tendons of a 322 similar age and size, standardised biomechanical test blocks, a single surgeon preparing all the tendons and 323 another performing all the tenodeses. This variability therefore suggests that mal-rotation and damage to the 324 tendon are serious considerations with this technique and that avoiding them can improve the biomechanics 325 of fixation. The custom sheath device reduced the risk of mal-rotation and protected the tendon on screw 326 insertion. It is therefore unsurprising that the range of maximum loads to failure in this group were very much 327 smaller than any other group.

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329 Groups C and D were tested to evaluate whether decreasing the maximum load on cyclical testing (under-330 tensioning or lengthening the tendon) and pre-tensioning (over-tightening or shortening the tendon) affected 331 the biomechanics of the construct. Unfortunately, this aspect of our study had some significant limitations. 332 The first is that physiological loads and resting tension in the LHB tendon in vivo are not known. It is therefore

333 difficult to know what figures to use when designing a biomechanical study. We used a figure of 70N as we felt 334 a 30% decrease in loading compared to our standard testing regime represented a significant reduction in load 335 and in fact this figure has been used in previous studies [12,17]. However, we did not find any significant 336 difference when comparing Groups A and C in any regard. Similarly, little is known about the effect of over-337 tensioning on biceps tenodesis. As there are no figures available to guide a study of pre-tensioning we 338 increased the lower limit of our cyclical loading by 100% to 20N as we felt this represented a significant 339 increase that would be appreciated by the surgeon in vivo at the time of tenodesis. Both over and under-340 tensioning are suggested as reasons for ongoing pain after tenodesis but there is no reliable way to precisely 341 restore the normal length at the time of fixation if using an interference screw technique. Although anatomical 342 landmarks can be used to assist in guiding the restoration of length [24] but the actual process of inserting the 343 screw or a sheath can entrain tendon tissue or rotate it such that the intended length, and thus tension is 344 changed. Despite this we did not see any significant differences between Groups A and D on biomechanical

- 345 testing and so this issue may contribute to persistent physical symptoms it appears not to significantly affect 346 the strength of fixation.
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349 This study highlights some of the issues with biceps tenodesis performed with a sheathed device or a screw 350 alone. These include failure of fixation, damage to the tendon or mal-rotation on insertion of the implant, and 351 entrainment of the tendon making it difficult to accurately restore length and tension. An alternative 352 technique for biceps tenodesis using a cortical button has recently been investigated. The use of suture 353 fixation and a button has been shown to be biomechanically superior to an interference screw technique, with 354 higher maximum load to failure and greater stiffness [25,26]. The use of a cortical button technique potentially 355 reduces the risk of tendon damage and may explain these findings considering the techniques reliance on

- 356 suture fixation which is generally considered inferior. However, further clinical studies are required to 357 establish long term results.
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360 5. Conclusions

361 Concerns with current implants for biceps tenodesis include damage to the tendon on insertion, mal-rotation, 362 and entrainment, leading to potential early failure and difficulty in restoring tension accurately. We 363 experienced some of these issues during the study and this in part explains the wide range of maximum loads 364 to failure and extension even within groups. However, using a custom made sheath device that minimised 365 damage to the tendon on insertion and reduced mal-rotation we demonstrated more uniform outcomes,

- 366 higher maximum loads to failure and increased stiffness of the construct. This study serves to highlight some 367 of the technical pitfalls of biceps tenodesis but also has implications for biomechanical considerations of future implant design.
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370 We did not demonstrate any affect on the properties of fixation by increasing the pre-tension in an attempt to 371 simulate over-tensioning, but our study was limited by the lack of good data regarding the normal tension in 372 the LHB and therefore this is an area for further study. 373

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375

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385 7. References

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