Biomechanical evaluation of a tubular braided construct for primary flexor tendon surgery
Abstract

Purpose
Immediate post-operative mobilization has been shown to avoid adhesion formation and improve range of motion after flexor tendon repair. A tubular braided construct was designed to allow for these rehabilitation protocols.

Methods
In this ex vivo study, 92 ovine flexor tendons were randomly divided into two equal groups. After creating a transection, the tendons of the first group were repaired using a tubular braided construct. This construct, consisting of a tubular braid of polypropylene and polyethylene terephthalate fibres, exerts a grasping effect on the transected tendon ends. The control group received a multistrand modified Kessler repair with a looped PDS 4-0 and a Silfverskiöld epitendinous repair using an Ethilon 6-0. After the repair, both a static and an incremental cyclic tensile test was performed until failure.

Results
During the static test, the tubular braid resulted in a significantly higher load at 3 mm gap formation (86.3 N ± 6.0 versus 50.1 N ± 11.6), a higher ultimate load at failure (98.3 N ± 12.7 versus 63 N ± 11.1), higher stress at ultimate load (11.8 MPa ± 1.2 versus 8.1 MPa ± 3.1) and higher stiffness (7.1 N/mm ± 2.9 versus 8.7 N/mm ± 2.2). For the cyclic tests, survival analyses for 1, 2- and 3-mm gap formation and failure demonstrated significant differences in favour of the construct.

Conclusion
The tubular braided construct withstands the required loads for immediate rehabilitation not only in static tests but also during cyclic tests. This is in contrast with the control group, where sufficient strength is reached during static tests, but failures occur below the required loads during cyclic testing.

Clinical Relevance
The tubular braided construct provides a larger safety margin for immediate intensive rehabilitation protocols.
The repair of flexor tendon injuries remains one of the most intriguing topics in hand surgery. Recently, there seems to be a consensus that a multistrand core suture with at least four strands, in combination with a peripheral epitendinous suture, should be used.\(^1\) Also, passive or early active rehabilitation protocols should be started immediately after surgery, mainly to counter adhesion formation. The necessary strength for immediate mobilization is estimated between 35 to 45 N, depending on the study and interpretation.\(^2-5\)

Different suture techniques reach ultimate failure loads of 40-70 N in biomechanical tests\(^6-10\), which is within the range of the required strength for immediate mobilization. When considering the initial weakening of the tendon during the first weeks after repair, clinical failure with gap formation at lower loads, and possible compliance issues of the patient, there still exists a delicate balance between post-operative mobilization and the strength of the repair. Therefore, some surgeons continue to be reluctant to start immediate mobilization. Although a repair using a combination of a multistrand core suture and epitendinous suture results in fair outcomes\(^11\), the tendon repair complex only regains its strength after biologic repair of the tendon itself. Full recovery and return to normal function still takes at least three months.\(^11-13\)

Ideally, a repair technique that increases the strength of the repair complex substantially would give the surgeon and patient confidence to start rehabilitation immediately. If strong enough, the technique would be less dependent on biologic healing of the tendon. There have been attempts to increase mechanical strength by using devices such as Dacron splints\(^14\) or more recently, a Tenofix device.\(^15,16\) The latter has been tested in two clinical series and showed equivalent results as existing suture strategies. In the field of biologic repair, there have been trials with growth factors, mesenchymal stem cells and scaffolds to improve gliding.\(^17,18\) Although some show slight improvements, they either have not improved clinical outcomes significantly or are thus far too expensive to implement in daily practice.

In this study, a tubular braided construct, was designed to provide a mechanically stronger repair for flexor tendon injuries. This repair technique could be used in zone 3 or more proximal flexor tendon
injuries. An *ex vivo* biomechanical analysis was performed to evaluate its potential to withstand immediate rehabilitation after repair.
Materials and methods

Specimens
Ninety-two ovine flexor tendons obtained from the hind limbs were randomized in equal groups of forty-six. Specimens were gathered from local abattoirs. Dissection and freezing at -25°C of the tendons was done within two hours. Since literature has shown that the diameter of flexor tendons of sheep is slightly larger than the flexor tendons of humans, dividing and stripping of the tendons was done as described by Ward et al. to standardize the cross-sectional area (CSA) and to improve comparability with human tendons. Frozen tendons were thawed one hour before the experiment and were sprayed with a saline solution during repair and biomechanical testing to avoid dehydration.

Design of the construct
The design of the construct is based on a tubular braid. When an elongation is performed, the diameter of the braid inherently reduces, thereby grasping any structure within the braid. In a classic tubular braid, the angle of braiding remains constant. In the construct used in this experiment, the braid has multiple segments in which the angle of braiding changes between the central segment and the two peripheral segments.

The central segment has a small braiding angle (14°, figure 1A), which leads to a relatively larger diameter (figure 1B). This is necessary to create room to enable an overlap of the tendons needing repair. These overlapping tendons serve multiple purposes. First, when traction is applied, the tubular structure needs some pretension to initiate the grasping effect. Second, it allows for more contact between the two peripheral ends of tendons. Thirdly, it is not necessary to have a perfect transverse cut at the ends of the tendons. Using this device to repair an oblique cut might even be advantageous because there is more contact between the tendon segments. This idea has been proposed in the past by Becker et al.

The two peripheral segments have a larger braiding angle (34°, figure 1A), which leads to a relatively smaller diameter to achieve a better grasping effect (figure 1B). The peripheral ends of the construct were thermally cut using a laser cutter to avoid unravelling.
The construct is 1.8 cm long and the outer sections have an inner diameter of 3.5 mm (CSA 9.6 mm²).

Since the average CSA of deep flexor tendons ranges from 8.8 mm² (FDP 5) to 14.4 mm² (FDP 3), this diameter can accommodate the tendons and provide a sufficient trapping effect.\textsuperscript{20} The construct is a combination of polypropylene monofilament fibers (0.18 mm) and polyethylene terephthalate multifilament strands (0.027 mm, 190 decitex). Decitex is a measuring unit for yarn and accounts for 1 gram per 10000 meters.

**Surgical technique**

In the experimental group, the tubular braided construct was used. First, a single temporary suture loop was placed at the ends of both tendons (figure 2A) to guide them through the construct. By applying tension on these sutures, an overlap of approximately 3 mm of both tendon ends was achieved at the repair site (figure 2B). Then the construct was secured at the outer ends of the construct to the tendon using a continuous interlocked circular suture with 4-0 Polypropylene (Prolene, Ethicon Inc. Somerville, NJ, USA) (figure 2C). This suture initiates the necessary pretension to activate the trapping effect.

In the control group, the repair was done using a modified 4-strand Kessler suture (4-0 PDS loop, Ethicon Inc. Somerville, NJ, USA) combined with a Silfverskiöld epitendinous suture (6-0 Ethilon Nylon, Ethicon Inc. Somerville, NJ, USA) (Figure 3).\textsuperscript{22,23} This technique was chosen because it remains one of the most used techniques in daily practice.\textsuperscript{24–26} Literature has shown that the supplementation of an epitendinous suture increases the strength of the repair and smooths the tendon coaptation site.\textsuperscript{27,28} The Silfverskiöld suture is simple to perform and superior to the simple running suture.\textsuperscript{27,29}

**Testing**

**Mechanical testing**

All biomechanical tests were done with a hydraulic tensile testing machine (LRX Plus with 250 N load cell, Lloyd Instruments, Bognor Regis, UK) using custom made clamps (fig. 4). Each tendon was subjected to a preload of 1 N for both static and cyclic testing.
First, a static load to failure test was performed in 23 tendons for both groups. The tendons were elongated until failure at a rate of 20 mm/s after pre-tensioning, and the ultimate load (N), stress at ultimate load (Mpa), and stiffness (N/mm) were recorded. Also, gap formation at 1, 2, and 3 mm and the mode of failure were recorded with a camera connected to the software (Nexxygen Plus) and analysed by two independent observers.

Next, the remaining 23 tendons in each group were used for a cyclic loading protocol until failure. An adapted incremental loading protocol based on that of Matheson et al. and Viikainen was used. Every 500 cycles, the load was increased without interruption (2–20 N, 3.3–33 N, 4.5–45 N, 6–60 N, 7.5–75 N, 9–90 N, and finally 10.5-105 N). The cycle rate was 1 mm/s at 20 N, 1.5 mm/s at 33 N, 2 mm/s at 45 N and 60 N, 2.5 mm/s at 75 N, 90 N and 105 N. After every 100 cycles the appearance of a 1, 2- or 3-mm gap or complete failure was analysed by two independent observers. The presence of gap formation was measured at the lowest force during the cycle range.

Statistics

For the static test a sample size of 23 in each group was calculated with a power of 0.80 and a significance level of 0.05 based on Gil-Santos et al. In their study an average ultimate load of 32.7 N for a combined repair with a modified Kessler and epitendinous repair was reached. We estimated a required mean difference of 10 N reaching an average ultimate load of 42.7 N. After verifying normality using the Shapiro-Wilk test and equality of variance using the Levene’s test, an independent T-test was done to compare the ultimate load, gap formation, stress at ultimate load and stiffness between the two groups.

For the cyclic test, a Kaplan Meier survival curve was made to compare the survival time between both repairs at 1, 2, and 3 mm gap and complete failure during cyclic testing. The intraclass correlation coefficient (ICC) was calculated for the visual assessment of the gap formation (1, 2, and 3 mm) and failure in both cyclic and static tensile testing for both repair techniques.
Results

The mean CSA of the tendons used for the construct before the repair was 8.4 mm² (SD 1.5) and 8.4 mm² (SD 2.0) for the control group.

The results of the static biomechanical tests are shown in table 1. There were statistically significant differences between the groups for all parameters: mean ultimate load (p< 0.05); mean load at 1, 2, and 3 mm gap formation (p< 0.05); mean stress at ultimate load (p< 0.05); and stiffness (p< 0.05).

Different modes of failure were observed for the repair techniques in the static test. For the braided construct, 70% of the specimens failed due to gradual suture pull-out. The other 30% failed due to the suture breakage of the continuous interlocked circular suture. Ultimate failure always occurred after the appearance of a 3 mm gap. In the control group, 100% of the specimens failed due to suture breakage in different steps. In 17/23, failure occurred before the 3 mm gap formation. In the remaining specimens, the peripheral suture broke before the core suture, resulting in greater gap formation ranging from 8-15 mm at ultimate failure.

For the cyclic tensile tests, survival curves for 1, 2, and 3 mm gap formation and failure are shown in figure 4. All curves show statistical differences (p< 0.05). For the braided construct, a gap of 1 mm appeared between 1100 (4.5-45 N) and 3300 (10.5-105 N) cycles, a gap of 2 mm between 1100 (4.5-45 N) to 3400 (10.5-105 N) cycles, a gap of 3 mm between 1300 (4.5-45 N) and 3500 (10.5-105 N) cycles, while failure occurred between 1700 (6-60 N) and 3500 (10.5-105 N) cycles.

In the control group, gap formation of 1 mm appeared between 800 (3.3-33 N) and 1800 (6-60 N) cycles, a gap of 2 and a gap of 3 mm appeared between 900 (3.3-33 N) and 1800 (6-60 N) cycles, while ultimate failure occurred between 1000 (4.5-45 N) and 1800 (6-60 N) cycles.

For the static tensile tests, the ICC for the assessment of gap formation and failure was 0.931 for the braided construct and 0.950 for the control group. For the cyclic tensile tests, the ICC was 0.999 for the braided construct and 0.983 for the control group.
Discussion

The advantages of early post-operative mobilization after flexor tendon repair have been well recognized. However, there remains a relatively small margin of safety between the minimum required strength for mobilization and most current repair techniques. In this study, it was demonstrated that flexor tendon repair with a tubular braided construct provides a significantly stronger repair in both static and cyclic testing, which might allow for immediate mobilization protocols with a larger safety margin. The testing was performed on ovine flexor tendons, because they show similar biomechanical characteristics compared to human flexor tendons.\textsuperscript{19,33}

In the static tests, the tubular braided construct showed a significantly higher ultimate failure load of 98.3 N compared to 63 N in the control group. When only looking at these values, both groups should be able to withstand the loads required for mobilization. The mean result of 63 N in the control group is one of the highest ultimate failure loads for a 4-strand Kessler combined with an epitendinous suture in the literature (reported range 16.3 N – 62.7 N)\textsuperscript{5,14,29,34}, making it a good control group with which to compare. When looking at the gap formation, the usefulness of the addition of a epitendinous suture in the control group is demonstrated. The ultimate load is usually reached before gap formation. In almost all repairs (17/23), complete failure happened immediately after gap formation, which demonstrates the division of the loads between the core and epitendinous repair.\textsuperscript{32,35} In the samples where the peripheral suture broke before the core suture, a massive gap was noted at much lower loads, which is a known problem for the Kessler repair.\textsuperscript{32,35}

Because our focus is on early mobilization, the results of the cyclic testing are considered more important because they better simulate the stress of early exercises. The results of the survival analyses clearly demonstrate the potential for mobilization of the tubular braid. When looking at the number of cycles at failure, a large contrast is seen between the groups. While in the control group, the last surviving sample failed at 1800 cycles, for the braided construct, the first failure occurred at 1700 cycles. Further, in the control group, 50% of the samples showed 3 mm gap formation and even complete failure during cycles of 4.5-45 N. All samples failed during cycles of 6-60 N, most of them (8/9 remaining)
within the first 100 cycles. When looking at the tubular braid, 50 % of the samples show 3 mm gap formation during cycles of 7.5-75 N, and only at 9-90 N did 50% of the repairs show ultimate failure. It is noteworthy that the braided construct withstood the same loads as in the static test, which is in contrast with the control group, where sufficient strength is reached during static tests, but failures occur below the required loads for mobilization during cyclic tests. These results indicate, similar as stated by Pruitt and Mishra\textsuperscript{35,36}, that one should not rely only on reported ultimate failure loads of static tests to estimate the potential of a suture technique for early mobilization, but should instead rely on cyclic analysis.

We believe the braided construct repair technique could be used for the repair of zone 3 or more proximal flexor tendon injuries. Aside from the biomechanical advantages, the repair with a tubular construct does not require a transverse cut at the tendon ends to be repaired. Oblique cuts or frayed tendon ends could be repaired as well because the areas where the tubular construct grasps the tendon lie distant from the site of injury. Also, as in the Becker suture repair, the contact area of the repair zone increases and might facilitate biologic healing.\textsuperscript{37}

This study has several limitations. The main concern is the presence of a synthetic structure around the tendon. This might induce adhesion formation, it also increases the diameter of the repair complex, and the gliding resistance might be affected as well. An \textit{in vivo} experiment is warranted to weigh the biomechanical advantages against these possible disadvantages. The tubular braid though, causes a decrease in diameter when tension is applied through elongation. Further, it is known that when using existing suture techniques, it is recommended to slightly overtighten the sutures to achieve a slight compression at the repair site and failing to do so can lead to gap formation at lower loads. With this compression, the diameter of a repair complex also increases substantially. Also, suture techniques such as the Savage suture or the Silfverskiöld suture have a fair amount of suture material on the outside of the tendon as well, creating potentially similar resistance to gliding.\textsuperscript{27} Another concern is the grasping effect on tendon vascularization. The decrease in diameter on elongation could have a negative influence, but repeated tension and relaxation might also cause a pumping effect.
stimulating circulation. These effects on vascularization should again be evaluated in an in vivo experiment.

Further, the experiment does not allow to differentiate if the performance of the tubular braid results from the underlying mechanism of the braid itself or from the used material. Finally, the act of stripping tendons might have altered the outcomes. Nonetheless, as mentioned above, our control group also reached a high average value on tensile testing, while if anything, stripping would have weakened the potential for sutures to hold or grasp the tendon.

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1. References


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**Figure Legends**

**Figure 1**
(A) Design of the tubular braid with a different angle of braiding in the central and peripheral segments
(B) Different angle of braiding leads to different diameters (C) Tubular braid in its relaxed state (D) Tubular braid in its compressed state

**Figure 2.**
Illustration of the surgical technique of the case group. For illustration purposes one tendon end is coloured black. (A) Temporary sutures to guide the tendon ends through the braid. (B) Applying tension on the sutures creates an oblique overlapping section and compression of the tendon ends. (C) Completed repair using two interlocked continuous sutures at the end of the constructs to secure the construct.

**Figure 3.**
Illustration of the surgical technique of the control group. (A) Looped PDS 4-0 to start the modified Kessler. (B) Finished repair using a modified Kessler in combination with a Silfverskiöld epitendinous suture.

**Figure 4.**
Kaplan Meier survival curves. (A) 1 mm gap formation (B) 2 mm gap formation (C) 3 mm gap formation (D) Failure. Blue line = control group. Red line = case group.
Table 1.

Results of static tensile tests.