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Performance of a knotless four-strand flexor tendon repair with a unidirectional barbed suture device: a dynamic ex vivo comparison

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Abstract
With increased numbers of reports using barbed sutures for tendon repairs we felt the need to design a specific tendon repair method to draw the best utility from these materials. We split 30 sheep deep flexor tendons in two groups of 15 tendons. One group was repaired with a new four-strand barbed suture repair method without knot. The other group was repaired with a conventional four-strand cross-locked cruciate repair method (Adelaide repair) with knot. Dynamic testing (3–30 N for 250 cycles) and additional static pull to failure was performed to investigate gap formation and final failure forces. The barbed suture repair group showed higher resistance to gap formation throughout the test. Additionally final failure force was higher for the barbed suture group compared with the conventional repair group. When used appropriately, barbed suture materials could be beneficial to use in tendon surgery, especially with regard to early loading of the repair site and gap formation.

Keywords
Barbed suture, cyclic testing, flexor tendon repair, gap formation, Adelaide repair, ultimate failure load

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Introduction

The best approach for restoring flexor tendon function after injury has evolved with time. Primary repair with a core and peripheral suture is now standard (Kleinert et al., 1973; Strickland, 1995). Multi-strand core suture techniques are ideal, although contention exists

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regarding the ideal number of strands (Barrie et al., 2000; Barrie et al., 2000; Gill et al., 1999; McDonald et al., 2012; Thurman et al., 1998; Viinikainen et al., 2004). Together with the emphasis on early mobilization (Aoki et al., 1997; Evans and Thompson, 1993; Kitis et al., 2009; Strickland, 2000; Strickland and Glogovac, 1980), these represent major developments in tendon reconstruction. Four-strand techniques in general, and the four-strand cross-locked cruciate repair in particular (also known as Adelaide repair, modified Savage repair or four-strand Savage repair), provide a good compromise between complexity and performance (Angeles et al., 2002; Sandow and McMahon, 2011; Vigler et al., 2008).

There are several limitations with conventional tendon repairs. Primarily, the presence of a knot introduces a weak point into the system (Le et al., 2012; Momose et al., 2000; Rees et al., 2009). Furthermore, conventional repairs are dependent upon the holding configuration of the suture in the tendon to prevent pullout and gapping. Therefore, grasping configurations were superseded by locking techniques (Barrie et al., 2001; Hatanaka et al., 2000; Hotokezaka and Manske, 1997; Pennington, 1979; Wu et al., 2011; Wu and Tang, 2011); loop-locks were superseded by cross-locks (Peltz et al., 2011; Sandow and McMahon, 1996; Savage, 1985). Despite these advancements the effect of constricting elements in a conventional repair configuration on vascularity and healing of tendon remains uncertain (Gelberman et al., 1991; Manske et al., 1985; Wong et al., 2010; Wong et al., 2006).

Barbed suture tenorrhaphy offers theoretical benefits to circumvent some of these issues. It may allow better distribution of loads along the entire intratendinous suture length, rather than localizing stress loading to isolated anchoring or 'locking zones'. Also, the constricting forces may be reduced. Both factors theoretically could lead to less gapping of the loaded repair construct.

Concepts of using barbed devices to repair flexor tendons were reported in the early 1950s by Jennings (Jennings et al., 1952) and Bunnell (Bunnell, 1954), but the first scientific investigation of a barbed nylon suture for tendon repairs was only published in 1967 by McKenzie (McKenzie, 1967). While McKenzie confirmed a potential role for barbed sutures, further optimization of the concept was not pursued by his group.

The recent commercialization of barbed suture materials has reignited interest in the utility of a barbed material for various surgical applications, in particular wound closure (Sulamanidze, 2007; Zaruby et al., 2011), but also aesthetic facial surgery (Paul, 2008; Villa et al., 2008), abdominal and gastrointestinal surgery (Demyttenaere et al., 2009; Patri et al., 2011; Rosen, 2010; Warner and Gutowski, 2009) and gynaecological applications (Greenberg, 2010). The main advantages of barbed sutures are claimed to be an even distribution of tension across the wound, no knot and a potentially faster repair. These facets are all ideal for flexor tendon reconstruction and support the re-investigation of barbed sutures for this purpose.

This ex vivo study compares the biomechanical performance of a new three-dimensional knotless four-strand barbed suture flexor tendon repair to the four-strand cross-locked cruciate technique (Adelaide repair) in a dynamic testing model. A dynamic investigation of a barbed suture tenorrhaphy focussing on gap formation and final load performance has not yet been published.

Materials and methods

Forty deep flexor tendons were harvested from sheep fore-limbs. This animal model has been reported to best mimic human flexor tendon biophysical properties (Hausmann et al., 2009; Mao et al., 2011). A standardized point in Zone II was marked 5 mm proximal to the long vinculum using our previously described method (Peltz et al., 2011). Tendons were wrapped in phosphate-buffered saline-soaked gauze, placed inside plastic specimen bags and deep frozen at –20 °C.

On the day of experimentation, tendons were thawed at room temperature (22 °C–25 °C) and randomly allocated to two groups of n = 15 and one additional group of n = 10 tendons. The sample size of n = 15 per group was based on an a priori power assessment using a significance level of 5% and power of 80%. The thawed tendons were cut at the previously marked point with a size 15 scalpel and immediately repaired according to the group allocation.

Tendons in the conventional repair group underwent a four-strand cross-locked cruciate core repair (from now on referred to as 'Adelaide repair') (Figure 1) using a 3-0 silicone-coated braided polyester suture (Ticron; Syneture, Norwalk, CT). Suture purchase was 10 mm and cross-locks were 4 mm wide (Peltz et al., 2011). A five-throw square knot was tied between tendon ends. An epitendinous repair was not performed.

Tendons in the barbed suture repair group underwent a novel three-dimensional (3D) four-strand reconstruction (from now on referred to as 'barbed suture 3D repair') (Figure 2) using a 3-0 unidirectional barbed glycolic-carbonate suture (V-Loc 180™; Covidien. Mansfield, MA) (Figure 3). Again a suture

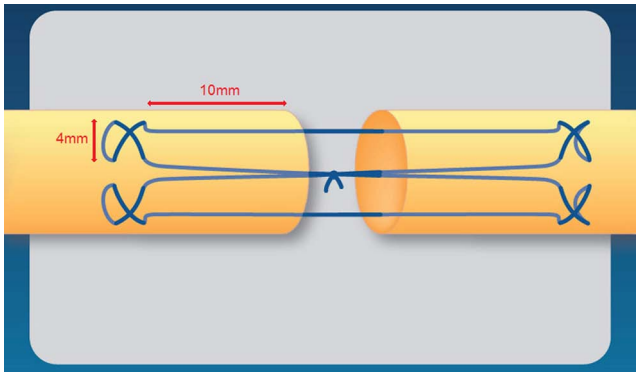

Figure 1. Illustration of the four-strand cross-locked cruciate repair technique (Adelaide repair). Tendon purchase and cross-lock width indicated in millimetres.

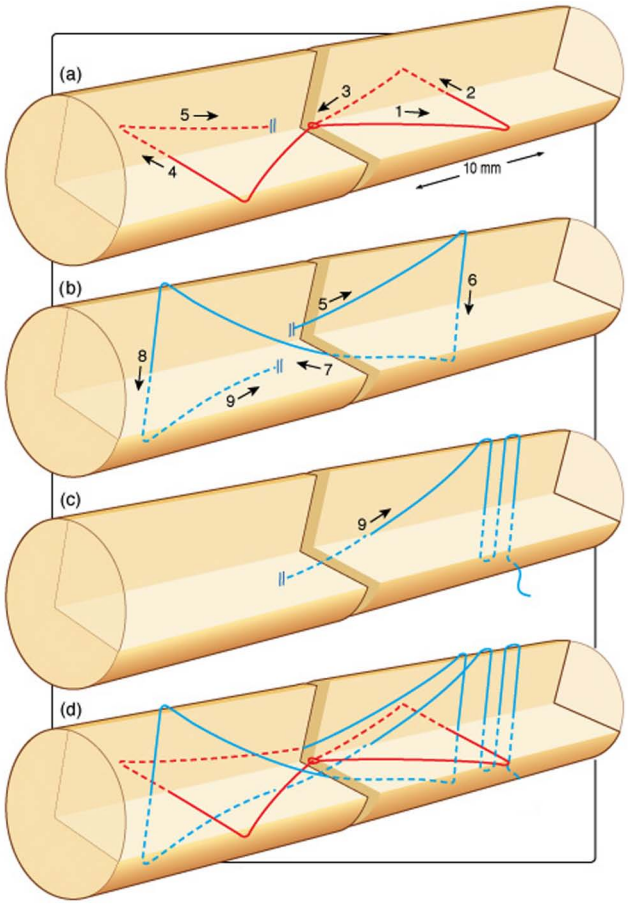

Figure 2. Illustration of our three-dimensional knotless four-strand unidirectional barbed suture repair technique (barbed suture 3D repair). Tendon purchase indicated in millimetres. (a) First strand runs in the horizontal plane. Note, it passes through the suture loop at the end of the suture thread (see 3). (b) Second strand (see 5) runs from horizontal into vertical plane (3D repair). Third strand (see 7) runs in the vertical plane. (c) Fourth strand stays in the vertical plane and finishes with a triple zigzag. (d) Suture is cut flush with the tendon.

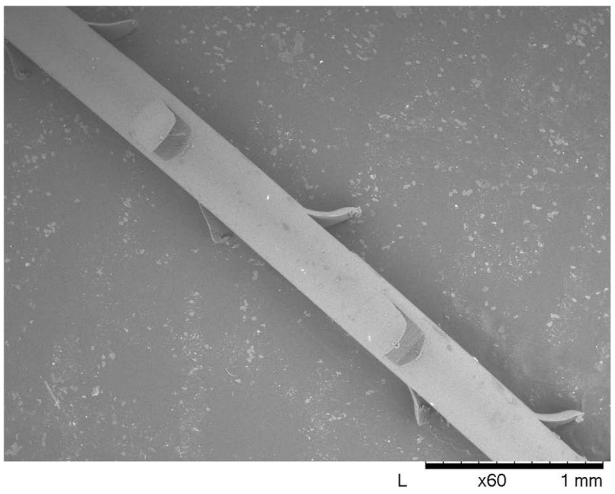

Figure 3. Scanning electron microscopy (SEM) picture of the used 3-0 unidirectional barbed glycolic-carbonate suture (V-Loc 180™; Covidien. Mansfield, MA).

purchase of 10 mm was used, and no epitendinous repair was applied. No knot was required.

To complete and further analyse this comparison we added an additional group of 10 tendons repaired with the above described 3D four-strand repair method, but using a conventional 3-0 silicone-coated braided polyester suture (Ticron; Syneture, Norwalk, CT) and a five-throw square knot between the tendon ends (from now on referred to as 'conventional suture 3D repair').

Repaired tendons were mechanically tested with the MTS 858 Mini Bionix material testing machine (MTS Systems Corp. Eden Prairie, MN). Uniaxial testing was performed using a 500 N load cell. Tendon ends were gripped in the same orientation between pneumatic grips with a clamping pressure of 60 psi. The testing gauge length (distance between the two grips) was standardized at 40 mm. A 3 N preload was maintained for 10 s before the cyclic loading protocol started. Loads between 3 N (minimum) and 30 N (maximum) were applied for 250 cycles at 1 Hz (i.e. one cycle of loading and unloading per second). These loads are reflective of the dynamic stress applied during early active rehabilitation (Schuind et al., 1992). A total of 250 cycles were chosen since a previous dynamic tendon repair study showed that 90% of the measured gap at 1000 cycles is reached by 200 cycles in a core-only repair experiment (Haddad et al., 2010).

To evaluate gap formation during this dynamic phase of loading, testing was paused at 10, 20, 30, 40, 50, 100, 150, 200, 250 and digital images of the repair site were captured. The loading and imaging sequence is illustrated in Figure 4. Pictures were taken using a Canon EOS 1000D digital camera with a 100 mm

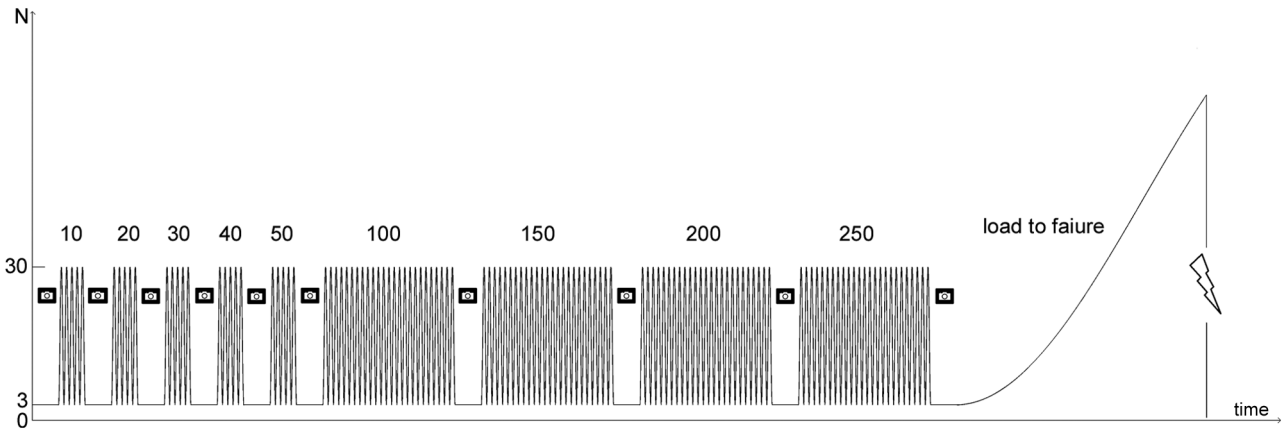

Figure 4. Dynamic and static testing sequence: Testing was paused at 3 N trough load and standardized pictures were taken at 10, 20, 30, 40, 50, 100, 150, 200, and 250 load cycles. Then the repair construct was pulled to failure at 20 mm/min distraction rate.

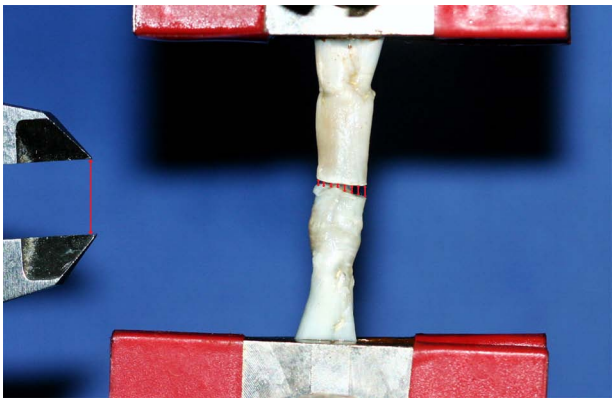

Figure 5. Testing set up with repaired tendon in hydraulic clamps held at 3 N trough load. Calliper fixed at 10 mm and mounted in same plane. Eight measurements were made using digital measurement software and averaged to determine average gap in each picture.

Canon macro lens (Canon Inc., Tokyo, Japan). The camera was set up on a stable tripod positioned at a constant distance and level to the repair site. A digital calliper (CD-6_CS Absolute Digimatic; Mitutoyo, Tokyo, Japan) fixed at 10 mm was secured in the same plane as the tendon to serve as a measurement reference in the images (Figure 5).

After 250 loading cycles, the repaired tendon was distracted to failure at a distraction rate of 20 mm/min. Load, displacement, and time were continuously recorded at 100 Hz and load–displacement curves were generated from the recorded data. No slippage of the tendon within the clamps was observed during testing. Care was also taken to avoid tendon dehydration by intermittent spraying with phosphate-buffered saline.

The primary endpoints were gap formation during dynamic loading (mm), number of cycles to 2 mm gap formation, ultimate failure load (N) and mode of final failure (suture pull out or breakage). Gap measurements were made in each taken picture at eight locations across the repair site using Image analysis software (Image J 1.410, National Institutes of Health, Bethesda, MD). Mean gap (mm) was then determined by averaging the eight measured lengths (Figure 5). The number of cycles necessary to create a 2 mm gap was calculated by correlating the recorded gap data with the amount of cycles at each measurement point (logarithmic interpolation).

All data were analysed in SPSS v17.0 (SPSS Inc., Chicago, IL). Independent sample *t*-tests with equal variances not assumed were used for comparisons of groups. A *p*-value of less than 0.05 was considered statistically significant.

Results

Gap formation

Mean gap was smaller at each cycle point for the barbed suture 3D repair group compared with the Adelaide repair group (Figure 6). The differences in gap formation were statistically significant at 10 cycles ($p < 0.001$), 20 cycles ($p = 0.007$), 30 cycles ($p = 0.018$) and 250 cycles ($p = 0.031$) of dynamic testing. The additional repair group using the conventional suture 3D repair showed significant less resistance to gap formation at all cycles of dynamic testing to both other groups (Figure 6).

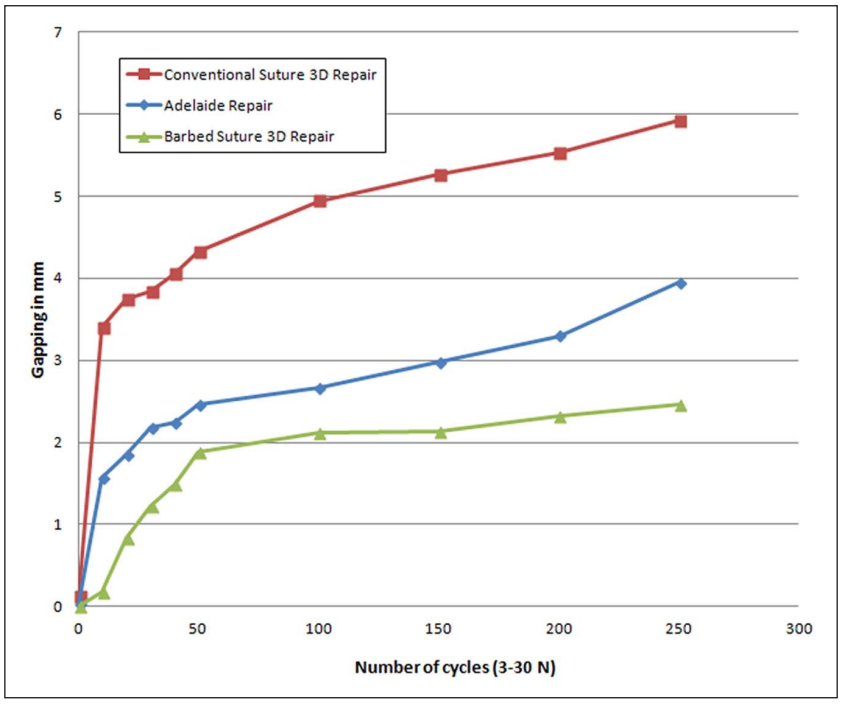

Figure 6. Gapping in millimetres per load cycle.

Ultimate load

The ultimate loads on failure testing after 250 cycles were 61.5N (±9.3N) for the barbed suture 3D repair group compared with 48.6N (±5.9N) for the Adelaide repair group (p = 0.002) and 47.2N (±6.3N) for the conventional suture 3D repair group ($p < 0.001$) (Figure 7). There was no significant difference in ultimate failure force between the Adelaide repair group and the conventional suture 3D repair group (p = 0.623).

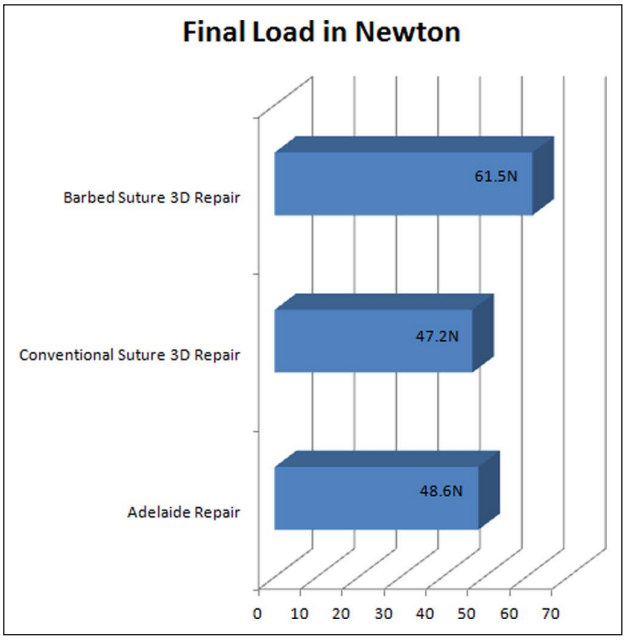

Figure 7. Ultimate load in Newton.

Cycles to 2 mm gap

A logarithmic regression equation was applied to the data and used to calculate the number of cycles necessary to create a 2 mm gap. The Adelaide repair group required 24.4 cycles (y = 0.6501l n(x) – 0.0754, R^2 = 0.9251) of loading to gap by 2 mm compared with 102.5 cycles (y = 0.6711l n(x) – 1.1073, R^2 = 0.9383) for the barbed suture 3D repair group. The conventional suture 3D repair group needed an average of 4.7 cycles to gap by 2 mm (y = 0.9791l n(x) + 0.4936, R^2 = 0.9759) (Figure 8).

Mode of final failure

In the Adelaide repair group one suture pull out was noted and 14 repairs failed by suture breakage. Thirteen sutures broke at the knot, one suture broke adjacent to the knot. In the barbed suture 3D repair group, five repairs failed by suture pull out and 10 by suture breakage. In the conventional suture 3D repair group four pull outs were noted and six repairs failed by breakage of suture material at knot.

Discussion

This ex vivo study supports a potential role for barbed suture materials in tendon repair surgery. Our barbed suture 3D reconstruction demonstrated an improvement in ultimate repair strength of 27% compared with the Adelaide technique. Additionally, a significant reduction in gap formation throughout the testing was noted in the barbed suture group. The conventional Adelaide repairs resisted an average of 24 cycles of loading before gapping by 2 mm, the barbed suture repairs resisted an average of 103 cycles of loading before gapping by 2 mm. Our control group, with the conventional suture 3D repairs using a knot, performed significantly worse than the main testing groups in regards to gap formation. A 2 mm gap was already noticeable after an average of five cycles of loading. In regards to final failure loads the conventional suture 3D repairs showed similar loads to that of the Adelaide repair group. It should be noted that no circumferential stitch was applied to any of the repairs of all three groups to exaggerate the behaviour of the core suture materials and methods tested in isolation. An additional circumferential suture would have masked differences and not helped to investigate the principle differences in these repair constructs.

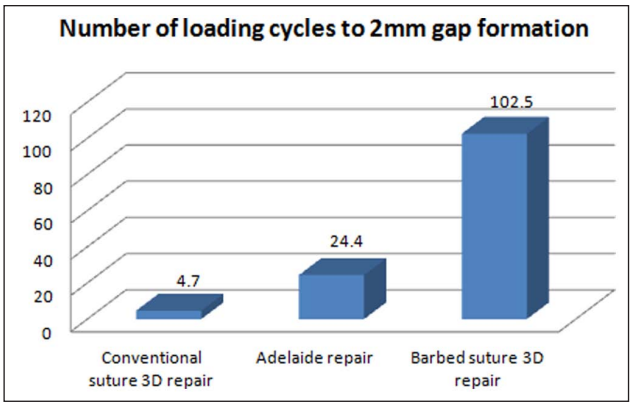

Figure 8. Avarage amount of loading cycles (3 N to 30 N) to cause a 2 mm gap.

The Adelaide repair technique performed with a braided polyester suture was chosen as our comparator because of its common use and high regard among several authors for superior performance and stability in comparison to other four-strand repairs (Angeles et al., 2002; Barrie et al., 2001;

Table 1. Comparison table of published data on tendon repairs with barbed sutures.

Publication	Year	Core repair method	Strands	Suture material	Knotted/ unknotted	Epitendinous repair	Static/ dynamic testing	Final failure force	2mm gap
McKenzie	1967	simple passes	two	bidirectional 3/0 nylon	unknotted	no	static	20N-25N	–
Trocchia et al.	2009	mod. Kessler	two	bidirectional 2/0 polypropylene (Quill)	unknotted	no	static	29.6N	at 22.2 N
Parikh et al.	2009	authors own	three/ six	bidirectional 2/0 polypropylene (Quill)	unknotted	no	static	36N/88N	–
Zeplin et al.	2011	mod. Kessler	two/four	monodirectional 3/0 polyglyconate (V-Loc)	unknotted	no	static	38N/145.6N	–
Marrero-Amadeo et al.	2011	mod. Kessler	four	bidirectional 2/0 polydioxanone (Quill)	unknotted	no	static	50N	at 32N
Buschmann et al.	2011	mod. Kessler	two/four	bidirectional 4/0 polypropylene (Quill)	knotted	yes/no	static	30N/38N	at 25N/30N
McClellan et al.	2011	authors own	four	bidirectional 1/0 polypropylene (Quill)	unknotted	no	static	72.39N	at 62.84N
Peltz et al.	2012	authors own	four	monodirectional 3/0 polyglyconate (V-Loc)	unknotted	no	static + dynamic	61.5N	after 103 loading cycles

Barrie et al., 2000; Croog et al., 2007; Hirpara et al., 2007; Strickland, 2000).

Two barbed suture materials are commercially available. The Quill™ device (Angiotech. Vancouver, BC, Canada) is a bidirectional, double armed, barbed suture material; and, the V-Loc™ device (Covidien. Mansfield, MA, United States) is a unidirectional, single armed, barbed suture. The literature examining the use of these materials in tendon surgery is limited (Table 1). Most studies use the bidirectional suture device in tendon experiments. Little data is reported on the mono-directional device. There are no studies available reporting on the biomechanical behaviour of barbed suture repair constructs when put under repetitive cycling loads to investigate the gapping performance of such repair constructs.

Parikh et al. (2009) investigated the use of the Quill device for tenorrhaphy in an ex vivo analysis using a novel repair method with either three or six strands. They reported loads to failure of 36 N for their three-strand barbed suture repair and 88 N for their six-strand repair method (no peripheral repair was performed in any group). The six-strand variation, constructed using two Quill devices, performed significantly better than the conventional four-strand cruciate repair. The three-strand barbed suture technique, sutured with one Quill device, was not different from the conventional four-strand repair. Since a 2-0 suture and a three- or six-strand method was used for the barbed repairs and 4-0 sutures and a four-strand method was used for the conventional repairs, comparison is limited. More importantly, no dynamic testing or quantitative evaluation of gap resistance was carried out.

Trocchia et al. (2009) performed a modified Kessler-Bunnell tendon repair with the 2-0 Quill bidirectional suture device and compared it with a modified Kessler repair using a 3-0 conventional polyester suture. In their static testing scenario the two-strand barbed suture repair was weaker than the conventional two-strand modified Kessler repair, but they did not demonstrate a difference in 2 mm gap forces between groups. No dynamic testing was carried out.

Zeplin et al. (2011) investigated ultimate failure forces of a four-strand modified double Kessler repair performed with either 3-0 conventional sutures or 3-0 V-Loc barbed sutures, the same device tested in our study. The mean ultimate repair strengths published by this group were in the order of 145.6 N for the barbed suture repairs and 149.5 N for the conventional repairs. No significant difference between groups was demonstrated. Nevertheless, these reported loads appear significantly higher than those reported in the literature. This may be explained by their unconventional testing methodology considering the tendons were repaired end-to-end, creating a looped testing configuration. Comparisons to this data are therefore rather complex. This study did not utilize dynamic testing nor comment on gap formation.

Marrero-Amadeo et al. (2011) investigated deep flexor tendon repairs using a Quill bidirectional barbed suture device in an ex vivo cadaver model. Their unusual approach of testing a four-strand Tajima repair augmented with a circumferential epitendinous repair versus a four-strand modified double Kessler barbed suture repair, in contrast not augmented by a circumferential repair, showed no significant differences in groups in regards to final load or 2 mm gapping. No dynamic testing was carried out.

McClellan et al. (2011) showed similar biomechanical performance for their knotless four-strand barbed suture repair construct in comparison to a modified four-strand Savage repair. Although they used two Quill suture devices for each barbed suture repair in their static ex vivo testing scenario, they could show that, in comparison with the conventional knotted repairs, the cross-sectional area of the barbed suture repairs was significant smaller after testing.

On balance there is modest support for McKensie's positive conclusions regarding the use of barbed sutures in tendon repairs half a century ago. Nonetheless, many studies have reiterated the importance of gap formation for tendon repair failures (Barrie et al., 2000; Gelberman et al., 1999; Haddad et al., 2010; Walbeehm et al., 2009; Wu et al., 2011; Zhao et al., 2004). Many studies have also pointed out the importance of using a dynamic testing protocol to safely make a statement about gap formation (Alavanja et al., 2005; Barrie et al., 2000; Gibbons et al., 2009; Haddad et al., 2010; Matheson et al., 2005; Pruitt et al., 1991; Sanders et al., 1997). We could find no study applying a dynamic testing protocol to barbed suture repairs.

A common problem in biomechanical tendon repair studies is that authors do not specify how they access the load at the 2 mm gapping point, or how they measure the 2 mm gap itself. We feel confident that with our method of accessing the gap of the repair site at several time points with exact digital gap measurements we were able to precisely analyse this endpoint.

The reported principal benefit of barbed sutures is that tension is broadly distributed along the path of the suture, and not concentrated at localized, high-stress points/areas. We think this is an important factor for resisting gap formation when used in tendon repairs. Furthermore, we believe that merely applying a traditional repair configuration with barbed devices fails to draw the greatest utility from this material. Traditional repair techniques are designed for conventional sutures and derive their performance by the

number and configuration of holding zones in the tendon (Savage and Risitano, 1989; Viinikainen et al., 2004), as well as relying on knots (Barrie et al., 2000; Momose et al., 2000; Rees et al., 2009; Xie et al., 2005). With our knotted conventional suture 3D repair group we could show that a repair construct without locking configurations might hold final failure loads comparable with constructs with locking configurations, but in regards to gap formation the unlocked construct shows significant inferior stability. Much research has been done on improving the design and geometry of these locking zones (Barrie et al., 2000; Cao et al., 2006; Dona et al., 2004; Hatanaka and Manske, 1999; Hotokezaka and Manske, 1997; Lee et al., 2010; Peltz et al., 2011; Sandow and McMahon, 1996; Savage and Risitano, 1989; Strickland, 2000; Wada et al., 2000; Walbeehm et al., 2009; Wu et al., 2011). Still, these holding zones are sites of stress concentration. They tighten and are the points of cheese wiring and constriction, which inevitably leads to gapping.

It is likely that a sufficient/threshold number of barbs need to be 'buried' within the tendon to achieve stable repairs. This can be attained by increasing suture purchase (Cao et al., 2006; Lee et al., 2010) or increasing the number of strands (Barrie et al., 2000; Gill et al., 1999; Thurman et al., 1998; Viinikainen et al., 2008). To make our comparisons consistent, we chose to use four strands and a common suture purchase of 10 mm for all three groups. Barbed suture repair constructs with less strands and/or less suture purchase length may produce insufficient repair stability (Buschmann et al., 2011; McClellan et al., 2011; Trocchia et al., 2009; Zeplin et al., 2011).

We also believe that repairing tendons in a 3D fashion using the whole body of the tendon for maximal load distribution and barb interaction with tendon fibrils helps to improve barbed suture tendon repairs. As we could show with our control group, this does not apply to conventional suture constructs to the same degree.

Exact tendon apposition and equal tensioning on each strand during repair is important for the repair performance (Tang, 2007), but difficult to achieve in practice when using conventional multi-strand tendon repair methods. We noted that tendon apposition and equal strand tensioning is more easily maintained during repair with barbed sutures since sustained apposition of tendon ends can already be achieved after the first repair pass. Although the illustration of our repair construct looks complicated, it essentially consists of four simple passes through the tendon body in two planes and can be performed very quickly. The placement in two planes is easily achieved by rotating the tendon 90° to the left and right.

In spite of the attractiveness of barbed material, several downsides remain. The used 3-0 barbed suture in fact has the calibre of a 2-0 material, with the strength of a 3-0 suture. In general, exposure of barbs on the tendon surface is a concern. There is a potential for these to abrade the lining of the flexor sheath, adversely affecting gliding resistance as well as promoting adhesions. Exposure can be minimized, but not entirely avoided, by re-entering the tendon very closely to the exit point of the suture at each pass. Perhaps another caveat is the current limitations of the available barbed material. Most devices are absorbable and primarily marketed for wound closure. The needle has a cutting edge and hence is not ideal for tenorrhaphy.

In conclusion, this study shows promising biomechanical characteristics of our barbed suture tendon repair method. Barbed sutures better distribute loads throughout the tendon and therefore help to produce a stable repair, especially with regards to early gap formation. This might be an important factor for positive outcomes of early active rehabilitation regimes. But further refinements in the material and in vivo studies will be necessary before its use can be appraised in a common clinical setting.

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Conflict of interests

None declared.

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