Biomechanical Evaluation Of A Hybrid Barbed Suture In The Repair Of Flexor Tendons

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Abstract

This study was developed to test the utility of a simple hybrid barbed-suture in the core repair of digital flexor tendon. The barbed suture was constructed by inserting three steel barbs into the weaved construct of a braided polyester suture. These sutures were inserted into 28 porcine lateral extensor tendons yielding a single sided core repair. Linear load testing to failure was undertaken. The barbed suture technique demonstrated a maximum load to failure of 40.4 (SD 16.4) N. Excursion of the repair at failure point was 31.4 (SD 11.6) mm. Stiffness of the repair derived from the linear elastic portion of the load displacement curve was 1.0 (SD 0.6) N/mm. Use of this barbed suture construct offers a fast, easily applied method of flexor tendon repair. The maximum load to failure is comparable to the commonly used non-barbed suture methods. Further testing with design modifications may limit suture excursion.

INTRODUCTION

Adequate repair of injured digital flexor tendons has remained one of the most challenging problems facing the hand surgeon. Although there have been significant advances in both suture techniques and materials the characteristics of an ideal primary flexor tendon repair outlined by Strickland (1995) remain to be met. The possibility of using “barbed sutures” was investigated in the 1960’s by Mckenzie (1967) and Shaw (1968). This work has been expanded recently (Gussous et al., 2011).

Barbed sutures continue to garner interest owing to the potential of gaining an easily applied knot free repair. Though complex multiple strand suture based repairs fulfill the requirement of sufficient strength and resistance to gap formation, they are technically demanding and can reduce the tendons ability to glide (Gussous et al., 2011). Despite offering advantages over traditional suture methods concerns over the cost, strength to failure and biocompatibility of barbed sutures have hindered their development and consequently they have not found widespread usage. Moreover the recent designs have been very complex. This is despite almost no testing of simple designs. Without understanding what can be achieved with simple designs it is difficult to develop the best lines of research for more complex designs.

We have attempted to develop and test a simple barbed suture to assess further the viability of barbed sutures in flexor tendon repair and in particular to establish a baseline for the efficacy and modes of failure of a simple design in order to help provide a basis for future research.

METHOD

DEVICE AND REPAIR TECHNIQUE

Our “barbed suture” was designed to provide an easily produced, potentially cheap construct, which also offers potential for further development. This suture was required to pass easily into the tendon at the point of injury, with the aim of providing a core repair of adequate strength. An epitendenous repair was not undertaken as we were simply assessing a core suture.

A novel approach to development of a barbed suture was taken by inserting metal barbs into the weaved construct of a commonly used braided suture. Size 2 Ethibond Excel sutures (Johnson & Johnson, USA) were selected. A 25G needle was passed through the braided polyester strands creating an interval for the passage of a steel barb. Initially the barbs were simply placed in the suture. At initial testing the barbs often rotated losing purchase. Subsequently a small amount of cyanoacrylate glue was applied at the apex of the barb to ensure the barb remained fixed in the suture.

The device tested used three barbs placed into each suture with a 5mm gap between each barb. Once the primary barb was placed as a reference, the further two barbs were added at with approximately 60° of rotation in the axial plane providing barbs at equal points around a 360° axis (fig 1). Each steel barb was at an angle of 25° to 30° to the line of the suture to provide adequate grip but without being too bulky. The span of the barbs was 3 - 4 mm.

The 1/2c tapercut needle of the suture was used for insertion into the tendon at its artificially lacerated end. The needle was passed up the tendon 25mm and then pulled out. The 15mm long barb construct was pulled through the tendon until the 3 rd barb was seated within the tendon tissue, approximately 5mm from the lacerated end.

Figure 1

Fig 1a - Orientation of 3 barb placement into braided suture.
Fig 1b – Barbed suture once inserted into the porcine tendon

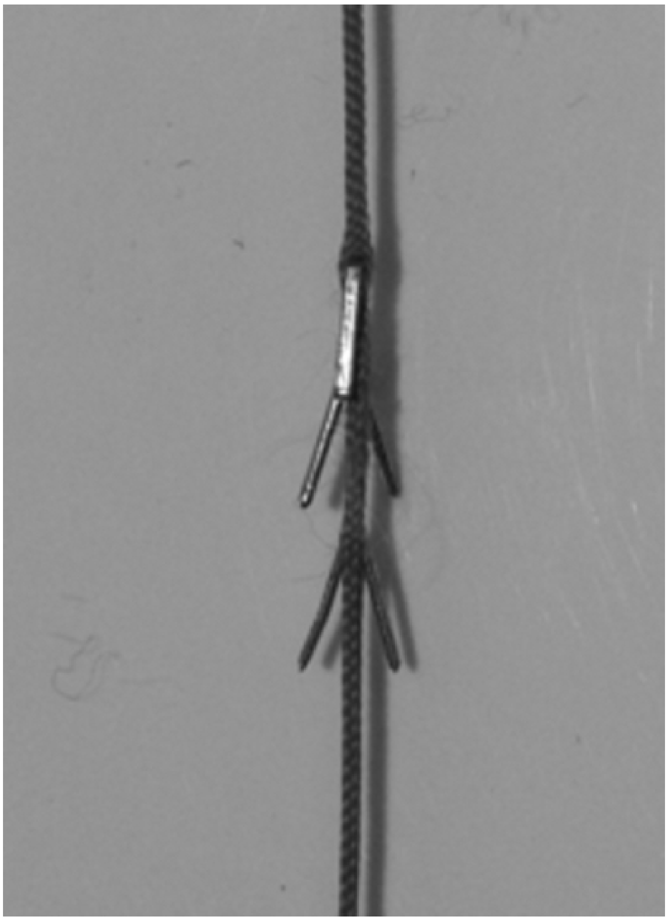
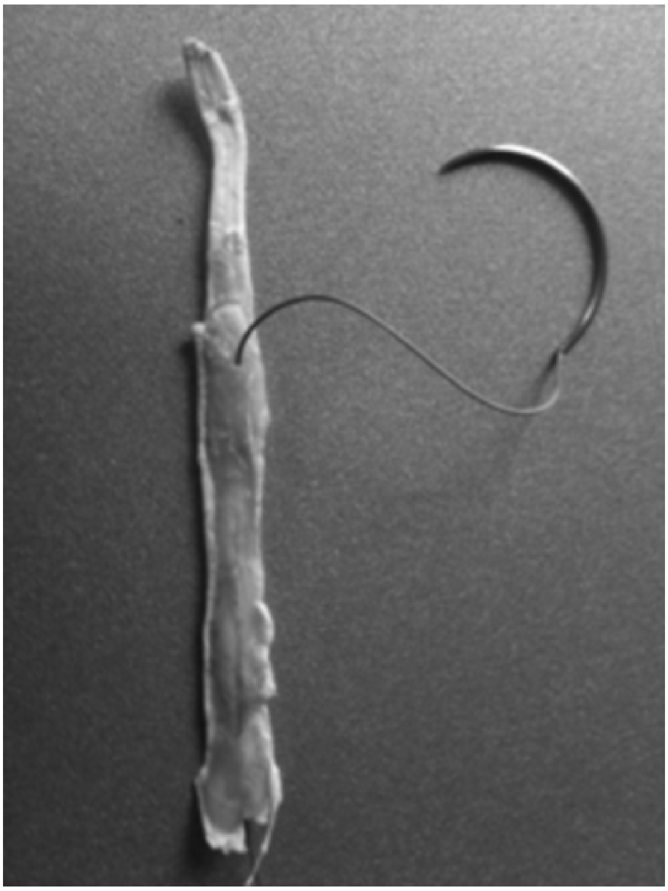


Figure 2



TESTING PROTOCOL

Fourteen porcine lateral extensor tendons were harvested for the testing procedure. The porcine forelimbs were sourced within 24 hours of sacrifice and frozen to -20°C. Following thawing, extraneous tissue was removed and the tendons were excised as close as possible to their proximal and distal musculo-tendenous attachments. The tendons were kept moist using Ringer's Solution and then frozen a second time to -20°C until the day of testing.

Prior to testing the tendons were thawed at 21°C. Each tendon was transected sharply at its midpoint providing 28 specimens for testing. Barbed sutures were then placed as described above, yielding 28 single sided tendon repairs for tensile testing. A full repair with apposition of the two transected ends of the tendon was not undertaken as we wished to test only the barbed suture/tendon construct.

Tensile testing of the repair was undertaken using an Instron 3365 Dual Column Tabletop testing System (Instron Norwood, MA) with bespoke cryo-clamps for fixation of the tendon.

The portion of tendon distal to the laceration and not containing the repair was placed in the cryo-clamp. The clamp was stored in dry ice prior to testing, providing a surface temperature of -50°C. The clamp bolts were then tightened to 10Nm securing the tendon portion whilst minimising tissue damage. The suture end, running from the midpoint of the transected end of the tendon, was then tied securely to a locked bolt at the base of the tensile testing rig.

A preload of 0.5N was applied to the tendon following initiation of linear load tensile testing at a rate of 25mm/minute until repair failure. The load (N)/clamp displacement (mm) was recorded every 0.1sec.

The maximum force sustained (N) was derived from the load/displacement curve. The stiffness of the repair expressed as a ratio of load to displacement (N/mm) was derived from the linear elastic portion of the graph of the plot through the addition of a least square linear trendline.

Figure 3

Fig 2a – Position of the tendon in the open cryoclamp. Fig 2b - Complete testing rig.

Figure 4

RESULTS

The maximum load applied to produce failure of the construct was 40.4 (range 12.1 - 67.8 SD 16.4) N. The mean excursion of the suture construct at the point of failure was 30.9 (range 15.3 - 43.4 SD 11.8) mm.

The stiffness of the repair measured from the linear elastic portion of the graph was found to be 1.1 (range 0.4 - 2.0, SD 0.6) N/mm.

Figure 5

Table 1 : Testing results (SD)

Maximum Load prior to failure (N)	40.4 (16.4)
Excursion to the point of failure (mm)	31.4 (11.6)
Stiffness (N/mm)	1.1 (0.6)

There were two types of failure of the repairs. There was either pullout of the barbed suture construct or failure at the glued apex of the barb-suture interface. The pull out of the barbed suture seemed to be resisted by the collagen links between longitudinal tendon fibres with no grip on the fibres themselves as in locked suture repairs. This is more akin to the Savage repair (Savage, 1985). In the second instance the barb would flip within the tendon and then pullout under increasing load. Pullout of the barbed suture did cause damage to the tendon substance but not sufficient to preclude further repair.

DISCUSSION

The intention of this study was to explore the ease of development and efficacy of a simple barbed suture for repair of flexor tendon injuries. The aim of the suture design was to make a repair device that can be placed easily into the tendon with minimal tissue damage, of sufficient strength to allow early movement. Many authors have strived to fulfill these suture characteristics, outlined by Strickland (1995), leading to the production of complex suture patterns utilising multi-strand core tendon repairs. Others have explored non-suture based methods such as butyl cyanacrylate glue (Powell et al., 1989), argon and CO2 welding (Kilkelly et al., 1996) and the stainless-steel Tenofix device (Su et al., 2005). Although Shaw (Shaw, 1968) trailed the use of barbed sutures in 1967, achieving repair strengths of 30.4N the techniques did not enter widespread use or comprehensive design progression and trialing.

Through the repair process it was found that the modified suture passed easily into the substance of the tendon. The repair process appeared to induce minimal tissue damage, although this was not assessed in detail, with only a small addition of bulk added to the tendon structure. There is also no suture on the outside of the tendon, which should reduce the inflammatory response and the resistance to gliding.

The barbed suture method offers potential technical benefits owing to the ease of application. Though, in this study, the device was inserted in isolated tendons, it is envisaged that only the insertion site into the lacerated tendon ends needs visualisation, the exit point of the needle through skin 25mm from its insertion may not need formal dissection. The ease of application in this instance would hopefully offer a method more amenable to non-specialist and trainee staff.

To the authors' knowledge the use of a composite structure of braided suture and metal barbs has not yet been explored in the literature. The flexibility of the inter-barb sections has the advantage of compliance with bending stress. The biggest advantage of this design is its ease of construction and flexibility of design. Multiple variables can be changes singly or in combination to begin to understand further the optimum configurations for a barbed suture. The following variables can easily be altered: the number of barbs; the orientation of the barbs relative to each other; the distance between the barbs and thus the overall length of the barb construct; the length of the barbs; and the angle of each barb to the long axis of the suture.

The mode of failure seems to differ from locked suture techniques. The barbed sutures will therefore be more dependent upon the collagen crosslinks within the substance of the tendon than current techniques. These crosslinks may not vary greatly between tendons so the barbed suture may be applicable to "all" flexor tendon injuries. The strength of the crosslinks may however vary markedly with biological variables such as age and gender. This will need to be considered in the development and testing of future devices. For example it may be that barbed sutures will work very well for tendon injuries in younger men but not older women. Moreover, the traditional tendon model of the porcine extensor tendon may be less suited for comparison with human flexor tendons. At present this is only speculation to raise questions for future researchers.

The barbed suture device exhibited a maximum load to failure of 40.4 (16.4) N. Under unrestricted passive flexion, flexor tendons are subject to 2 to 4 N of force (Strickland, 1995). Active flexion with mild to moderate resistance results in 10 – 17N of force respectively with 70N reported in strong composite grasp (Strickland, 1995). Full load to failure with this barbed suture device under a standard treatment regimen would appear to have adequate repair strength for protected early mobilisation even without an epitendinous suture. Trials of barbed suture repairs have reported varying construct strengths. Shaw (1968) reported a metallic barb suture load to failure at 1.8 to 2kg (ie 17.7 – 19.6 N). Hirpara et al (2010) using a novel multi-barbed Nitinol metal construct loaded onto a suture report load to failure strengths of 25.61N with one device and 58.39N with the use of two devices . The modified Kessler suture techniques gives repair strengths of 39N (Barrie et al., 2000) , 33N (Smith & Evans, 2001) and 37.68N (Stein, Ali, Hamman, & Mass, 1998) using 4-0 Ethibond. By comparison our repair used only one strand. A double strand repair should in theory be stronger than established two strand repairs although bulkier in the tendon.

Though it is accepted that resistance to failure is an important component in repaired tendons, ultimately return to strength and excursion of the tendon is also dependent on a gap resistant repair between the two ends of tendon (Strickland, 1995). Gaps as small as 2mm have been associated with poor outcomes (Gelberman et al., 1999). This study assessed a single sided repair and so gap formation was not assessed. However, suture stiffness calculations report excursion of the repair of 1.1mm per N. The authors feel that the low starting load of 0.5N applied to the repair prior to testing may not be adequate to sink the barbs into the tendon substance, hence early suture excursion as the load increased. Further testing should assess higher primary loads to assess whether this can ameliorate early excursion followed by assessment of gap formation in complete repairs.

There are deficiencies in this study. The suture used was larger than normally chosen for flexor tendon repair. As the barbed suture is effectively a single strand repair in this design that may not be material. The size of suture was simply chosen for ease of construction. It was probably not material to the results. The barbs used were very simple with their orientation, separation and rotational alignment chosen base on informed estimation rather than scientific studies. This is because there is so little science in this area and hence the need to start testing simple designs. The fixation of the barbs to the suture was not always adequate and that will need improvement. The use of a single tendon end precluded study of gap formation. That will be important but can await the development of better designs. Ultimately this is not a viable design for tendon repair at present but is a model for future testing

In an effort to adhere to Strickland's (1995) gold standard guidelines for flexor tendon repair many authors continue to apply both different techniques and materials to this challenging yet common facet of surgical practice. Improvements in biomaterials have seen a resurgence of interest in the concept of barbed sutures (Gussous et al., 2011). Results from this study highlights their ease of application and strength to failure of a simple design. Further developments of this and other deigns may lead to a viable alternative to the current repair techniques. We recommend a programme of testing different barb variables on porcine extensor tendons and then testing on human flexor tendons until an "optimum" configuration is achieved and then testing that and other similarly successful designs on human flexor tendons. This research may lead to a viable simple barbed suture that can be used in vivo. At the least it should help direct researchers looking at complex barb designs.

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