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Beyond the Core Suture: A New Approach to Tendon Repair

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Background: Despite significant improvements in zone II flexor tendon repair over the last 2 decades, function-limiting complications persist. This article describes 2 novel repair techniques utilizing flexor digitorum superficialis (FDS) autografts to buttress the flexor digitorum profundus (FDP) repair site without the use of core sutures. The hypothesis being that the reclaimed FDS tendon autograft will redistribute tensile forces away from the FDP repair site, increasing overall strength and resistance to gapping in Zone II flexor tendon injuries compared with the current clinical techniques.

Methods: Two novel FDP repair methods utilizing portions of FDS have been described: (1) asymmetric repair (AR), and (2) circumferential repair. Ultimate tensile strength and cyclical testing were used to compare novel techniques to current clinical standard repairs: 2-strand (2-St), 4-strand (4-St), and 6-strand (6-St) methods. All repairs were performed in cadaveric sheep tendons (n = 10/group), by a single surgeon.

Results: AR and circumferential repair techniques demonstrated comparable ultimate tensile strength to 6-St repairs, with all 3 of these techniques able to tolerate significantly stronger loads than the 2-St and 4-St repairs ($P < 0.0001$). Cyclical testing demonstrated that AR and circumferential repair were able to withstand a significantly higher total cumulative force ($P < 0.001$ and $P = 0.0064$, respectively) than the 6-St, while only AR tolerated a significantly greater force to 2-mm gap formation ($P = 0.042$) than the 6-St repair.

Conclusion: Incorporating FDS as an autologous graft for FDP repair provides at least a comparable ultimate tensile strength and a significantly greater cumulative force to failure and 2-mm gap formation than a traditional 6-St repair. *(Plast Reconstr Surg Glob Open 2020;8:e3280; doi: 10.1097/GOX.0000000000003280; Published online 17 December 2020.)*

INTRODUCTION

Zone II flexor tendon injuries have always posed a challenge to the reconstructive surgeon, with the region earning the moniker, "no man's land" as such injuries are difficult to approach and fraught with complications, specifically adhesions, due to the presence of an extensive fibro-osseous sheath. That being said, significant improvements have been made in zone II injury outcomes, mainly due to innovation in postoperative care.[1–8] Passive and active postoperative motion protocols have been developed to mitigate adhesion formation and maximize final range of motion.[9,10] With early motion, unfortunately, the risk of rupturing the healing tendon increases, especially in regimens such as controlled active motion and early use of the involved hand.[3,6] Rupture of a repaired tendon is considered a tremendous obstacle on the road to healing, as this requires at least 1 additional surgery, possibly 2 if staged reconstruction is required. Additionally, any subsequent operation is often more difficult due to the presence of scarring and inflammation from the initial procedure.[11]

To mitigate the risk of postoperative tendon rupture, much focus has been placed on increasing the strength of the tendon repair. Reports have demonstrated that two-stranded methods of repair are not strong enough for controlled active motion or for the early use of the involved hand, with a

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rupture rate of 11.7%.[12] Many methods have been developed to improve repair strength, but all such techniques are driven by 2 principles: (1) increasing the number of core sutures, and (2) using stronger/larger caliber suture material.[13–17] Additionally, to maximize the success of tendon repair, it is generally recommended that a locking technique be used rather than a grasping technique.[18–21] The extremes of these principles have even led to the development of steel devices[22] and use of 8-stranded repair techniques,[14] which demonstrate a predictable increase in strength during ex vivo testing. While such techniques may increase strength, it is often done so at the cost of additional bulk and introduction of more foreign material into the body.[23,24] While a bulky repair site can occur by design as reported by Tang et al., typically bulk is considered to negatively impact gliding of the newly repaired tendon.[17,24] Despite these efforts, outcomes remain unpredictable.[25] Active motion rehabilitation results in an 11% complication rate, composed of 5% ruptures and 6% decreased motion.[5] Clearly, we, as a field, have yet to strike the perfect balance between early motion and tendon healing.

The vast majority of studies assess the ultimate tensile strength of a repair or the maximum amount of pull force the repair can take before failing.[26,27] Another method to measure tendon repair strength is cyclical testing, in which the repair is loaded and unloaded repeatedly over time to simulate the physiologic and dynamic conditions of postoperative range of motion protocols.[19,28–32] From cyclical studies, one can calculate cumulative force (summation of the number of cycles at each tested load) to failure, which can be defined as total repair failure or 2-mm gap formation.[18,33] This methodology is most relevant when considering clinical protocols such as TAM.

A recent review of zone II flexor tendon repair suggested that in cases where the flexor digitorum superficialis (FDS) is severely damaged, leaving it unrepaired or resecting a segment of the exposed FDS is not detrimental to finger motion.[17] It has also been suggested that if the FDS is left unrepaired, patients may experience improved gliding of the repaired flexor digitorum profundus (FDP) tendon.[34] In such instances that call for FDP repair only, we believe that the damaged FDS tendon can be reclaimed and used as autologous graft to supplement the repair of the FDP tendon. This FDS tissue would serve as an available and easily accessible source of high-strength autograft. In this study we propose 2 novel methods of FDP tendon repair, each utilizing a segment of FDS graft, when possible, for load bearing support. We hypothesize that the use of reclaimed FDS tendon graft in FDP repair will redistribute tensile forces away from the repair site, thus increasing overall strength and resistance to gapping in Zone II flexor tendon injuries compared with the current clinically utilized techniques.

MATERIALS AND METHODS

Tendon Model

This study utilized a cadaveric sheep tendon model. Adult, 18- to 25-month-old female sheep (ewes) of mixed breed (Tarhee, Polypay, Dorset, Dorset Cross) were used. Eighty FDP tendons were resected from the lateral digits of forelimbs, given their strength and structure similar to those of human finger flexor tendons within Zone II.[35] Distally, all of the tendons were harvested to include their insertion on distal phalanx. Proximally, the tendons were harvested at least 10 cm proximal to the bifurcation of the FDP. The tendon injury was created before explantation via laceration of the FDP tendon with a scalpel exactly 1 cm proximal to the proximal edge of the annular ligament (similar to the A2 pulley in humans). Measurements were taken from the proximal edge of the posterior hoof to the proximal edge of the annular ligament to qualify anatomy and quantify uniformity amongst the limbs being used. Additionally, tendon circumference at the site of transection was measured using a silk tie. This measurement was repeated 3 times and the mean recorded. All tendons were stored at room temperature in phosphate buffered saline moistened gauze while awaiting repair.

Tendon Repair

Two novel methods of tendon repair were tested: The asymmetric repair (AR) (Fig. 1A) and the circumferential repair (CR) (Fig. 1B). The AR consisted of a 3-cm strip of FDS tendon incorporated as an onlay graft spanning the repair site. Two pairs of simple sutures were used to anchor the graft to the underlying tendon on each side of the repair at approximately 1 cm and 1.5 cm from the repair site. The CR used a 3-cm long piece FDS tendon as a wrap around the repair site. A single 5-point suture was used to anchor the graft to the underlying tendon on each side of the repair approximately 1 cm away from the cut edge.

The experimental repairs were compared to 3 controls composed of classic flexor tendon repair techniques: 1) the 2-strand modified Kessler technique (2-St),[18] 2) the 4-strand modified Kessler technique with a looped suture (4-St)[33] and 3) the 6-strand modified Tang technique (6-St).[17] All repairs consisted of 4-0 cable nylon with a tapered needle (S. Jackson, Inc., Alexandria, Va.) as the load bearing suture, which is used either to secure the FDS to the FDP in both novel repairs or as core sutures for the controls. The novel repairs did not contain core sutures and rely on the strength of FDS across the repair site. Every repair (novel and control) was supplemented with a running, epitendinous 6-0 Prolene suture (Ethicon).

Biomechanical Testing

All the tendon repairs were assessed on a MTS 858 Bionix servo hydraulic test system. The distal portion of each tendon containing the phalanx was potted into a mold with auto-body filler and anchored to the base of the load frame. The proximal end of the repaired tendon was clamped to the hydraulic ram such that the distance from the ram to the repair site was equal to the distance from the repair sit to the phalanx, keeping the repair site in the center portion of the test length. Once the repaired tendons were securely fastened to the load frame, the ram was positioned to create a pre-load of approximately 2N. Additionally, an extensometer was placed into the body of the tendon straddling the repair to record displacement between the proximal and distal tendon segments. For ultimate tensile strength testing, the system

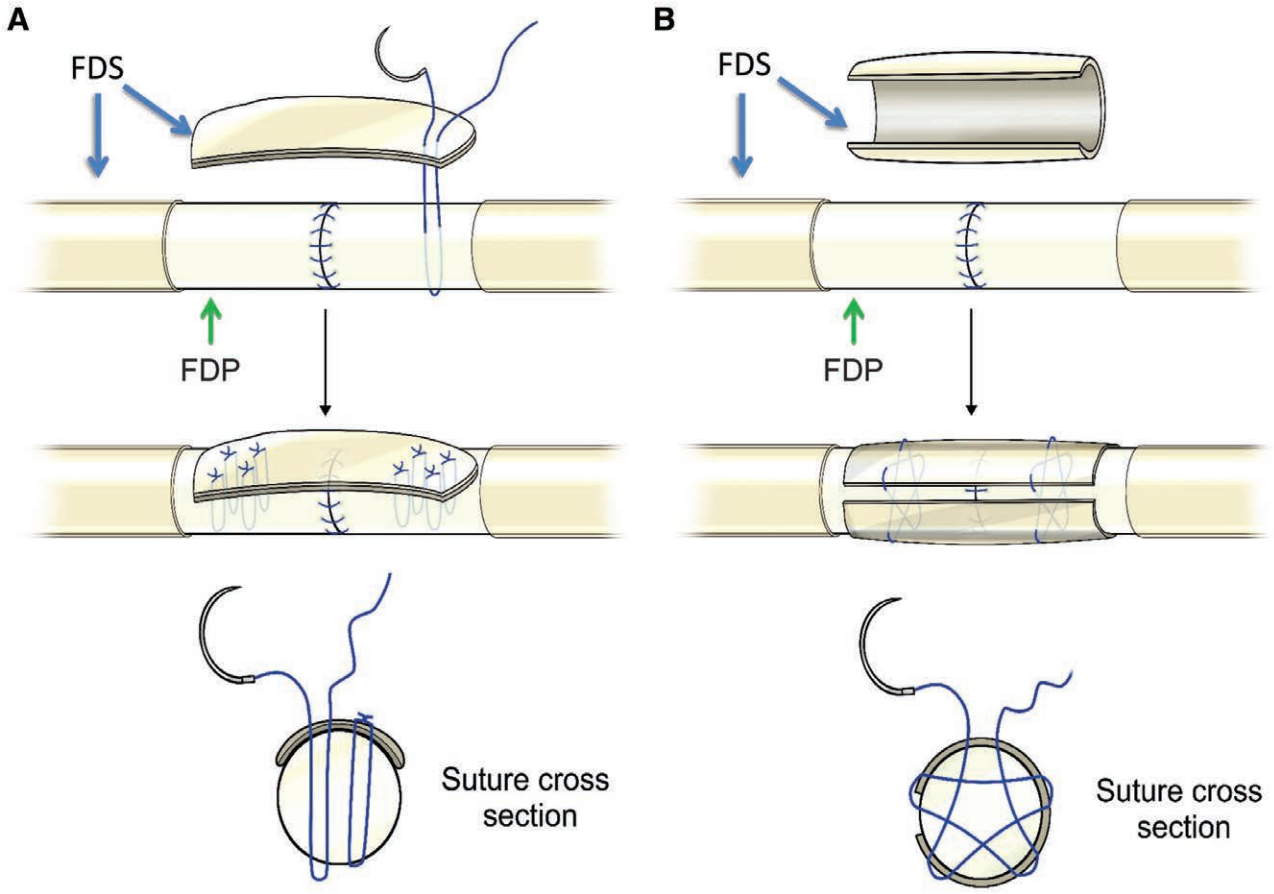

Fig. 1. Illustrations of novel flexor tendon repair techniques. A, AR involves the use of a segment of flexor digitorum superficialis (blue arrows) as an in situ onlay graft, which spans the repair site and incorporates 4 individual anchoring sutures at each end. B, The CR involves the use of a segment of flexor digitorum superficialis as an in situ wrap, which spans the graft site and is anchored by a single 5-point suture at each end.

was programmed to pull the tendon at a constant rate of 20 mm/minute, which meant to best simulate the forces acting on an immobilized tendon during active flexion during rehabilitation treatment.[21,36–39]

During testing, both load force and displacement were recorded. The highest force recorded before complete failure was considered the peak force and used to define the ultimate tensile strength of the repair.

The repair techniques that produced the highest ultimate tensile strength values were selected to undergo cyclical testing; an evaluation meant to simulate the regular loading and unloading of flexor tendons during postoperative motion protocols. To perform cyclical testing, the repaired tendons were again mounted to the Bionix test system with a preload of 2N. The system was programmed to load and unload the repairs repeatedly at a rate of one cycle per second (1 Hz). Each tendon began testing at 25N for 100 cycles. After completion of a cycle of 100 the peak load was increased by 10N. This was performed until failure of the tendon. From this test, the cumulative force to complete failure was calculated by the sum of each force multiplied by the number of cycles run at that force. We measured cumulative force to complete failure as well as cumulative force until 2-mm gap formation, which is widely considered the point at which the integrity of the repair has failed. For both ultimate tensile strength and cyclical testing, the modes of failure were assessed and recorded. Specifically, we recorded suture failure and tissue failure (cheese wiring). When assessing tissue failure, failure of the native tendon, graft or both were noted as well as proximal or distal location.

Statistical Analysis

The 3 primary outcomes, ultimate tensile strength, cumulative force to failure and cumulative force to 2-mm gap formation, were compared amongst control and experimental groups using unpaired *t*-tests. The significance level was set at 0.05 and the statistical analysis was performed using GraphPad Prism, version 8.3 (GraphPad Software, LLC).

RESULTS

Anatomy

The distance from the transection site to the proximal edge of the hooves was measured as (4.50 ± 0.68) cm. The mean circumference of the tendon at the site of transection was measured to be (12.71 ± 0.66) mm.

Ultimate Tensile Strength

The peak force sustained before complete failure of the repair defined the ultimate tensile strength of each technique. These values are summarized in Fig. 2A. The 6-St repair (mean = 56.84N ± 8.79), AR (mean = 66.38N ± 15.24) and CR (mean = 65.86N ±15.17) were able to tolerate significantly greater peak loads before complete failure than the 2-St (mean = 30.22N ± 3.89) and 4-St (34.64N ± 6.37) repairs ($P < 0.0001$) (Fig. 2A). No statistically significant difference was found among AR, CR, and 6-St techniques.

Mode of Failure

The modes of failure observed in ultimate tensile strength testing is summarized in Figure 2B. In 2-St and 6-St repair techniques, the predominant mode of failure is suture failure, comprising 100% and 82% of failures, respectively. However, analysis of the 4-St repair demonstrated that tissue was the dominant mode of failure, comprising 83% of failures. AR and CR techniques demonstrated 100% tissue failure.

Cyclical Testing

The cumulative force causing complete failure in each repair is summarized in Figure 3A. Both the AR (mean = 38076N ± 12303) and CR (mean = 25295N ± 7652) techniques were able to withstand a significantly greater cumulative force than the 6-St(17156N ± 3312) repair before completely failing ($P < 0.0001$ and $P = 0.0064$, respectively). Interestingly, the AR repair was also significantly stronger than the CR technique ($P = 0.012$). The cumulative force tolerated before 2-mm gap formation is summarized in Figure 3B. Tendons repaired with the AR method (mean = 5683N ± 2829) tolerated a significantly greater

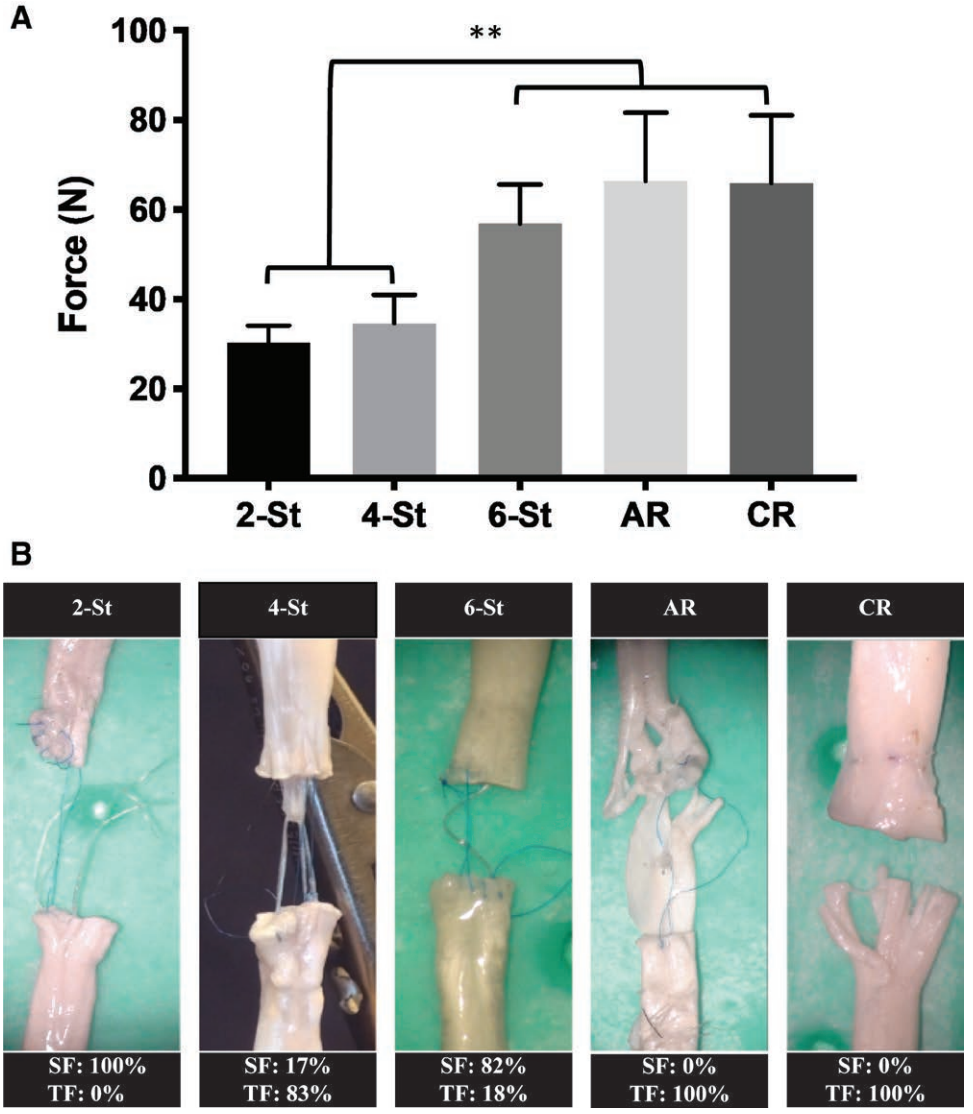

Fig. 2. Ultimate tensile strength results. A, Graphical representation of ultimate tensile strength data demonstrating that 6-St, AR, and CR significantly outperformed both 2-strand (2-St) and 4-strand (4-St) repair methods. B, Representative images of break mode (suture failure [SF] or tissue failure [TF]) for each of the repair methods tested.

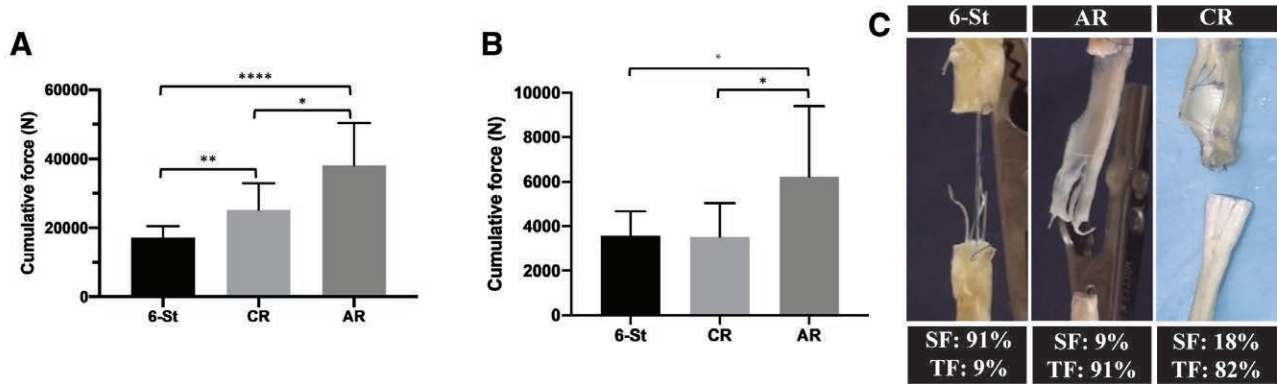

Fig. 3. Cyclical testing results. A, Graphical representation of cumulative force to failure during cyclical testing of 6-St, AR, and CR. B, Graphical representation of cumulative force to 2-mm gap formation during cyclical testing. C, Representative images of break mode (suture failure [SF] or tissue failure [TF]) during cyclical testing.

force before forming a 2-mm gap than both 6-St (mean = 3553N ± 1118) and CR (mean = 3521N ± 1508) techniques ($P = 0.022$ and $P = 0.026$, respectively) (Fig. 3A). No significant difference was appreciated between 6-St and CR methods ($P = 0.96$).

Mode of Failure

The modes of failure observed during cyclical testing are summarized in Figure 3C. Of the 6-St repairs, 91% of repair failure was due to suture failure, while 9% was due to tissue failure. In the AR and CR techniques, only 9% and 18% of failure were due to suture breakage, respectively. Tissue failure represented 91% of failures in AR and 82% of failures in CR.

DISCUSSION

Despite the many efforts to increase the strength of flexor tendon repairs, zone II flexor tendon injuries remain a challenge. As evidenced by the variety of clinically utilized surgical techniques and rehabilitation protocols, we, as a field, have yet to develop a gold standard, which optimally balances tendon healing, and range of motion. Tendon rupture and adhesions are still common complications that can be unpredictable and significantly disrupt a patient's road to recovery.[17,40–42] Needless to say, room for innovation exists.

While it is widely accepted that all damaged structures within a zone II flexor tendon injury should be repaired, there are instances where it is not possible or becomes impractical to repair the FDS.[17] It is in these cases that we propose the reclamation of the remaining FDS as an autologous graft to be used to buttress the 2 healing edges of the injured FDP tendon (Fig. 1). This study focused on the development of 2 novel repair techniques centered on the use of autologous tendon graft with the intent of producing a repair of superior strength and ability to tolerate a range of motion without compromising structural integrity.

To more completely assess the quality of our novel repair techniques, we chose to perform both ultimate tensile strength testing and cyclical testing with large groups. While we are unaware of another study that has utilized both testing modalities, we are confident in the fidelity of our results, as they mirror the separate findings published in the literature.[13,42] Specifically, our control or "classic" tendon repairs demonstrated a significant increase in ultimate tensile strength with an increased number of core sutures as the 6-strand technique proved stronger than both 2- and 4-strand repairs. Interestingly, when assessing the novel repair techniques, both AR and CR methods demonstrated significantly greater ultimate tensile strength than the classic 2- and 4-strand repairs. While the difference in ultimate tensile strength between both novel techniques and the 6-strand methods was found, it was not significant (Fig. 2A). While such findings can be useful and provide some preclinical evidence, there are several limitations to its validity in isolation. Virtually all ultimate tensile strength testing occurs in cadaveric tendon models, which, unfortunately, lack the critical elements of tendon healing and the physiologic processes associated with this. While animal models for flexor tendon repair exist, there are considerable limitations relating to rehabilitation compliance of animals, leading to excessive rupture rates.[43]

As cyclical testing is meant to more closely replicate the dynamic activity of loading and unloading the tendons that occurs with finger flexion, we assessed the performance of our novel techniques against the strongest control repair (6-St) in a more clinically relevant application. As mentioned above, the outcome measure of cyclical testing is cumulative force, which is essentially the sum of each repetition (one cycle of loading and unloading) at a given force. Specifically, we chose to measure cumulative force to complete failure and cumulative force required for 2-mm gap formation. It has been demonstrated that gapping can lead to poor tendon healing, adhesions, and catching of the tendon over the pulley during tendon mobilization.[9,19,24,37,44–46] Additionally, gapping >3 mm will compromise the strength of a repair and ability of healing.[24,44] Both the AR and CR novel repair techniques were able to tolerate a significantly greater cumulative force than control 6-St technique (Fig. 3A). Interestingly, the AR repair was able to tolerate significantly greater cumulative force before the formation of a 2-mm gap when compared

with both CR and the 6-St repair (Fig. 3B). Additionally, there was no significant difference between CR and the 6-St repair in their ability to resist a 2-mm gap.

While the results of our study thus far have been favorable regarding these novel techniques, direct comparison with classic techniques is difficult given that the novel methods lack core sutures. Given these differences, it is even more important to establish why the novel technique(s) appear to be outperforming the controls. Following the completion of every test run, we recorded the manner in which the repair failed with the two modes of failure being tissue failure (cheese wiring) versus suture failure (Fig. 2B and 3C). These data helped inform our analysis of these novel techniques and reinforce classic tenets of tendon repair.

A tendon repair relies on balance between the strength of the suture used and the grip friction between the suture and the tendon. In order for a repair to exploit the maximum strength of the suture involved, the force required to overcome the grip of the suture on the tendon must exceed the force required to break the suture. When a repair "cheese wires," the repair fails to achieve the full strength of the suture involved. This is where the importance of a locking technique comes into play. A locking technique allows for a more secure interface between the suture and the tendon, thus increasing the chance of maxing out the suture strength.

As we apply this to our study, we see that the modes of repair failure for the classic techniques were as follows: (1) 2-strand, modified Kessler—suture breakage, (2) 4-strand, double Kessler—tissue failure, and (3) 6-strand, modified Tang—suture breakage (Figs. 2B, 3C). It can be postulated that the 4 core strands of the double Kessler were too strong for the grasping nature of the technique, but the addition of the 5th and 6th core sutures with a locked loop suture in the modified Tang technique shifted the balance so that once again, the strength of the suture/tendon interaction was stronger than that of the core suture material. The fact that the novel repairs were able to withstand the same amount of tensile force that caused failure of the 6-strand technique without experiencing suture breakage or cheese wiring suggests that the novel repair techniques are able to better distribute force between the tendon and suture. When considering the fact that AR outperforms CR in cyclical testing, it is important to note that both fail due to cheese wiring and not suture breakage. The AR repair takes advantage of four separate, locked sutures while none of the passes of the CR repair are able to fully lock. Improving the suture technique in the CR method to enhance tendon locking would likely increase the strength of the repair.

Furthermore, in the traditional repair techniques, the strength of a repair depends on the strength of the core sutures crossing the repair site. Increasing the number of core sutures to achieve greater strength inevitably adds more volume to the tendon and leads to a bulky repair site, which has been demonstrated to increase resistance to gliding.[23] The AR and CR techniques use reclaimed FDS tissue, which anatomically comprises a portion of the natural volume within the tendon sheath; therefore avoids introducing additional bulk at the repair site. Additionally, the sutures used in both novel repairs are placed perpendicular to the tendon away from the repair site, which, when tightened, can serve to decrease the diameter of the tendon at these locations. That being said, the knots of these perpendicular sutures remain external to the tendon, which can lead to increased resistance to gliding and increase load on the healing tendon during rehabilitation, though this fact has also been disputed in the literature.[17,47,48]

Future work will focus on the importance of locking techniques in these novel models to provide a greater strength to the repair site, as well as alternative materials allowing the use of this technique without compromising FDS repair for wider application. In vivo application of these techniques is also required to take into consideration the full range of biological mechanisms, including tendon adhesion formation, which are currently underrepresented in the pre-clinical literature.

CONCLUSIONS

Outcomes following zone II flexor tendon repair have improved significantly over the last 2 decades but still remain a challenge, as function-limiting complications are not uncommon. While the teaching remains that all structures within zone II should be repaired, there are circumstances in which repair of the FDS tendon is not possible or impractical. In such a situation, we have demonstrated that novel tendon repair incorporating the FDS as an autologous graft is possible and results in greater ultimate tensile strength (AR and CR) and greater resistance to gapping (AR) when compared with a traditional 6-St flexor tendon repair. The use of FDS as a graft takes advantage of the available, strong and biocompatible material that can help avoid addition of bulk and potentially serve as a physical barrier between the healing tendon edges and the surrounding tissue. While these novel techniques have performed well as standalone interventions, they are not necessarily meant to replace current techniques but possibly serve to supplement high-risk repairs in an effort to expedite early motion protocols. Future work focusing on alternative materials in which to replace scavenged FDS will provide wider applicability to flexor tendon repair.

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