Biomechanical Evaluation of a Cable-Crimp System Designed for Repair of Tendons and Ligaments in the Hand

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The goal of this study was to evaluate the biomechanical properties of an alternative method for connecting sutures using a crimp and to compare this method with a knot connection. Multifilament stainless steel suture (3-0 USP size) was connected by means of knot tying or crimp application and compared with FiberWire (3-0 USP size) connected by knot tying. Ultimate tensile strength (UTS) and stiffness were tested on a servohydraulic testing machine. The total UTS of the crimped constructs was significantly stronger and stiffer than the knotted groups, although the strength per strand was not statistically significant. Crimps offer an alternative method for connecting sutures. They have mechanical advantages over knot tying and allow the connection of multiple suture strands as well as the additional advantage of attaching both sides of the repair independently. This may provide precise pretensioning and potentially reduced surgical exposure. (Journal of Surgical Orthopaedic Advances 22(4):288–294, 2013)

Key words: ACL repair, biomechanics, crimp, fixation, flexor tendon, ligament, stainless steel, suture, tenorrhaphy

In current surgical practice, sutures are connected to each other exclusively using knots. This connection is known to be the point of failure when the strength of connected sutures are tested (1, 2). In flexor tendon repair, the suture knot is often the weakest point of the repair. In the presence of a firm attachment of the suture to the tendon, the repair will usually fail at the knot attachment, but it has also been reported that the stronger and larger the suture and knot, the more likely that the repair will fail by pullout (3). Given the evidence related to repair failure with tied sutures, the study goal was to assess whether the biomechanical properties of strength and stiffness would make a crimp attractive for potential use in connecting sutures in tendon and other soft tissue repair. To test this, the strength and stiffness of a crimp connection was compared with a classically tied suture.

Cable-crimp systems have been previously described for their use in stabilization of large musculoskeletal structures, where suture and cable size make knots impractical. Cable-crimp systems were first described for use in fixation of the greater trochanter (4). A modified cable-crimp system was later adapted for use in posterior cervical stabilization and repair of pars defects (5–8). Smaller crimp systems could be applied to approximate smaller tissues, such as tendons or ligaments in the hand. Crimp-clamp systems have been described in the veterinary literature for their use in stabilization of the canine stifle joint. Vianna and other researchers found that crimps have high stiffness, eliminate the need for a potentially bulky knot, and have little permanent deformation after application (9–17).

By attaching each side of a divided tendon or ligament independently, a crimp may provide several additional benefits. A crimp has the potential to reduce the surgical exposure needed for the repair because only one side of the lacerated tendon needs to be brought into the repair site

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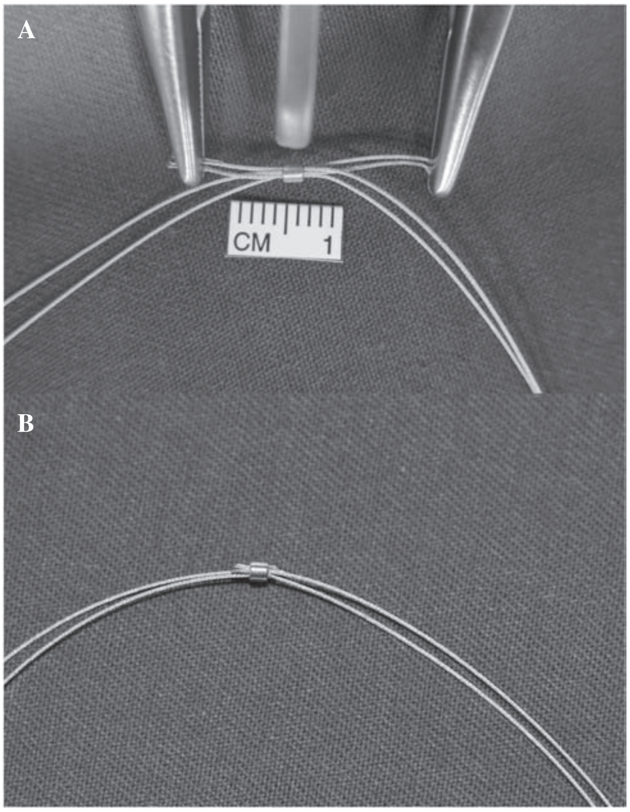

FIGURE 1 (**A**) Sutures threaded from each side through the crimp before crimping with jaw of the crimp tool shown in center. (**B**) Sutures crimped after compression and ends of the sutures are cut short.

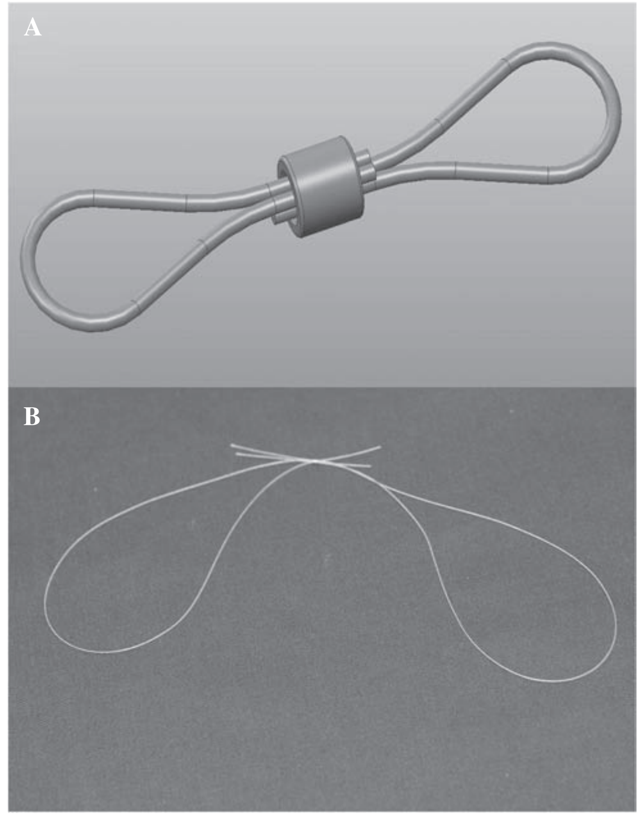

FIGURE 2 (**A**) Computer-aided design (CAD) diagram representation of two suture ends passed through the crimp from each side. The suture loops would need to be attached to the tendon on each end. (**B**) Study hardware as represented by a CAD diagram.

at a time. The repair can be pretensioned before crimping as each end of the structure to be repaired is approximated at exactly the desired tension and the sutures are then connected at the time of crimping.

Both two- and four-strand configurations of this system connected with a crimp were tested, and the properties of these connections were compared to the properties of nonmetallic suture [FiberWire (FW)] as well as the multifilament stainless steel (MFSS) cable connected with a knot. A repair equivalent to a two-strand tendon repair would have two suture strands entering the crimp from each side of the repair so that there would be four strands within the crimp at the time of connection or crimping (Figs. 1 and 2). A four-strand repair would have four suture strands entering the crimp from each side with eight strands within the crimp (Fig. 3). The loose suture strands would then be cut close to the crimp on each side.

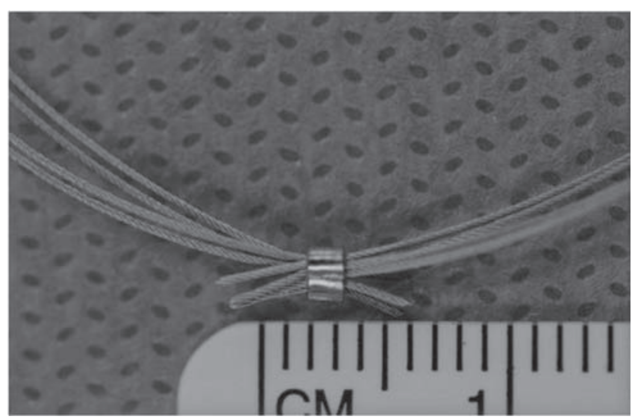

FIGURE 3 Four suture ends passed through the crimp for each side to represent a four-strand repair. The suture loops would need to be attached to the tendon on each end. The outside diameter for the crimp for the four-strand repair measures 1.8 mm and the crimp is 1.6 mm in length.

Materials and Methods

The mechanical properties of the following configurations were tested: MFSS connected with a knot, FW connected with a knot, and MFSS connected with a crimp in both two- and four-strand configurations. The MFSS suture was comprised of 49 filaments of 316LVM

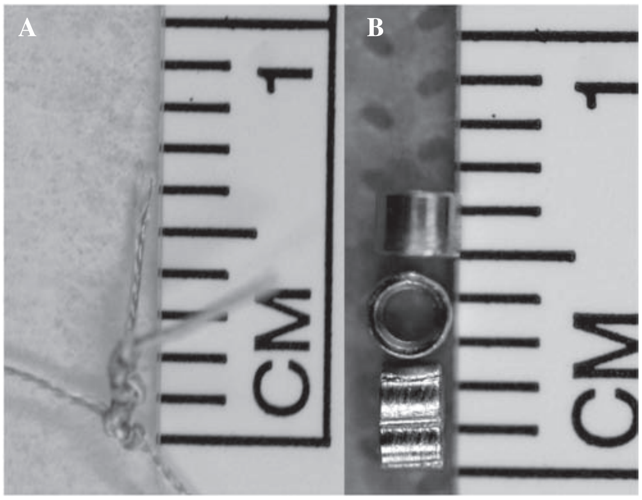

FIGURE 4 (**A**) A 3-0 FW knot with five throws. The suture knot is 2.0 mm in length and 0.9 mm in width. (**B**) Side and top views of two crimps (top and middle) in the preapplication state. The bottom crimp is in the postapplication state. The outside diameter of the crimp in the preapplication state measures 1.6 mm and the crimp is 1.6 mm in length. The size of the postapplication (compressed) crimp measures 0.8 mm in thickness, 1.6 mm in length, and 2.1 mm in width.

stainless steel to form a 3-0 size suture (2). The FW was a multifilament ultrahigh-molecular-weight polyethylene core with a braided polyester jacket in a 3-0 size (Arthrex, Naples, FL) (Fig. 4A). Stainless steel crimps were designed and optimized for compatibility with either two- or four-strand MFSS cable in the 3-0 size (Fig. 4B) (Core Essence Orthopaedics, Fort Washington, PA) by changing the inside diameter and wall thickness. The FW was not tested in a crimped configuration because it was technically impossible to thread through the crimp. Additionally, a nonmetallic suture is at risk of structural compromise because of metallic crimp shear force (9). FW was chosen on the basis of prior testing of sutures and knots that demonstrated FW as the strongest nonmetallic suture connection (2).

Each construct was assembled around a 7.6-cm-diameter cylinder to ensure consistent lengths (Fig. 5A). Each FW configuration was tied with a surgeon's knot and three additional throws (Fig. 5B) for a total of five throws based on the our previous evaluation of the number of throws required to prevent untying in this suture type (2). MFSS suture configurations were tied with a surgeon's knot and one additional throw, which we have demonstrated to be adequate to prevent untying.

Crimp Design

The cable-crimp system consisted of a small stainless steel crimp with an outside diameter of 1.6 mm (Fig. 6) used in conjunction with a MFSS cable composed of 49 separate filaments (2). The crimps were specially designed for the number of strands and the suture size. For optimal holding strength, the exact length, inside diameter, and wall thickness of the crimp is needed to match the suture size and number of strands. For this reason, crimps need to be fabricated with these factors in mind. Additionally, the lumen must be of adequate size to allow for the suture to be threaded through the crimp. To satisfy these requirements, the minimum inside diameter of the crimp was determined by the "packing factor" of four inscribed circles within a circle. The minimum amount of clearance that would allow sutures to be threaded through the crimp but prevent excess clearance when the crimp was compressed was determined. The wall thickness of the crimp must provide enough resistance to hold the sutures in place after the crimp is flattened. The wall thickness was made to be sufficient to hold the sutures but not to add excess bulk to the repair. The length was made to have sufficient surface area to retain the sutures well but not add too much bulk.

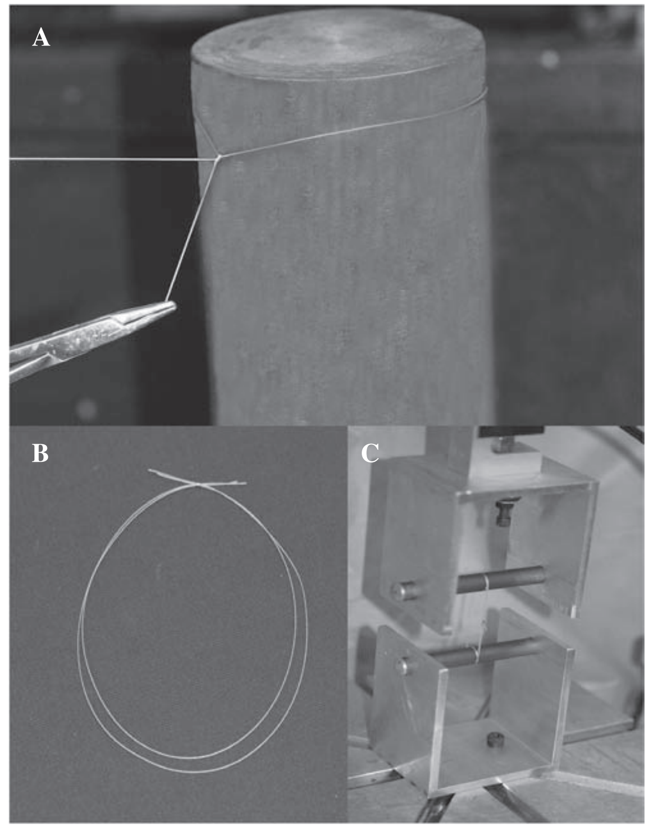

FIGURE 5 (**A**) Sutures crimped around a 7.6-cm cylinder. (**B**) Crimped suture removed from the cylinder. (**C**) Sutures tested on an MTS machine.

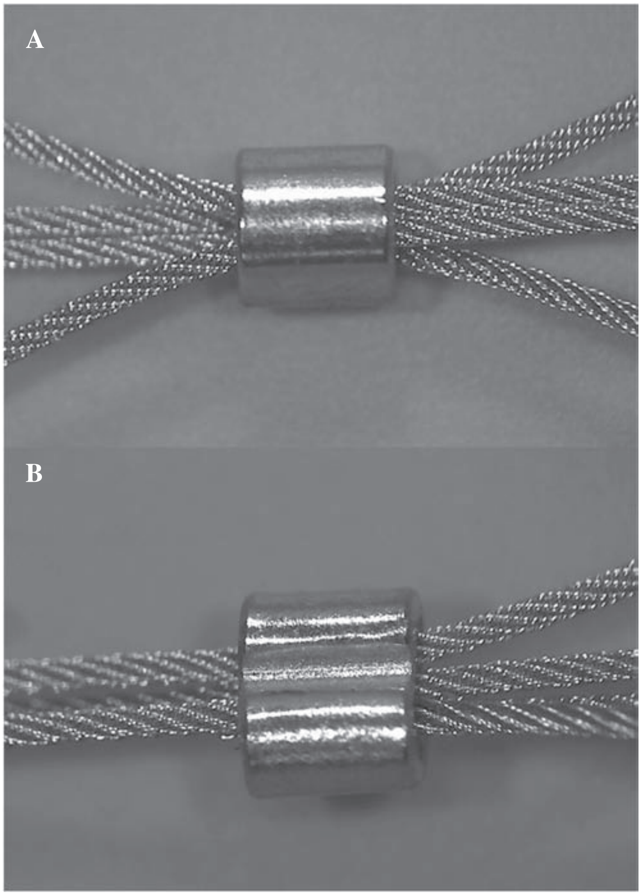

FIGURE 6 Crimp in preapplication (**A**) and postapplication (**B**) state applied to 3-0 MFSS in a two-strand configuration before cutting the postcrimp suture ends.

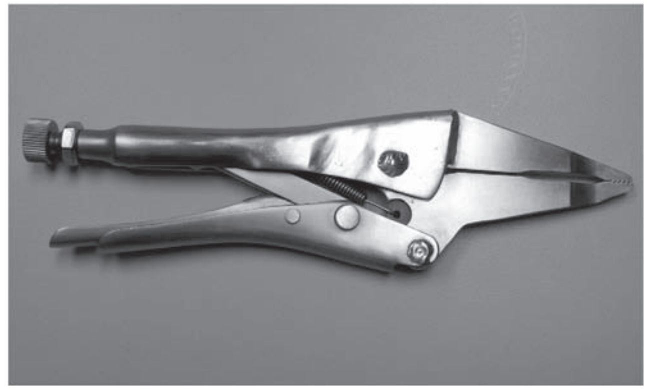

FIGURE 7 Crimp tool, designed to deform the stainless steel crimp. Crimp tool width measures 2.2 mm.

Crimping Tool Use and Calibration for Optimal Ultimate Tensile Strength

The crimp tool (Figs. 1A and 7) applied a calibrated pressure to the crimp to achieve optimal deformation and grip of the MFSS. This tool was calibrated by iterative measurement of ultimate tensile strength (UTS) of crimped MFSS constructs measured on an MTS machine (Fig. 5C). Each crimp tool was calibrated independently to compensate for differences between the size of the sutures and crimps being secured.

Testing the Connected Suture

Each construct was placed around a two-spool jig on an MTS device and the system was cyclically pretensioned by loading 10 times from 5 to 10 N (Fig. 5C). The constructs were then tested to failure at a rate of 1 mm/s. The materials were not presoaked in saline, because our previously reported data demonstrated that this had no effect on results (2). The ultimate load was measured and the stiffness for each sample was calculated as the slope of a best-fit line from 15 to 30 N on the force versus displacement curve. The load per strand was then calculated from the ultimate load data, dividing by the number of participating strands. Knotted configurations consisted of two connected suture strands, one from each side. A two-strand crimped configuration consisted of four participating suture strands, two from each side, which would be clinically analogous to a two-strand tendon repair (Figs. 1 and 2). A four-strand crimped configuration consisted of eight participating suture strands, four from each side (Fig. 3). The relative retained strength (efficiency) was calculated as the quotient of measured strength after connection and the measured strength of an intact suture before connection. The intact suture strength was based on previously reported values from our laboratory (2).

Statistical Analysis and Comparison

A correction was made for multiple comparisons, which consisted of either a Bonferroni correction (parametric) or Dunn's correction (nonparametric). The statistical significance for the UTS of each construct (Table 1) was evaluated, as well as the UTS and stiffness per strand.

TABLE 1 Absolute strength of constructs reported in mean with 95% confidence intervals (CI)

Construct	Average Strength	95% CI
Tied 3-0 MFSS	120.98 N	118.67–123.29 N
Tied FiberWire	57.15 N	50.11–64.19 N
Two-strand crimp MFSS	182.55 N	164.25–200.85 N
Four-strand crimp MFSS	265.44 N	227.61–303.41 N

Note: The MFSS constructs are significantly stronger. The two-strand crimp MFSS contains four strands (two from each side, producing the equivalent of a two-strand repair).

Results

Ultimate Tensile Strength

The UTS of the crimped connections was statistically significantly higher than that of the connections that were tied ($p < .05$) (Fig. 8). The two-strand repair using the cable-crimp construct was stronger than the two-strand FW construct connected by a knot ($p < .05$). The four-strand cable-crimp construct had the greatest strength of all the constructs (Table 1). Tied MFSS was stronger than tied FW ($p < .05$).

Ultimate Tensile Strength per Strand

The tied 3-0 MFSS had the highest strength per strand, while the two-strand MFSS crimped configuration was found to be the second strongest ($p < .05$) (Fig. 8). Tied FW (3-0) was found to have a strength per strand that was statistically comparable to the MFSS in its four-strand configuration. No immediate suture compromise resulting from crimp application or knot tying was observed.

Stiffness

MFSS suture provided the stiffest constructs, with a crimp increasing that stiffness per strand between the tied MFSS and the two-strand MFSS ($p < .05$) (Fig. 9). When comparing FW to MFSS, MFSS had greater stiffness even when compared without the added stiffness from the crimp ($p < .05$). Of the crimped MFSS constructs tested, the two-strand MFSS had statistically greater stiffness compared to the two-strand MFSS. It was noted that as the number of strands passing through the crimp increased, the stiffness decreased.

Relative Retained Strength

The Tied MFSS was found to retain the greatest percentage of its untied suture strength ($p < .05$) (Fig. 10). The MFSS in a four-strand configuration was found to be statistically equivalent to the tied FW ($p > .05$), although with an overall lower average efficiency. Similar to per-strand UTS and stiffness, an inverse relationship between the number of strands passing through a given fixation and the average relative retained strength was observed.

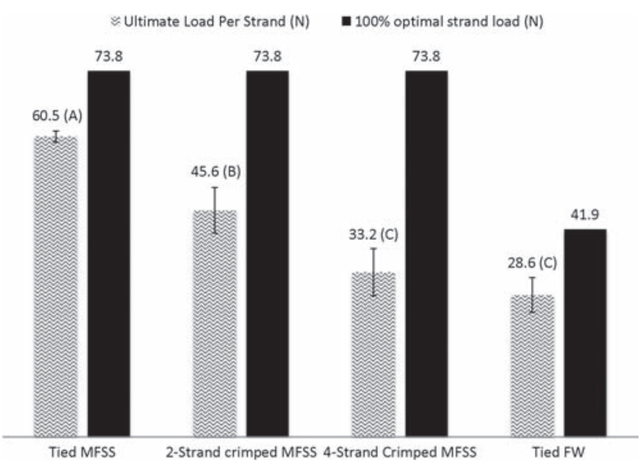

FIGURE 8 Ultimate tensile strength per strand in Newtons, compared to the strength of intact suture (not tied or crimped). Error bars represent 95% confidence intervals. Letter designation indicated statistically significant levels with a p value $< .05$. If the letters are the same, there is no statistical significance between the groups.

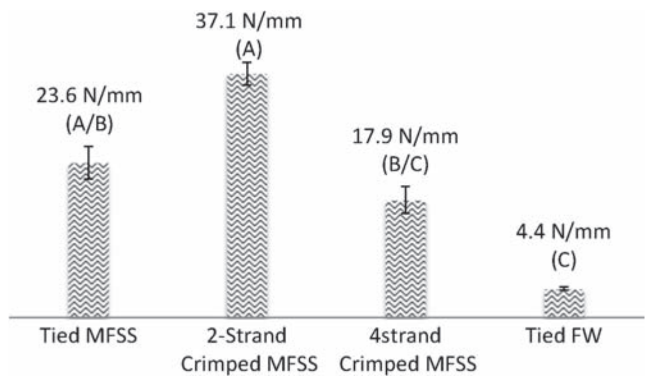

FIGURE 9 Stiffness per strand (N/mm). Error bars represent 95% confidence intervals. Letter designation indicates statistically significant levels with a p value of $< .05$. If the letters are the same, there is no statistical significance between the groups.

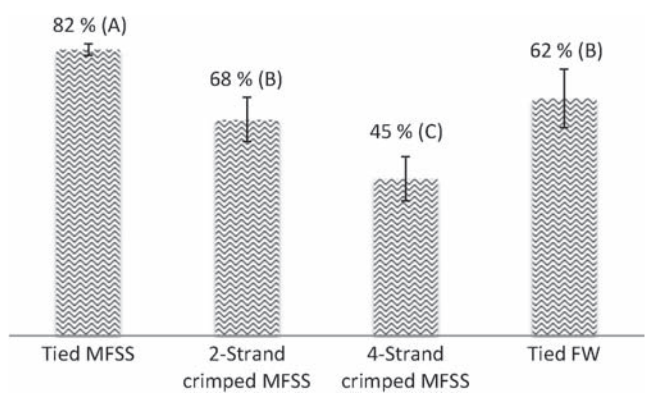

FIGURE 10 Relative retained strength reported as a per-strand percentage of ideal suture strength (i.e., suture alone) based on measurement of suture alone (no knot or crimp). Error bars represent 95% confidence intervals. Letter designation indicates statistically significant levels with a p value of $< .05$. If the letters are the same, there is no statistical significance between the groups.

Discussion

In 1940, Sterling Bunnell used monofilament stainless steel for the primary repair of severed tendons (18–21). Stainless steel has been used extensively in orthopaedic and general surgery with a long and positive track record of safety and a low level of immunogenicity (22–26). Previous studies have also shown that multifilament metal cables are significantly stronger than their monofilament metal wire counterparts (8). We have previously reported on the biomechanical parameters of this MFSS suture (2). The MFSS suture and crimp evaluated in this study are entirely composed of stainless steel. We confirmed that the suture material chosen for the system was compatible with the metal crimp, both made of similar material. We would expect the use of these stainless steel devices to be safe for implantation based on the excellent safety profile of this metal.

This article reports on the strength of two- and four-strand crimp constructs (Table 1), which would represent a clinical two- or four-strand flexor tendon repair. In a clinical application, the suture would be connected to the tendon on each side of the tendon laceration. The suture strands from each side would then be brought through the crimp. With gentle traction, the sutures slide inside the crimp, which approximates the tendon ends. The crimping device is then used to compress the crimp and fix the sutures together, using the crimp in place of a knot (Fig. 6). In the case of a two-strand repair, the crimp contains four strands, with two strands coming from each side of the repair (Figs. 1 and 2). A four-strand repair includes eight strands within the crimp with four strands coming in from each side (Fig. 3).

Having a different number of strands creates unequal comparison groups, although the point of failure was the crimp or knot in all tests. Because a nonmetallic suture could not be threaded through a crimp of this size, there is no way to create a multistrand configuration using FW or any other nonmetallic suture. Also, the clinical benefit of using a crimp is the ability to attach the tendon or ligament separately on each side of the repair. This type of crimp repair necessitates two strands entering the crimp from each side. For this reason, a single strand of MFSS attached by a crimp would not be clinically relevant. We also report on the strength and stiffness per strand to provide an additional valid comparison of crimps and knots.

Crimp systems have a unique set of mechanical properties, which are distinct from those with knot tying. Our study confirms that crimp systems have higher stiffness and as a result more resistance to mechanical deformation. This has been shown in both static and cyclic loading models (9, 10). The results show that the UTS of the two-strand crimp system is significantly stronger than a two-strand tied system for repair of tendons and ligaments in the hand. However, when measured per strand, there is no statistical difference. The data also demonstrate that when used with MFSS, the strength per strand of a multistrand crimp system decreases with an increase in the number of strands. This suggests possible unequal loading when more strands pass through the crimp. It is probable that the weakest strand is likely to fail first and will result in a decrease in the efficiency of the system. The systems with multiple strands were stronger overall, but by adding opportunities to form the weakest link the per-strand strength and stiffness decreased.

The small diameter of the crimp used in this study prohibited use of a nonmetallic suture, which may be compromised by the metallic crimp. We did not observe any incidence of immediate MFSS compromise associated with crimp application. The results of our testing of this cable-crimp system indicate that such a system provides strong fixation with increased stiffness and less elongation than tied suture. The stiffness of the cable-crimp system is especially beneficial when gapping threatens the integrity of the repair, as has been demonstrated in tendon repair (27, 28). This makes such a tool attractive for the repair of tendons and ligaments in the hand.

Further, there are potential technical advantages of crimped fixation over a knot in certain surgical settings. Crimped fixation may be advantageous when a divided tendon or ligament needs to be approximated. The use of a separate attachment on each side before approximation before connecting the sutures potentially allows the surgeon to bring the cut ends together and exactly gauge the tension. When a knot is used, one of the greatest challenges is exact coaptation of the tendon ends. Both sides are usually exposed for the repair as the sutures are passed back and forth across the repair site. A crimp provides the potential to optimize this tension. Because the two ends can be carefully approximated before crimping, this presents a potential advantage because the suture is attached to each side independently and then approximated so that the surgeon can exactly gauge the optimal tension. In addition, use of a crimp also has the potential to reduce the surgical exposure needed for the repair because only one side of the lacerated tendon is introduced into the repair site at a time.

Although our laboratory studies demonstrate the biomechanical benefits of crimp repair providing a stronger and stiffer construct, laboratory testing of tendon repairs in cadavers and clinical studies will be needed to fully explore strength of repair, 2-mm gap force, friction, and surgical outcomes. Important clinical elements must be examined to include the effect of stress shielding on healing resulting from the stiffness of the construct and pretensioning of the repair.

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