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ORIGINAL ARTICLE

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Development and preclinical testing of a new tension-band device for the spine: the Loop system

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Abstract Wire sutures, cerclage constructs, and tension bands have been used for many years in orthopedic surgery. Spinous process and sublaminar wires and other strands or cables are used in the spine to re-establish stability of the posterior spinal ligament complex. Rigid monofilament wires often fail due to weakening created during twisting or wrapping. Stronger metal cables do not conform well to bony surfaces. Polyethylene cables have higher fatigue strength than metal cables. The Loop cable is a pliable, radiolucent, polyethylene braid. Creep of the Loop/locking clip construct is similar to metal cable constructs using crimps. Both systems have less creep than knotted polyethylene cable constructs.

Keywords Tension band · Spinous process · Sublaminar wires · Polyethylene cable · Creep · Fatigue strength

Introduction

Wire sutures, cerclage constructs, and tension bands have been used for many years to re-appose bone fragments, to tether ligaments or tendons to bone, and to improve stability in weakened constructs following trauma or surgery. Closure of a sternotomy following cardiovascular surgery, trochanteric reattachment in reconstructive hip surgery, and stabilization of long bone fragments are a few examples of procedures utilizing tension-band systems [5, 14, 26, 48, 50, 57, 59, 65].

The natural posterior spinal tension member is comprised of several ligaments that are attached to the bones of the spine lying dorsal to the spinal canal: the inter- and supra-spinous ligaments, the ligmentum flavum, the facet capsular ligaments, and the posterior longitudinal ligament [3, 4, 36, 37, 41, 42]. When intact, the posterior spinal ligamentous structures function to limit flexion, rotation, and anterior and posterior translation of the spine [27, 42]. In spine surgery, wire and other strands and cables have been widely used to re-establish stability of the posterior spinal ligament complex [7, 11, 12, 24, 30, 34, 39, 60, 62].

Although much of the compression load of the spine is borne by the vertebral bodies and intervertebral discs of the anterior column [3, 40], attaching posterior tension bands around the laminae, spinous processes, or transverse processes can improve stability [12, 22, 24, 31, 39, 46, 49]. Easy surgical access to the spinous processes allows the surgeon to pass wires around these bony appendages or through holes prepared in individual spinous processes. However, variable strength of the bone and the relatively small surface area of the wire can cause the wire to cut through the spinous process, leading to loosening of the construct and loss of stability [6, 43, 65]. Inventors

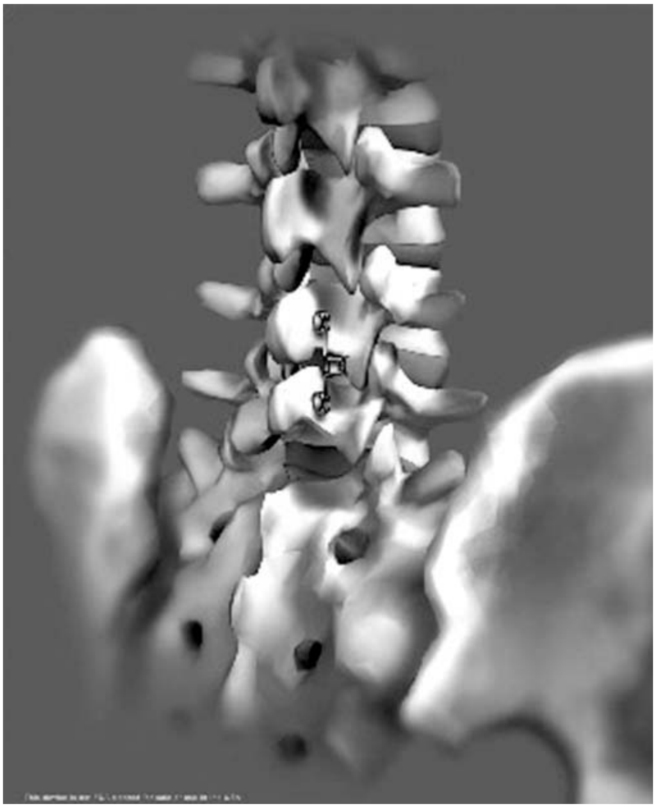

Fig. 1 The Loop system uses a braided polyethylene cable that is passed through two ferrules placed at the base of the spinous process. After tension is applied by use of the tensioning tool (Fig. 3), the locking clip (Fig. 2) secures the construct

have developed techniques and devices to address this problem. Examples include the "Wisconsin technique," wherein the Drummond Button is placed on the sides of the spinous process, and K-wires are passed through the spinous process [21, 28, 47].

When the spinous process is weak, fractured, or missing, the lamina can be utilized for wiring one spinal segment to another. The lamina is a stronger point of attachment than the spinous process [12, 20, 23, 25, 53, 64]. However, passing a wire or cable into the sublaminar space can lead to injury of the dura or spinal cord [18, 51, 54, 60, 61]. In spite of this possibility, sublaminar wiring techniques have been widely used for segmental fixation of spinal instrumentation to the posterior spine, in most cases, without nervous system injury [2, 33, 35, 45, 58, 65].

Rigid monofilament wires (Ethicon wire, Codman Sof'wire) often fail due to weakening created during twisting or wrapping [10, 15, 19, 20, 23, 51]. To address these deficiencies, multi-strand cables (Acromed Songer cable, Sofamor Danek Axis cable), which have better static yield, and tensile and fatigue strength, have been developed [12, 13, 29, 32, 38, 54, 55, 56, 63]. More recently, polyethylene cables (e.g., Smith & Nephew Richards SecureStrand), which are soft, flexible, and radiolucent, have become available. Tests indicate that they have tensile strength equivalent to multi-strand cables [8, 9, 16, 19, 38, 56, 63]. The soft polyethylene cables are easier to handle than wires or metal cables, and they conform to the bone surfaces, leading to a distribution of loads over a greater contact area [15, 18].

The Loop system

The Loop system (Spineology Inc., Stillwater, Minn.) consists of a braided polyethylene cable, a locking clip, and an optional ferrule that can be placed in the spinous process (Fig. 1). The Loop cable is a polyethylene braid with material properties similar to SecureStrand [68]. The Loop system is supplied in two versions: small cable and small locking clip for the cervical and upper thoracic spine, and large cable and large locking clip for the lower thoracic and lumbar spine.

Table 1 Physical properties of single constructs. Properties were determined with the construct held between two "S" hooks on the testing machine

	AcroMed Songer titanium cable [a]	Smith & Nephew SecureStrand [b]	Spineology Loop [a]
Mean tensile failure load (N)	2068	1565	Large – 1953 Small – 1301
Construct stiffness (N/mm)	477	322	Large – 438 Small – 410
Construct creep maximum (mm) at % of construct strength	1.8 mm @ 75%	3.7 mm @ 75% 2.8 mm @ 50% 2 mm @ 30%	2.4 mm @ 75% 1.9 mm @ 50% 1.4 mm @ 30%
Fatigue strength (N) @ 3 million cycles	<44	578	Large – 578 Small – 333

[a] Data from testing at Phillips Plastics Technical Center
[b] Data from Dickman et al. [19]

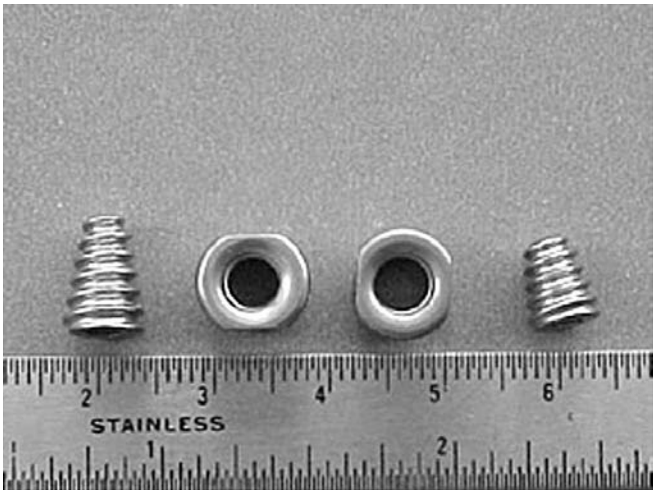

Fig. 2 The Loop locking clip utilizes friction between the female outer shell and the male inner cone, both of which are smoothly threaded. Once the male portion is secured in place, with the cable wedged between the male and female parts, the construct is exceptionally secure, with very little creep

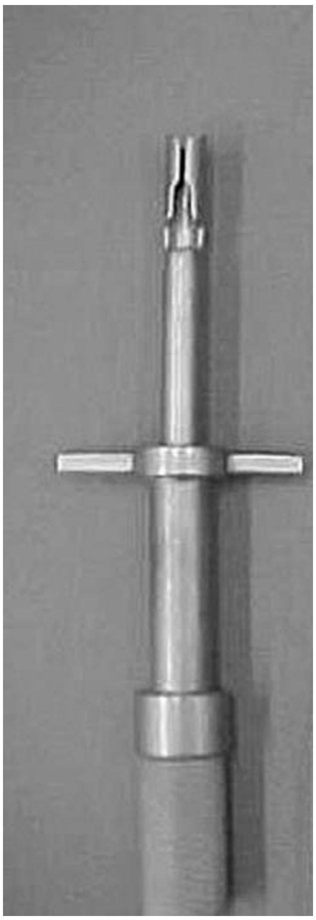

Fig. 3 The tensioning tool allows the surgeon to apply the desired degree of tension before securing the construct with the male portion of the locking clip

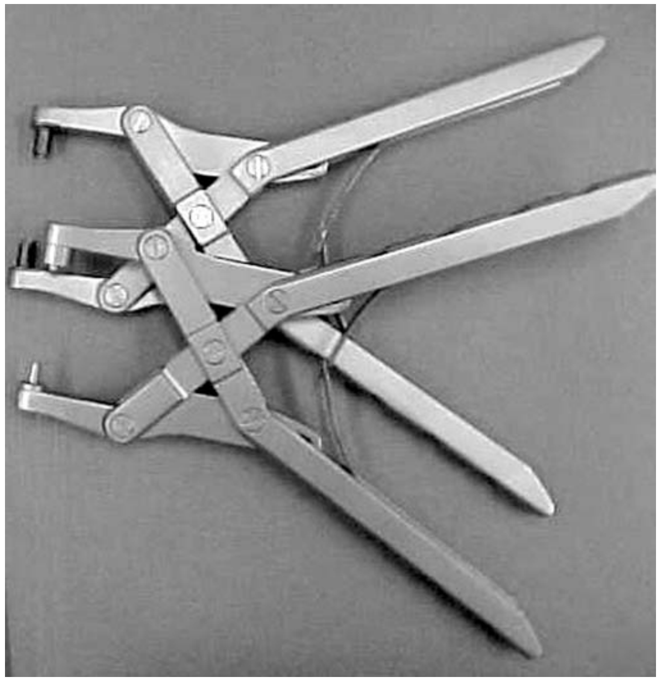

Fig. 4 The ferrule punch allows the surgeon to create a precise hole for placement of the ferrule using the ferrule inserter

Posterior spinal ligaments range in strength from approximately 67–208 lb (300–927 N) in the cervical and upper thoracic spine to about 145–321 lb (647–1432 N) in the lower thoracic spine and the lumbar spine [44]. The testing setup for the Loop construct was designed to conform to the test setup used by Dickman et al. [19], in which multiple tension-band constructs were tested. Dickman found the tensile strength of the Songer titanium cable system to be 465 lb (2068 N), which was superior to that of the SecureStrand, at 352 lb (1565 N) [19]. The Loop construct (cable and locking clip) was found to have a tensile strength of about 293 lb (1301 N) for the small cable and small clip construct and about 439 lb (1953 N) for the large cable and large clip construct [68] (Table 1). Both Loop systems exceed the expected failure loads of the spinous processes and laminae in their respective areas of use in the spine [12, 25].

The Loop locking clip consists of two mating pieces of titanium alloy that secure the polyethylene cable without the need for knots (Fig. 2). Testing of the construct for creep, again compared to testing done by Dickman [19] on several different constructs, shows that the creep of the Loop construct is comparable to the Songer cable with metal crimp lock, and superior to the weave and knotted lock of the SecureStrand [67]. The Loop tensioner (Fig. 3), used to create tension in the construct prior to locking, allows the surgeon to precisely control the degree of tension on the band material [55]. The male portion of the Loop clip is locked into the female portion of the clip using a self-limiting torque wrench.

The Loop ferrule is designed to distribute stress over a broad surface area. The smooth internal surface of the ferrule provides for passage of the cable without damaging the fibers. A standard towel clip, dental drill, or curved awl is used for making a hole in the spinous process for some wiring procedures or for passing a K-wire through the bone [1, 17, 47, 48, 52, 54, 60]. The Loop ferrule hole cutter prepares a clean, precise hole for a press fit of the ferrule in the bone. The ferrule is positioned into place using the ferrule inserter tool Fig. 4.

Mechanical properties of spinal cable and wire fixation systems

The new Loop polyethylene cable system was tested and compared to published performance values for currently available metallic spinal cable fixation systems.

Materials and methods

Published data on nine different spinal cable and wire fixation systems were reviewed: titanium and stainless steel Codman, Danek and AcroMed cable, polyethylene Smith & Nephew SecureStrand, and Ethicon 20 and 22-gauge stainless steel monofilament wire. Static tensile and fatigue strength, stiffness, and creep properties were evaluated. In all systems, a loop of the cable or wire was formed and connected, using the manufacturers suggested method. The Loop device was tested on the EnduraTec SmartTest system.

Results

The new Loop polyethylene cable system proved to be stronger in tensile strength, 1953 N, than all the other systems by 10–89% (P=0.01), except for the AcroMed Songer titanium system using end loop attachment, with a strength of 2068 N. For all systems, the fatigue limit ranged from 44.8 N to 578 N. The Loop fatigue strength is 578 N [66].

The creep behavior breaks down into two parts:

1. Change due to initial settling of the system (conformance to bone and tightening of fastener, and
2. True system creep (cutting at the bone/band interface, slipping of the fastening method, stretch in the tension band)

Creep during the initial stretch of the new Loop tension band was 19.36 µm/m/N, compared to an average of 22.12 µm/m/N for metal cables, and 113.33 µm/m/N for 20-gauge and 106.35 µm/m/N for 22-gauge monofilament wires. Initial creep of the SecureStrand polyethylene band was 35.92 µm/m/N. After initial stretch on application of the load, none of the multifilament metal cables exhibited appreciable creep during the 24-h test period. The two polyethylene cables did stretch after initial loading. The SecureStrand stretched an additional 24.22 µm/m/N versus 7.4µm/m/N for the Loop tension band.

Discussion

In comparisons, the new tension band has equivalent strength to all band types, and has higher fatigue strength than the metal bands. Metal cables and wire systems easily cut through bone and are opaque on radiographs. The polyethylene systems are radiolucent and afford better radiographic observation of the fixation site. They also provide better conformation to the bone to distribute the load more evenly.

The creep behavior of the new tension-band system is more like that of the metal cable systems. Both polyethylene cable systems creep initially while the band conforms to the tissues. The SecureStrand has additional creep because the connecting knot continues to tighten over time. Additional creep of the new system is lower than the SecureStrand, because the creep is only due to the stretching of the polymer fibers. The unique, “no-slip clip” is designed to limit damage to the band while providing a secure lock for the construct. Unlike a knot, this lock will not slide.

Conclusion

Tension bands have been used in general orthopedics and spine surgery for many years. The Loop System has strength similar to titanium cable systems and has a no-slip locking clip designed to maintain construct tension. It combines the advantages of the metallic systems (lower creep) with the advantages of the polymer cables (high fatigue strength) without sacrificing strength, stiffness or ease of use.

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