A Tensionable Suture-based Cerclage Is an Alternative to Stainless Steel Cerclage Fixation for Stabilization of a Humeral Osteotomy During Shoulder Arthroplasty

Abstract

Introduction: Fixation of periprosthetic humeral fractures is most commonly obtained with steel-based wires or cables; however, disadvantages with these constructs are numerous. Suture-based cerclages offer the advantage of easy handling, less radiographic interference, and risk of metallosis, as well as decreased risk of cutting into the soft humeral bone. Therefore, the purpose of this study was to compare a suture-based cerclage to a stainless steel wire cerclage (SSWC) for stabilization of the humerus during shoulder arthroplasty.

Methods: In part I of the study, SSWC fixation was compared with single-looped tape cerclage and a double-looped tape cerclage (DLTC) fixation. In part II, a subsidence test was performed on 12 cadaveric humeri. After an osteotomy, the humeri were secured with either a SSWC or DLTC. Subsequently, a metal wedge was introduced into the humerus to simulate the stem of a shoulder arthroplasty.

Results: In part I, load to 2-mm displacement was significantly higher for the DLTC construct compared with the SSWC construct (2,401 ± 483 N versus 750 ± 33 N; P < 0.0001). Load to failure was 93 ± 143 N with the SSWC, 1,737 ± 113 N with the single-looped tape cerclage, and 4,360 ± 463 N with the DLTC constructs, and all differences were statistically significant (P < 0.05). In part II, load at 20-mm subsidence was higher for the DLTC (320 ± 274 N) compared with the SSWC (247 ± 137 N), but no significant difference was observed (P > 0.05). However, gap displacement at 20 mm subsidence was significantly lower with the DLTC construct (0.33 ± 0.31 mm versus 0.77 ± 0.23 mm; P = 0.009). Load to failure was higher with the DLTC construct compared with the SSWC construct (4,447 ± 2,325 N versus 1,880 ± 1,089 N; P = 0.032), but the final gap displacement did not differ significantly (DLTC 5.23 ± 6.63 mm versus SSWC 6.03 ± 8.82 mm; P > 0.05).

Discussion: A DLTC has higher load to failure and trends toward lower gap displacement compared with a SSWC. The DLTC construct may therefore be a viable alternative for fixation of periprosthetic fractures or osteotomies of the humeral shaft during shoulder arthroplasty.
Periprosthetic fractures sustained during shoulder arthroplasty or humeral osteotomy after the removal of a humeral stem may require stabilization and can be problematic. The incidence of a periprosthetic fracture during shoulder arthroplasty is reported as 1% to 3% during primary shoulder arthroplasty, but the complication rate including fracture displacement and nerve injury is high in these patients.\(^1,2\) In revision arthroplasty, the incidence of complications increases to up to 16%.\(^3\) Such fractures, and osteotomies for stem removal, frequently require secure fixation to ensure a stable implant during the 17 weeks of healing.\(^1\)

Humeral shaft fractures during shoulder arthroplasty or osteotomies for humeral stem removal are most commonly managed with cerclage fixation. Historically, such fixation has been obtained with stainless steel wires or cables. However, disadvantages of wires or cables include potential metallosis, risk to healthcare professional from sharp implant edges, soft-tissue irritation, and technically challenging application.\(^4,8\) Because these cerclage types were developed for femoral fractures, the use in humeral fractures may pose the risk of cutting into the softer bone of the humerus, leading to failure of the construct or osteonecrosis.\(^8,9\) In addition, patients with periprosthetic humerus fractures are commonly within their seventh decade of life\(^2\) and therefore have a greater risk of osteoporosis aggravating the above mentioned complication.

Recently, suture-based cerclage constructs have been introduced as an alternative to metal wires or cables. Suture-based cerclage constructs offer the advantage of easier handling intraoperatively, less radiographic interference, no risk of metallosis, less risk of cutting into the soft bone of the humerus during tensioning, and potentially quicker revisions.\(^8\) Common indications for nonmetallic cerclages involve fixation of the lesser tuberosity after osteotomy and proximal humerus fractures.\(^10-13\)

Biomechanical and clinical reports have suggested that suture-based constructs are suitable for cerclage fixation of the humerus and even the femur with higher loads to failure compared with steel-wire constructs.\(^8,14-16\) However, few studies evaluate the use of suture-based cerclages specifically in humeral shaft osteotomies in the setting of shoulder arthroplasty.\(^14,15\) One remaining disadvantage of suture-based constructs is that they require tensioning by hand (versus twisting of wire constructs). Recently, a cerclage construct using a 2 mm suture-tape with a preplaced half-racking knot (FiberTape Cerclage; Arthrex) has been developed, which allows tensioning of the construct, and because of its broader surface area, potentially avoids osteonecrosis or cutting through the humeral bone.

The purpose of this study was to compare a tensionable suture-based cerclage to a stainless steel wire cerclage (SSWC) for fixation of the humerus during shoulder arthroplasty. We asked whether single- (single-looped tape cerclage [SLTC]) and double-looped tensionable suture-based cerclages (double-looped tape cerclage [DLTC]) require similar loads to displacement and loads to failure compared with SSWCs and if there are biomechanical differences in gap displacement and load to failure in a cadaveric subsidence model between DLTCs and SSWCs? The hypothesis was that there would be no biomechanical differences between the two fixation methods.

### Methods

A two-part biomechanical investigation was performed to compare a suture-based cerclage to a SSWC for fixation of the humerus during shoulder arthroplasty. In the first part of the study, the fixation of two suture constructs and one SSWC construct were evaluated in a distraction test. In the second part of the study, a double-looped suture-based construct and a SSWC were evaluated in a cadaver model after a standardized humeral osteotomy and subsequent simulation of humeral stem implantation.

### Part I: Cerclage Distraction Test

Three different cerclage constructs were placed around a custom metal fixture. The metal testing apparatus was composed of two semicircular segments, spaced 2 mm apart, and with a total circumference of 4 inches to simulate a typical diameter of the proximal humerus\(^17\) (Figure 1). The lower semicircular segment was attached to the base of a dynamic testing machine (E10 kN ElectroPuls Dynamic Testing System; Instron), and the upper semicircular segment was attached to the actuator.

The first two constructs used a tensionable 2-mm suture tape (FiberTape
Cerclage System; Arthrex). In this system, the 2-mm suture tape is folded on itself to create a preplaced racking hitch on one end and two free limbs on the other end. After placing the construct around the semicircular segments, the free limbs were passed through the racking hitch loop. The construct was tensioned maximally with a specific device (FiberTape Cerclage Tensioner; Arthrex) according to the manufacturer’s recommendations, followed by a half-hitch knot and repeat tensioning, followed by two alternating half hitches. In the first construct, the suture limbs were passed a single time (SLTC) around the testing apparatus before passing them through the racking hitch loop and tensioning the construct. In the second construct, the suture limbs were passed twice around the metal apparatus (DLTC) before tensioning (Figure 1).

In the third construct, an 18-gauge SSWC (McMaster-Carr) was looped around the testing apparatus and maximally tensioned to at least 350 N by twisting the wire tails seven times with a pair of pliers and bending the crimp in the direction of the twists (forward) to avoid loss of tension.

First, maximum compression after tensioning of the three constructs with the tensioning devices (pliers and tape cerclage tensioner) still attached was measured. The constructs were then subjected to cyclic loading (distraction of the two semicircular segments) from 50 to 500 N for 50 cycles because 450 N is estimated for the physiologic load at the glenohumeral joint to simulate the activities of daily living during early postoperative therapy. Cyclic displacement was measured and defined as the difference between the displacement at the 500 N peak of the last cycle and the initiation of cyclic loading. Finally, load-to-failure testing was performed at 0.2 mm/s and the load at 2, and 4 mm displacement as well as the load-to-failure were recorded for each sample. Failure was defined as the breakage of the cerclage constructs and/or a sudden decrease in force.

Part II: Cadaveric Testing
Six matched pairs of fresh-frozen male proximal humeri with a mean age at death of 60.7 ± 5.5 years were used. All samples were dissected of skin and subcutaneous tissue and subsequently potted in sections of a cylindrical PVC pipe using fiberglass resin. A resection of the humeral head was performed at the anatomic neck with a humeral inclination of 135° using an intramedullary guide. The intramedullary canal of each sample was broached in the standard fashion for the placement of a non-cemented humeral stem in reverse shoulder arthroplasty (Univers Revers; Arthrex) until the desired press-fit was achieved for each individual specimen. An 8 cm vertical humeral osteotomy was then made along the bicipital groove beginning at the humeral head resection with an oscillating saw on the basis of previous research (Figure 2, A).

Each pair of shoulders received a DLTC and SSWC. Left and right shoulders were randomly assigned to either DLTC or SSWC such that each group had an equal number of left and right shoulders. Next, the osteotomy was secured 20 mm distal to the medial calcar using either a DLTC or a SSWC. The distance of 20 mm was chosen on the basis of clinical practice. The DLTC was selected as the suture construct for part II testing because it showed superior biomechanical strength in part I of the testing protocol. The DLTCs were tightened as described above using a specific device (FiberTape Cerclage Tensioner; Arthrex) (Figure 2, B). The SSWCs were sufficiently tensioned as described above (Figure 2, C). Sufficient tensioning of each construct was determined by two orthopaedic surgeons (P.J.D. and L.D.H.), as would be performed.
intraoperatively. Care was taken to avoid overtensioning and cutting of the cerclages through the bone. After repair, a subsidence test was performed. The samples were secured to the base of a dynamic testing machine (E10 kN ElectroPuls Dynamic Testing System; Instron) and oriented so that the humerus was vertically and axially aligned to the actuator. A custom-made conical wedge fixture with a diameter of 2.54 cm was secured to the actuator of the machine to simulate the stem of a reverse shoulder arthroplasty. The crosshead of the testing machine was then lowered so that the edge of the wedge’s conical section was horizontally aligned with the most distal edge of the humeral head osteotomy (“zero” point). Two dots were drawn 3 mm on either side of the osteotomy, both 3 mm above and below the cerclage construct using a marker. Each specimen was then preloaded with 50 N to account for an equal fit of the conical wedge in each specimen. The wedge was then advanced 20 mm into the humeral canal at a rate of 0.2 mm/s (Figure 3). Load at 20 mm subsidence of the wedge was measured, and video tracking (MaxTraq, Version 2.3.3.4; Innovision Systems) was used to observe gap formation at the osteotomy site relative to the markers at
20 mm subsidence of the wedge. Finally, load-to-failure testing was performed at 0.2 mm/s by advancing the actuator until its maximum range of travel was reached and the final gap formation was measured. Failure was determined as a sudden decrease in force, fracture, and cerclage construct breakage. The test was stopped if no failure occurred but the maximum range of travel of the actuator was reached.

**Statistical Analysis**

Data were described by mean and SDs. The significance level was defined as $\alpha = 0.05$. For part I of the study, a series of one-way analyses of variance were conducted to determine whether maximum compression, displacement during cyclic loading, load to 2 and 4 mm displacement, and load to failure differed markedly between the cerclage constructs. If a notable difference was noted between the groups, a subsequent Tukey multiple comparisons test was used. Where normality did not exist, a Kruskal-Wallis test followed by a Dunn multiple comparisons test were used. The statistical analysis was performed with Prism8 (Version 8.3.0; GraphPad).

For part II of the study, if normality existed, paired $t$-tests were performed to determine whether the resistive force and subsequent osteotomy gap formation differed markedly between the DLTC and SSWC groups. If normality did not exist, a Wilcoxon signed-rank test was used.

**Results**

**Part I: Cerclage Distraction Test**

Maximum compression after tensioning was $388 \pm 26$ N with the SSWC, $452 \pm 90$ N with the SLTC, and $739 \pm 247$ N with the DLTC constructs. All groups were statistically different from each other ($P < 0.05$).

After cyclic loading, total displacement with the DLTC construct was $0.6 \pm 0.2$ mm, $0.9 \pm 0.1$ mm with the SSWC construct, and $1.6 \pm 0.4$ mm for the SLTC construct. The displacement in the DLTC group was lower compared with the SSWC group but did not reach statistical significance ($P > 0.05$). The displacement was significantly lower in the DLTC compared with the SLTC construct ($P = 0.001$) and in the SSWC construct compared with the SLTC construct ($P = 0.002$).

Load to 2 and 4 mm displacements are shown in Figure 4 and were highest for the DLTC ($2.401 \pm 483$ N and $2.906 \pm 1,872$ N), followed by the SLTC ($785 \pm 375$ N and $1,304 \pm 581$ N) and the SSWC group ($750 \pm 33$ N and $501 \pm 450$ N). The loads to both 2 and 4 mm displacements were significantly higher for the DLTC group compared with the SSWC group ($P < 0.0001$ and $P = 0.033$).

Load to failure was $935 \pm 143$ N for the SSWC, $1,737 \pm 113$ N for the SLTC, and $4,360 \pm 463$ N for the DLTC constructs. The load to failure in the DLTC group was significantly higher than the SSWC group ($P < 0.001$) (Figure 4).

**Part II: Cadaveric Testing**

The cadaveric subsidence results are summarized in Table 1. Gap displacement at 20 mm subsidence was significantly lower in the DLTC group compared with the SSWC group ($0.33 \pm 0.31$ mm versus $0.77 \pm 0.23$ mm; $P = 0.009$), but no significant difference was seen in the final gap displacement with the DLTC construct compared with the SSWC construct ($P > 0.05$) (Figure 5, A and B).

Load to failure was significantly higher ($4,447 \pm 2,325$ N versus $1,880 \pm 1,089$ N; $P = 0.032$) for the DLTC construct compared with the SSWC construct, but no significant difference was seen in the final gap displacement with the DLTC construct.
construct compared with the SSWC construct (5.23 ± 6.63 mm versus 6.03 ± 8.82 mm; P = 0.05) (Figure 5, A and B).

**Discussion**

The purpose of this study was to compare a tensionable suture-based cerclage to a SSWC for fixation of the humerus during shoulder arthroplasty. The results of this study refute the hypothesis that the two techniques would be equivalent biomechanically. In the static metal apparatus, a double-looped suture construct was superior to SSWC. Likewise, in the cadaver model, the DLTC construct had a higher load to failure and lower gap formation at 20 mm subsidence of the simulated stem. The results of this study may have several important implications for fixation of the humeral shaft during a periprosthetic fracture or fixation of a humeral osteotomy.

Most periprosthetic fractures and humeral osteotomies require secure fixation to ensure implant longevity. Traditionally, SSWC or metal cables have been a common method of fixation of a periprosthetic humeral fracture or humeral osteotomy. Wagner et al reported a 16% rate of periprosthetic fracture during 230 revision arthroplasties. Risk factors for fracture included female patients, surgery for instability, and previous hemiarthroplasty. Fractures were stabilized with the stem itself or the addition of sutures, SSWC, or cables and led to implant survival comparable with a control group without fracture. Van Thiel et al reviewed 23 cases of vertical humeral osteotomies for stem removal during revision, which were secured with SSWC after stem extraction and reported no cases of postoperative stem loosening. Sahota et al reported that 17 of 19 humeral osteotomies healed with SSWC, cables, or #5 suture but they did not compare the results between the different techniques.

Drawbacks of SSWC or metal cables include the potential for metallic debris, risk to healthcare professionals from sharp implant edges, hardware prominence, and technical variability during fixation (ie, undertensioning or overtensioning). In a study of hip arthroplasty, for instance, Hop et al reported that metallic debris from the addition of cables led to accelerated polyethylene wear. Wahnert et al also illustrated how the biomechanical performance of SSWCs is affected by a variety of factors such as tension during twisting, cut location, and bending direction. Regarding bending direction in particular, any attempt to bend the wire to minimize soft-tissue irritation may decrease tension in the construct because tension is secured by the “last twist.” Consequently, nonmetallic implants with improved handling characteristics and reproducible fixation have been sought as an alternative to metal cerclages. Most studies investigating suture-based cerclages focused on fixation of osteotomies of the lesser tuberosity or proximal humerus and only few on stabilization of the humeral shaft osteotomies in the setting of shoulder arthroplasty. Edwards et al reported on 11 revision shoulder arthroplasties in which cerclage cables with ultrahigh molecular weight polyethylene fibers and a nylon core were used to secure humeral osteotomies. No evidence of stem loosening was observed, and no complications were identified related to these cables, demonstrating that nonmetallic

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DLTC = double-looped tape cerclage, SSWC = stainless steel wire cerclage
Suture and SSWC fixation have been compared in few studies. In the tension band constructs for securing transverse fractures, #2 suture has demonstrated equivalent\textsuperscript{21} or even superior results compared with metal wires.\textsuperscript{22} In a bovine femur model, Renner et al\textsuperscript{14} compared a double-looped #5 suture secured with knots to a double-looped SSWC construct secured with twists. They reported that the SSWC had an approximate fivefold higher initial tension (618 N versus 131 N; \( P < 0.05 \)) and suggested that the SSWC was better for reduction. On the other hand, in our study, initial tension was higher with the DLTC compared with SSWC (739 N versus 388 N; \( P < 0.05 \)). It is notable that our initial tension with the DLTC was much higher than that achieved with #5 suture by Renner et al. This difference is likely because we used a 2-mm suture tape which provides broader compression compared with #5 suture and because we were able to remove slack in the system with a tensioner as opposed to hand tightening used in their study. Although load to failure was higher with suture compared with SSW, Renner et al reported a lower force for 1 and 2 mm of displacement with suture. In our study, load to failure was significantly higher with the DLTC than the SSWC (\( P < 0.001 \)), and displacement trended toward lower values with DLTC (0.6 versus 0.9 mm; \( P \geq 0.05 \)). The high loads to failure and minimal displacement with the DLTC are likely a reflection of the broad 2-mm tape and the half-racking loop that optimizes loop security. Kelly et al\textsuperscript{23} previously demonstrated that a half-racking suture provides improved load to failure compared with commonly tied knots. The broader tapes dissipate the load better and therefore are less likely to cut into the bone, which is very relevant in older patients with osteoporosis, in those with disuse osteopenia or stress shielding, and in the humerus with its thinner cortices.

Finally, Renner et al also performed a subsidence test in cadaveric bone similar to the model in part II of our study. They performed a medial osteotomy and noted slightly greater gap opening with SSWCs, but the difference did not reach statistical significance. In our study, we performed an anterior osteotomy to mimic the osteotomy most commonly performed in clinical practice as opposed to a medial osteotomy. We observed that the DLTC outperformed the SSWC in a significantly higher load to failure (\( P = 0.032 \)) and trended toward less final gap formation (5.23 ± 6.63 mm versus 6.03 ± 8.82 mm; \( P > 0.05 \)).

The number of loops around the humerus seems important in cerclage fixation. Lenz et al\textsuperscript{6} compared cables and wires that were single- or double-looped around cortical half shells similar to the model used in part I of our study. Double loops were markedly stronger than single loops for both cables and wires, and cables were stronger than wires overall. Likewise, in the current study, load to failure and tension force were highest with a double-loop construct. Load to failure with the double loop (DLTC) was 250\% higher, and tension force was 163\% higher than with the single loop (SLTC) construct. Displacement was 2.8 times lower with the DFT than the SFT (0.6 versus 1.6 mm; \( P = 0.001 \)). More importantly, we found a markedly higher force needed to gap the DLTC construct to 2 and 4 mm compared with the SSWC. This is especially relevant because a displacement of 2 mm is often considered a threshold for repair failure in clinical practice. Based on these findings, we recommend a double loop for maximizing the biomechanical performance of suture-based cerclage fixation.

In conclusion, a tensionable DLTC has higher load to failure, higher initial tension, and trends toward lower gap displacement compared with a SSWC. The tensionable DLTC construct may be a viable alternative for the fixation of peri-prosthetic fractures or osteotomies of the humeral shaft during shoulder arthroplasty.
References

References printed in bold type are those published within the past 5 years.