

Testing of a Novel Method for Securing Ligaments Against Bone During Simultaneous Medial and Lateral Elbow Ligament Reconstruction

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Purpose A ligament reconstruction method that simultaneously tensions the medial and lateral sides of the elbow and maintains tension with compression plates on the proximal ulna is proposed for the treatment of bidirectional elbow ligament instability. Graft slippage, catastrophic failure, and excessive displacement were evaluated. Biomechanical stability without graft slippage was hypothesized.

Methods Eight cadaveric ligament reconstruction simulations were created through the dissection of three cadaver arms. Each reconstruction was statically tested with 160 N in a manner where it was first augmented with an absorbable suture and then without. Then, 3 more ligament reconstruction simulations were created for dynamic testing with each undergoing testing at 80 N for 2,000 cycles at 2 Hz. Construct displacement and graft slippage were recorded for each load application.

Results No grafts failed catastrophically and no graft slippage was observed with either static or dynamic loading. Under static loading, the mean change in displacement between augmented and nonaugmented ligament reconstruction simulations was $28.7\% \pm 21\%$ (augmented 3.95 ± 1.81 mm vs nonaugmented 4.89 ± 2.22 mm). The mean stiffness was 66.6 ± 26.6 N/mm for augmented and 64.6 ± 23.2 N/mm for nonaugmented simulations. With dynamic loading, the mean displacement for augmented graft ligament reconstruction simulations was 1.55 ± 0.16 mm compared with 2.18 ± 0.77 mm for nonaugmented reconstruction simulations.

Conclusions This method of fixation to the proximal ulna for the simultaneous reconstruction of medial and lateral elbow ligaments successfully prevented graft slippage without excessive construct displacement during static and dynamic testing. Ligament augmentation with absorbable sutures decreased the construct displacement.

Clinical relevance This ligament fixation method may be a viable alternative for the treatment of concomitant medial and lateral elbow instability. (*J Hand Surg Am.* 2023; ■(■):1.e1-e8. Copyright © 2023 by the American Society for Surgery of the Hand. All rights reserved.)

Key words Elbow, instability, ligament, novel, reconstruction.



POSTTRAUMATIC ELBOW INSTABILITY may occur in a lateral, medial, or bidirectional manner.¹⁻⁴ Bidirectional elbow instability represents

simultaneous deficiency of both the medial collateral ligaments (MCLs) and lateral collateral ligaments (LCLs). Treatment for this includes internal or

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Dr Kaufmann owns Arrch Orthopedics, which has developed this novel method of simultaneous ligament reconstruction. No benefits in any form have been received or will be received by the other authors related directly to this article.

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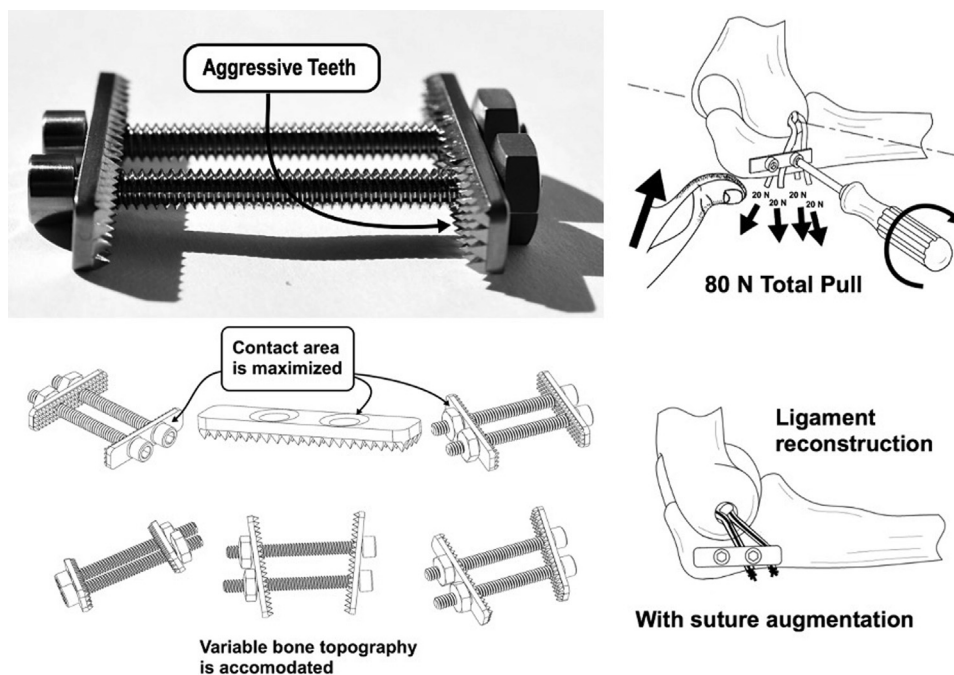


FIGURE 1: Demonstration of a proposed approach for simultaneous reconstruction of the medial and lateral ligaments of the elbow. Features of this design include an aggressive teeth pattern to hold the graft and maximize contact between the graft and bone. The construct is subjected to a tension of 80 N, which exerts 40 N of tension on either side of the elbow. Finally, a suture may be used to further augment the reconstruction by transmitting forces away from the graft during the immediate postoperative period.

external fixators, concomitant MCL and LCL reconstructions with two separate grafts, and boxed loop reconstruction techniques.^{2–5} A boxed loop ligament reconstruction uses a long graft in which substantial portions lie within the humerus and ulna. It is difficult to apply uniform tension throughout the graft, which may result in deformity or instability. Although good medium-term results have been demonstrated, simultaneous tensioning of MCL and LCL reconstructions may allow for easier technical application and eliminate these disadvantages.⁴

An alternative is the reconstruction of the MCL and LCL with fixation to the proximal ulna using plates that exhibit an aggressive tooth pattern, which imparts compression against the bone while healing occurs (Fig. 1). Tightening of the bolts against the plates causes a compressive force between the graft and the bone, which “locks in” the graft on each side. Graft integrity is variable and may require augmentation to better resist the forces that are experienced before graft incorporation. The suture may be woven into the ligament, which will increase the tensile strength of this construct by transmitting forces through the augmenting suture besides the graft.

A ligament reconstruction technique that uses compression between the plate and bone risks that the graft will either not resist the anticipated forces or pull from under the plate once the load is applied.

The objective of this study was to characterize the ability of this kind of reconstruction technique to resist forces and avoid catastrophic failure or excessive elongation, with particular focus on the ability of the toothed compression plate to adequately fix the graft. The effects of a 160 N static load, suture augmentation, and dynamic loading during 2,000 cycles were studied to assess catastrophic failure, construct displacement, stiffness, and graft slippage. We hypothesized that this ligament reconstruction technique would demonstrate acceptable graft displacement and stiffness, as well as prevent graft slippage under both static and dynamic loading conditions. We also proposed that augmentation would result in lesser displacement than a non-augmented construct.

MATERIALS AND METHODS

Three cadaver arm specimens were used in this study. Our primary outcome of interest was the catastrophic failure or excessive elongation of ligament reconstruction simulations, and the secondary outcomes included stiffness and a comparison between augmented and nonaugmented reconstructions. The number of specimens was determined after consideration of prior literature evaluating elbow ligament repair with or without suture augmentation.^{6,7}

Calculations of sample size using these data revealed that with an α of 0.05, a 2-tailed analysis between 2 independent means would require a minimum of 4–8 trials in each group to reach a power of 0.8. Each cadaver arm had eight flexor tendons available for harvest and two tendons were required for each simulation (three static and one dynamic testing).

The olecranon was dissected to allow for the placement of toothed plates and the tightening of nuts and bolts. Each cadaver arm was used for three static ligament reconstruction trials and one dynamic ligament reconstruction trial. Each of the 4 trials required 2 separate grafts that were at least 3.5 mm and no bigger than 4 mm in diameter. A combination of palmaris longus, flexor pollicis longus, flexor digitorum superficialis, and flexor digitorum profundus tendons was harvested. Each graft was then augmented with a #1 polydioxanone (Johnson & Johnson, NJ, USA) suture, which was woven through the graft and sutured to itself on the dorsum of the ulna. This suture was chosen because it has a tensile strength of 85 N in the acute setting, with 60% being retained at 6 weeks following the procedure.^{8–10} Bone preparation was performed by drilling transosseous tunnels in the proximal ulna for the passage of bolts. A tunnel was drilled into a plastic loading fixture, the outer dimensions of which represented those of the distal humerus.

The grafts were passed into a custom designed cylindrical ligament-retention device (CLRDR), which is a permanent method of fixing the graft and allows symmetric graft tension to be imparted to the medial and lateral sides of the distal humerus, as well as limits the amount of graft material residing within the bone (Fig. 2). The CLRDR tendon construct was pushed into the plastic loading fixture. The tendon grafts were subjected to a tension of approximately 80 N and secured to the proximal ulna using compressive toothed plates along with nuts and bolts secured to 2-finger tightness. The tension was set by a near-maximum pull, which is approximately 80 N, by the surgeon.^{11,12} This tension was determined after a review of previous studies, which demonstrated that the restoration of elbow kinematics occurs when the LCL is repaired with 20 N of tension, with a greater magnitude overcorrecting the varus instability.¹³ On the medial side, 20, 40, or 60 N all appear to provide elbow stability without altering the kinematics.¹⁴ During the ligament reconstruction, we recommend tensioning with 40 N applied simultaneously to both sides and therefore an 80 N load was used.

The CLRDR and ulna were secured to the test frame (Instron) so that a tensile force could be applied

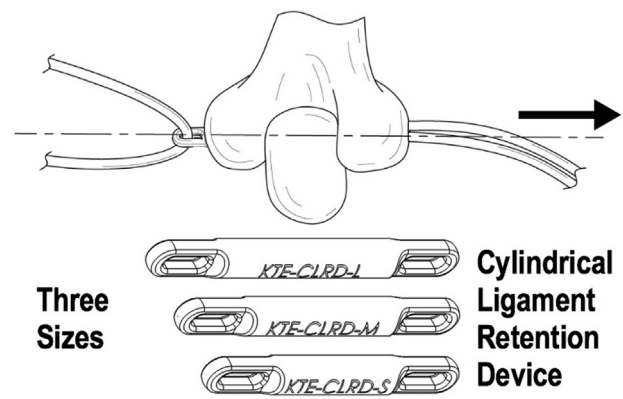


FIGURE 2: Schematic representation of the CLRDR, which allows for symmetric tensioning throughout the graft without wasting graft material. Two grafts are used, one medial and one lateral. Both grafts are tensioned symmetrically and locked in with plates that exert pressure from the medial and lateral sides against the bone.

(Fig. 3). The biomechanical properties were then measured by assessing the graft displacement and stiffness, as well as graft slippage under the plate in both static and dynamic loading environments. For each cadaveric specimen, three static loading tests and one dynamic loading test were performed.

Test 1: static loading

A load of 160 N was applied to the #1 PDS suture-augmented ligament reconstruction simulation (test 1a) and then the augmentation was removed (test 1b). Construct displacement, stiffness, graft slippage, and catastrophic failure were recorded. Ink markers were placed on the graft and graft slippage before and after tensioning was measured after each test with a caliper and on photographs. The difference in displacement between the augmented and nonaugmented constructs was calculated.

Test 2: dynamic loading

After the static loading test was completed, an augmented and a nonaugmented construct were subjected to dynamic loading for 2,000 cycles at 2 Hz and 80 N, which represents the recommended force during graft pretensioning. After each test, graft slippage that may have occurred before and after tensioning was measured with a caliper and on photographs.

Mean and SD were calculated for each recorded variable. The Mann-Whitney U test was used to compare augmented and nonaugmented constructs, which were adequately powered. Statistical analysis was performed with α of > 0.05 .

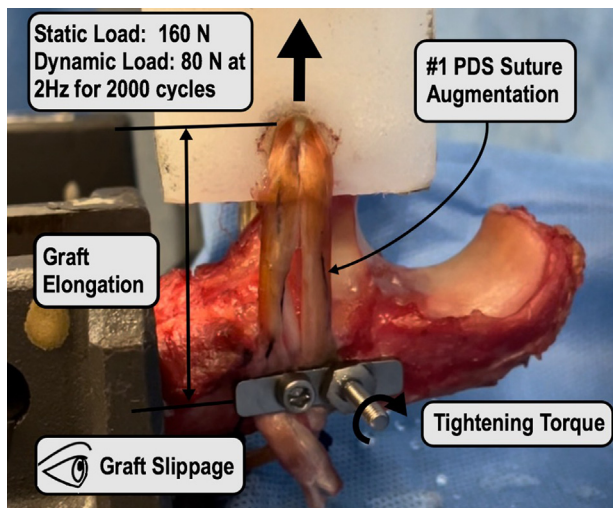


FIGURE 3: Example of the testing setup for static and dynamic load testing. A tensile force was applied to the CLRD in a proximal position.

RESULTS

Static testing

Static load testing was completed on eight cadaveric trials (Fig. 4). In one trial, the ulna slipped from the clamp and the trial was excluded. No grafts or CLRD failed catastrophically. No graft slippage occurred before or after static testing.

The mean change in displacement between augmented and nonaugmented ligament reconstruction simulations was $28.7\% \pm 21\%$ (Table 1). Although the displacement of augmented ligament reconstruction simulations was 3.95 ± 1.81 mm compared with 4.89 ± 2.22 mm for nonaugmented ligament reconstruction simulations, the difference was not statistically significant ($P > .05$). For augmented reconstruction simulations, the mean stiffness was 66.6 ± 26.6 N/mm, compared with 64.6 ± 23.2 N/mm for nonaugmented reconstruction simulations (Table 2, $P > .05$). Notably, augmentation did not uniformly increase the construct stiffness.

Dynamic loading

Dynamic loading was performed without failure in three augmented ligament reconstruction simulations and three without augmentation. No slippage of the graft occurred before or after tensioning. The CLRD and grafts demonstrated no evidence of failure. The mean displacement for augmented graft ligament reconstruction simulations was 1.55 ± 0.16 mm compared with 2.18 ± 0.77 mm for nonaugmented reconstruction simulations (Table 3).

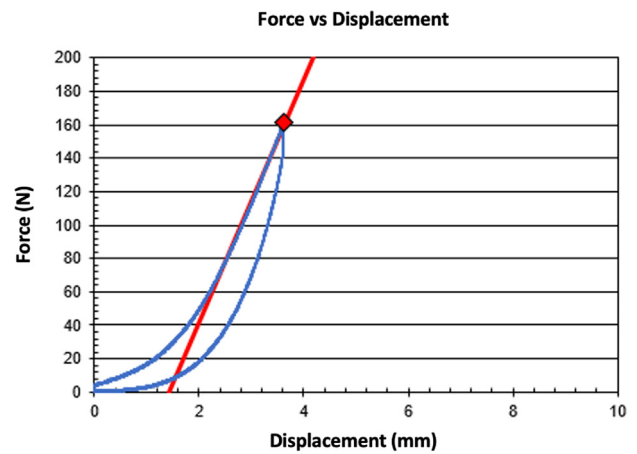


FIGURE 4: Representative graph for the third trial of non-augmented ligament reconstruction simulation using cadaver A. The blue curve represents displacement upon loading and after the load is removed. The red line represents the stiffness.

DISCUSSION

The main finding of this study was that the ligament fixation method prevented graft slippage under both static and dynamic testing conditions. Secondly, no evidence of graft failure was observed, and similar graft displacement and stiffness were recorded with or without augmentation. We chose a 160 N static force because this is twice the recommended load during implantation and is greater than the tensile loads expected in the postoperative period.^{13,14} The lack of graft slippage suggests that the plates contour to the irregular topography of the olecranon and apply compression between the ligament graft and bone, which may promote healing, although this was not tested in this investigation.¹⁵

Construct suitability

A standard palmaris longus graft has an ultimate stress of 145 MPa.¹⁶ With an average palmaris longus diameter of 3.5 mm and a graft tension for each limb of 20 N, the stress within the graft is 7.38 MPa. In this scenario, the palmaris graft is 19.5 stronger than required, which allows it to withstand a larger force; alternatively, a slightly smaller graft may be suitable.

In our specimens, the augmented or nonaugmented ligaments reached a maximum load at 160 N without graft slippage. This loading environment created a stress of 80 N on each side, which compares similarly with existing literature demonstrating that failure of the native MCL occurs between 143 N and 193 N and that of MCL reconstructions occurs between 53 N and 103 N.^{17,18}

TABLE 1. Displacement of Augmented and Nonaugmented Ligament Reconstructions Under Static Loading Conditions for the Eight Tests Included in the Analysis.*

Cadaver (Test Number-Test Type)	Displacement at 160 N (mm)	Cadaver (Test Number-Test Type)	Displacement at 160 N (mm)	Change in Displacement (%)
A (1-Augmented)	4.28	A (1-Nonaugmented)	5.26	22.9
A (2-Augmented)	1.72	A (2-Nonaugmented)	2.54	47.7
A (3-Augmented)	3.01	A (3-Nonaugmented)	3.62	20
B (1-Augmented)	4.07	B (1-Nonaugmented)	4.48	10
B (2-Augmented)	5.50	B (2-Nonaugmented)	6.04	9.8
B (3-Augmented)	7.37	B (3-Nonaugmented)	9.94	34.8
C (1-Augmented)	4.18	C (1-Nonaugmented)	4.61	10.3
C (2-Augmented)	1.50	C (2-Nonaugmented)	2.61	74
Mean (\pm SD)	3.95 \pm 1.81	Mean \pm SD	4.89 \pm 2.22	28.7 \pm 21

*Each test is denoted by cadaver (A, B, or C), test number, and type of ligament reconstruction (ie, 1-Augmented). Notably, in cadaver C, the ulna slipped from the clamp, resulting in erroneous data that was subsequently excluded.

TABLE 2. Stiffness of Augmented and Nonaugmented Ligament Reconstructions Under Static Loading Conditions for the Eight Tests Included in the Analysis.*

Cadaver (Test Number-Test Type)	Stiffness (N/mm)	Cadaver (Test Number-Test Type)	Stiffness (N/mm)
A (1-Augmented)	63.5	A (1-Nonaugmented)	39.4
A (2-Augmented)	109.8	A (2-Nonaugmented)	109.6
A (3-Augmented)	72.5	A (3-Nonaugmented)	75.6
B (1-Augmented)	42.5	B (1-Nonaugmented)	45.9
B (2-Augmented)	53.8	B (2-Nonaugmented)	57.5
B (3-Augmented)	30.8	B (3-Nonaugmented)	36.3
C (1-Augmented)	53.7	C (1-Nonaugmented)	81.6
C (2-Augmented)	106.2	C (2-Nonaugmented)	70.5
Mean (\pm SD)	66.6 \pm 26.6	Mean \pm SD	64.6 \pm 23.2

*Each test is denoted by cadaver (A, B, or C) and test number and type of ligament reconstruction (ie, 1-Augmented).

TABLE 3. Displacement of Augmented and Nonaugmented Ligament Reconstructions Under Dynamic Loading Conditions.*

Cadaver (Test Number-Test Type)	Displacement (mm)	Cadaver (Test Number-Test Type)	Displacement (mm)
A-Augmented	1.42	A-Nonaugmented	1.75
B-Augmented	1.45	B-Nonaugmented	3.26
C-Augmented	1.77	C-Nonaugmented	1.52
Mean \pm SD	1.55 \pm 0.16	Mean \pm SD	2.18 \pm 0.77

*Each test is denoted by cadaver (A, B, or C) and the type of ligament reconstruction.

Valgus elbow instability secondary to medial-sided ligament incompetence is present when greater than 2–3 mm of opening between the

coronoid and the trochlea occurs.^{18–21} Our ligament reconstruction simulation results demonstrate an augmented static displacement of 3.95 \pm 1.81 mm

and a nonaugmented static displacement of 4.89 ± 2.22 mm, which exceeds this limit. This displacement was measured in a lax position without the recommended graft pretensioning. Our force vs. displacement graphs demonstrate that approximately one-third of the displacement occurs in the toe region, which is the portion of the length-tension curve that precedes the linear region. Once the laxity of the system is removed, a linear force vs. displacement relationship is observed. Were this method of ligament reconstruction to be employed, the four ligament grafts should be pretensioned and displacement during *in vivo* loading will, hopefully, be governed by the linear portion of the force-displacement curve.

Our study demonstrated a smaller measured displacement for augmented ligaments compared with nonaugmented ligaments. Augmentation appeared to strengthen the ligament construct, although the difference in displacement between the two testing conditions was not statistically significant. These results should be interpreted cautiously because the toe region, which is the portion of the length-tension graph that precedes the linear region and represents the biomechanical properties of a lax graft, must be overcome via pretensioning during potential clinical use and yet be included in the measured displacement.

Our protocol also stopped pulling at a prescribed load that was less than the ultimate load to failure. A more accurate characterization of the suture augmentation would have occurred had we already pretensioned the graft. The goal of this study was to identify how the plates would resist graft slippage, which was best characterized from the zero-tension starting point. We believe that the ligament reconstruction stiffness is better at characterizing the biomechanical properties given that it is independent of the toe region. The addition of PDS did not add stiffness to the construct in this experiment; however, this might be because the #1 PDS tensile force is somewhat variable, with a range of 85 ± 8 N, and may not be strong enough. Given that it absorbs and can be easily woven into the ligament and presents another level of construct security, it may be reasonable for use for added stability at the time of surgery.

The mean stiffness was 66.6 ± 26.6 N/mm for augmented reconstructions compared with 64.6 ± 23.2 N/mm for nonaugmented reconstructions. These findings are similar to those reported in previous studies in which the mean stiffness of the intact ligament was 42.8 N/mm in a single load-to-failure model.²² Another study identified the stiffness of

the native ligament during cyclical loading as 98.7 N/mm, and that of the palmaris longus docking reconstruction as 30.8 N/mm.¹⁸

We did not apply force through a cadaver distal humerus. The humeral sides of the grafts were placed through the CLRD, which was then placed in a plastic block with an outer dimension and hole diameter mimicking that of a cadaver distal humerus. This allowed us to apply uniform tension through the testing machine. Our ligament reconstruction simulation aimed to study the forces that would be experienced by the ulna to assess graft slippage; therefore, the use of a plastic block fixture that maintained the origin of the humerus-sided ligaments during testing would be unlikely to affect the results of this experiment, as this change would only affect fixation at the proximal aspect of the graft (ie, at the humerus), although not using a cadaver humerus represents a source of error.

Our experimental setup was unable to load at an oblique angle and still used the correct graft lengths. We chose a location 2 mm proximal to the recommended location, which was centered on the supinator crest. The line of pull exerted by the tensile loading machine was not collinear with the line of pull that would be experienced during actual use in patients. Given that the goal of this test was to identify whether the ligaments would slip underneath the plates, we hypothesize that a slight deviation in plate placement or a different angle of force application would not affect the results, as long as the toothed plates are compressing a similar-sized graft against the bone and this does represent a potential source or error.

We used multiple flexor tendons for the ligament reconstruction effort and ensured that their dimensions matched those of the palmaris longus tendon. The choice of the graft may not matter because similar studies demonstrate no significant differences in displacement, the number of cycles to failure, or stiffness between reconstructions using the palmaris longus, gracilis, semitendinosus, or patellar tendons.¹⁸ Similarly, no significant differences in stress, strain, or modulus of elasticity under cyclic loading have been shown between the patellar tendon and hamstring tendon grafts.^{23,24}

In this study, ligament augmentation was performed with a PDS #1 suture, which has an ultimate tensile strength of 85 ± 8 N. Although using a different type of suture with a higher tensile strength could have strengthened the biomechanical properties of this construct, we chose #1 PDS because it is the largest absorbable suture that is readily available

commercially and its absorption prevents the risk of stress shielding to the ligament over time.²⁵

During the creation of transosseous tunnels in the ulna, there is a risk of olecranon fracture; this risk is increased when drill holes are placed too close to the dorsal border of the proximal ulna or if too much pressure is exerted by the plates. During our testing, a freehand drilling technique was employed because a specialized drill guide for this application was not available. In one specimen, the drilling was done too far dorsally, which created a hole only 3 mm from the subcutaneous dorsal border. After tightening the plates against the bone, the dorsal bone cracked directly over the drill hole. The construct remained stable, however, and the pull-out capability of the plates was not affected, suggesting that a suitable construct could still result.

Although consistent reference points were used to measure the graft displacement, there remains a potential for human error. Possible measurement error notwithstanding, inspection confirmed that the observed slippage was never greater than what could be measured with calipers or be visually evident. Additional early studies that measured graft slippage and displacement at different degrees of elbow flexion have been performed with no graft slippage being identified.²⁶

We used 2,000 cycles at the recommended force for the ligament reconstruction tensioning. This cycle number compares favorably to a similar biomechanical study that demonstrated failure or 5-mm joint gapping at 701 cycles for a docking reconstruction.¹⁷ Another study reported a 5-mm joint gapping of the palmaris longus reconstruction at 185 cycles.¹⁸

As described above, other notable shortcomings are the use of a plastic block instead of a humerus for proximal ligament fixation and exerting a line of pull that was less angled than in the live situation. Variations in these parameters may lead to different results than those found in our experiment. Because this experiment was designed as a reconstruction simulation to assess the fixation of the graft to the proximal ulna, extrapolation of the obtained data to the clinical setting remains hypothetical. It should be noted that although the primary outcome of this study was to assess catastrophic failure and elongation at the proximal ulna, the tests performed under dynamic conditions were underpowered because of limitations in the number of available cadaveric ligament grafts, because of which, although a 40% difference was recorded in the augmented and nonaugmented forms, statistical comparison between the two groups was not possible. Further limitations of this study include

the time-zero loading environment, the advanced age of the specimens, and the inability to test the effect of active muscle contraction or joint compression.²⁷

Our findings demonstrate that this ligament fixation technique successfully resisted failure during static and dynamic loading at similar or twice the stress levels that are expected to be present in the postoperative setting. Simultaneous tensioning of the collateral ligaments allows the application of equal force and may potentially restore stability when bidirectional elbow instability is encountered.

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