Original Research

Suture Tape Augmentation of Screw Fixation Reduces Fragment Migration in Tibial Tubercle Osteotomy

A Biomechanical Study

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Background: Tibial tubercle osteotomy (TTO) is a complex surgical procedure with a significant risk of complications, which include nonunion and tibial fracture.

Purpose: To determine whether an additional suture tape augmentation can provide better biomechanical stability compared with standard screw fixation.

Study Design: Controlled laboratory study.

Methods: Five matched pairs of human cadaveric knees were divided into 2 groups: the first group underwent standard TTO fixation with 2 parallel screws (standard group). The second group underwent a novel fixation technique, in which a nonabsorbable suture tape (FiberTape) in a figure-of-8 construct was added to the standard screw fixation for extra stabilization in the inferior-superior direction (augmented group). The specimens were biomechanically tested using a multistep cyclic loading protocol from 400 N up to 800 N to simulate the rehabilitation process. Tubercular fragment migration of >50% of the initial distalization length was defined as clinical failure. A pull-to-failure test was applied to the specimens that survived cyclic loading. Tubercular fragment displacement during cyclic loading and pull-to-failure force were recorded and compared between the 2 groups.

Results: Two specimens of the standard group exhibited clinical failure during cyclic loading to 400 N. All other specimens survived cyclic loading to 800 N. The augmented group showed less cyclic tubercular fragment displacement after every load level compared with the standard group, with statistically significant differences starting from 500 N ($P < .05$; power > 0.8). Mean ± standard deviation tubercular fragment displacement at the end of cyclic loading was 2.56 ± 0.82 mm for the augmented group and 5.21 ± 0.51 mm for the standard group. Mean ultimate failure load after the pull-to-failure test was 2475 ± 554 N for the augmented group and 1475 ± 280 N for the standard group.

Conclusion: The specimens that underwent suture tape augmentation showed less tubercular fragment displacement during cyclic loading and higher ultimate failure forces compared with those that underwent standard screw fixation.

Clinical Relevance: The augmentation technique could potentially increase the success of a TTO.

Keywords: distalization; suture tape augmentation; tibial tubercle osteotomy; TTO

There are many reasons for patellar instability. Risk of recurrent dislocation is shown to be highest among female patients aged 10 to 17 years. Approximately 17% of patients with a first dislocation have another episode, whereas 49% of patients with a second dislocation continue to have problems of instability.[5] Although many of these patients can be treated with nonoperative measures such as physiotherapy and analgesia, a significant proportion can develop recurrent instability and require surgical stabilization.

There are 2 distinct groups of patients with patellar instability. The first group is made up of individuals who have morphological abnormalities of the patellofemoral joint and lower limb, which predisposes them to instability. The second group comprises young, fit, active, and morphologically normal individuals with an acute injury that has led to damage to the medial patellofemoral structures and subsequent patellar dislocation. The most common surgical interventions for addressing the morphological abnormalities and restoring appropriate patellar tracking and

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stability are medial patellofemoral ligament reconstruction and the tibial tubercle osteotomy (TTO).[6]

Several techniques have been described for a TTO; however, the main corrections are medializing, anteromedializing, and distalization, or a combination of them.[11] It has been shown that TTOs have significant complication rates, particularly when detached from soft tissue when both medializing and distalizing.[10] Delayed union, nonunion, and tibial fracture are catastrophic complications that require further surgical intervention, with an associated increase in morbidity and risk of further complication. Complications of delayed union, nonunion, or fracture would also require the patient to have an extended period of reduced mobility and prolonged rehabilitation. Fithian et al[5] stated that up to 46% of TTOs had ≥1 complication, the most common being delayed union, occurring in 25% of cases. They also noted nonunion, screw breakage, and tubercular fracture as reoccurring complications. A study by Payne et al[10] showed a complication rate of 10% in distalizing TTOs, while a study by Johnson et al[7] demonstrated a fracture rate of 3% and highlighted early mobilization and full weightbearing as contributory factors in the occurrence of these complications.

Fractured tibial tubercles pose a technical challenge for revision fixation because often there may be inadequate bone for further screw placement and secure fixation of the tubercular fragments, making a robust solution for primary tubercular fixation paramount. In addition, a distalizing TTO is further compromised biomechanically by the need to detach much of the supporting soft tissue to accommodate the degree of movement.[10] This further increases the need for a form of fixation that can combat significant sheer forces.

A commonly applied primary fixation technique when undertaking a TTO is to use 2 parallel screws perpendicular to the osteotomy, engaging in the posterior cortices and compressing the tubercular fragment in its new position. In this study, we present a novel fixation technique of the TTO that uses a suture tape figure-of-8 augmentation in addition to the standard technique of 2 parallel screws.

The objectives of this biomechanical study were to compare the displacement under cyclic loading and to compare the ultimate load to failure of both techniques. We hypothesized that the novel suture tape augmentation technique would reduce displacement of the tubercular fragment by increasing its stability and resisting the longitudinal force of the quadriceps muscle.

METHODS

Specimen Preparation

Five matched pairs of fresh-frozen human cadaveric knees were obtained from a body donation program (Science Care Inc) and used for this study. Specimens were stored at −20°C and thawed overnight at room temperature before preparation and biomechanical testing. The mean ± standard deviation (SD) donor age was 55.8 ± 2.1 years (range, 53-59 years), and the male to female ratio was 4:1. The mean donor body mass index was 20.1 ± 3.9. Only specimens without prior knee surgeries or diseases were included.

The femur, fibula, and surrounding muscles were removed from the specimens, leaving only the patella and the tibia with attached soft tissue. The tibia was dissected down to the bone while preserving the patellar tendon as well as the lateral and medial retinaculum. The distal end of the tibia was embedded in a 2-component fast-cast resin (RenCast; Huntsman Advanced Materials GmbH). Specimens were kept moist with saline solution at all times during preparation and testing.

Surgical Technique

The specimens were randomly assigned to 1 of 2 groups, with the contralateral specimen used for the alternative technique. One group (standard group) underwent standard TTO fixation with 2 parallel screws perpendicular to the cortex. The other group (augmented group) underwent the novel fixation technique with 2 mm—diameter suture tape (FiberTape; Arthrex Inc) fixation in addition to 2 parallel screws. The 2 surgical techniques are shown in Figure 1.

The surgical procedure for both groups started with a distalization of the tibial tubercle. A straight cut from medial to lateral was made using a sagittal saw. To complete the osteotomy, a step-cut was performed using an osteotome just proximal to the insertion of the patellar tendon to the tubercle. Osteotomized fragments measured 60 mm in length and 5 mm in thickness. The fragments were then distalized 15 mm and were fixed to the tibia with 2 parallel 4.0-mm partially threaded cannulated screws (QuickFix Cannulated Screw System, AR 8740 XXPTS; Arthrex). The appropriate length of the screws was chosen after measurements were collected using a depth gauge so that the threads engaged in the posterior cortex. The

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Ethical approval was not sought for the present study.

screws were placed 15 mm apart, dividing the bone fragment into 3 parts of equal length.

In addition to the aforementioned procedure, for those in the augmented group, a suture tape in a figure-of-8 was added to the fixation for extra stabilization in the inferior-superior direction. A transverse bone tunnel was drilled 15 mm below the distal edge of the osteotomy. The suture tape was inserted into the bone tunnel, crossed between the screws, and passed behind the patellar tendon, creating the figure-of-8 suture tape construct. The suture tape was fastened with a tensioner (FiberTape Cerclage Tensioner; Arthrex) to the scale of 60 N·m, before tying the first and second half hitch. Three more half hitches were added to secure the construct.

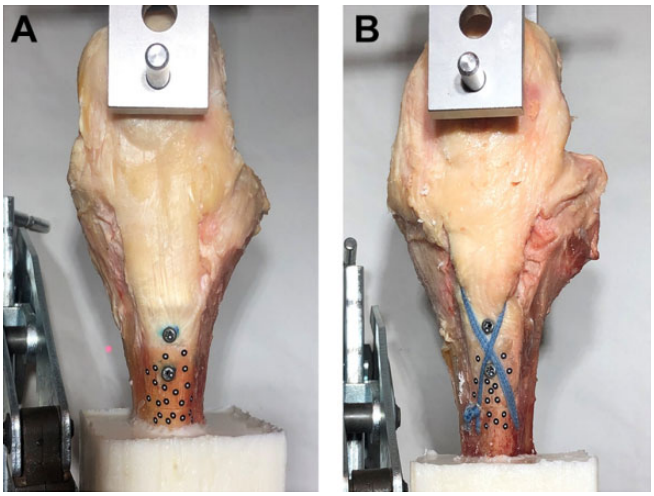

Figure 1. Matched-pair specimens showing both surgical techniques: (A) standard screw technique and (B) suture tape augmented technique. Markers for optical video tracking were placed on the tibia and the tubercular fragment to measure tubercular fragment displacement.

Biomechanical Testing

Biomechanical tests were performed using a dynamic tensile testing machine (ElectroPuls E10000; Instron). The setup is shown in Figure 2. The embedded tibia was secured using a vise on top of an *x-y* table, allowing movements in the transverse plane, preventing constraint forces. The *x-y* table was fixed to the baseplate of the testing machine. Optical tracking was performed using a 3-dimensional camera system (ARAMIS 4 M; GOM GmbH) to measure the displacement of the tubercular fragment while performing biomechanical testing. Markers were placed on the tubercular fragment and on the tibia as shown in Figure 1. Markers on the rigidly fixed tibia were used to define a local coordinate system to serve as reference. The displacement of the fragment's markers was evaluated in relation to the tibial reference to assess the biomechanical performance of the techniques.

The load was applied in the coronal plane via a 5-kN load cell, parallel to the tibial axis and perpendicular to the screws. Forces were introduced through an 8-mm steel bar, which was passed through a drill hole in the center of the patellar bone in the sagittal axis. Preload was set to 50 N, followed by a Locati test comprising cyclic loading starting

Figure 2. The biomechanical test setup used in the study. The specimens were mounted on an *x-y* table, preventing constraint forces. Load was applied through the patella and parallel to the tibial axis. An optical camera system was used to track displacement.

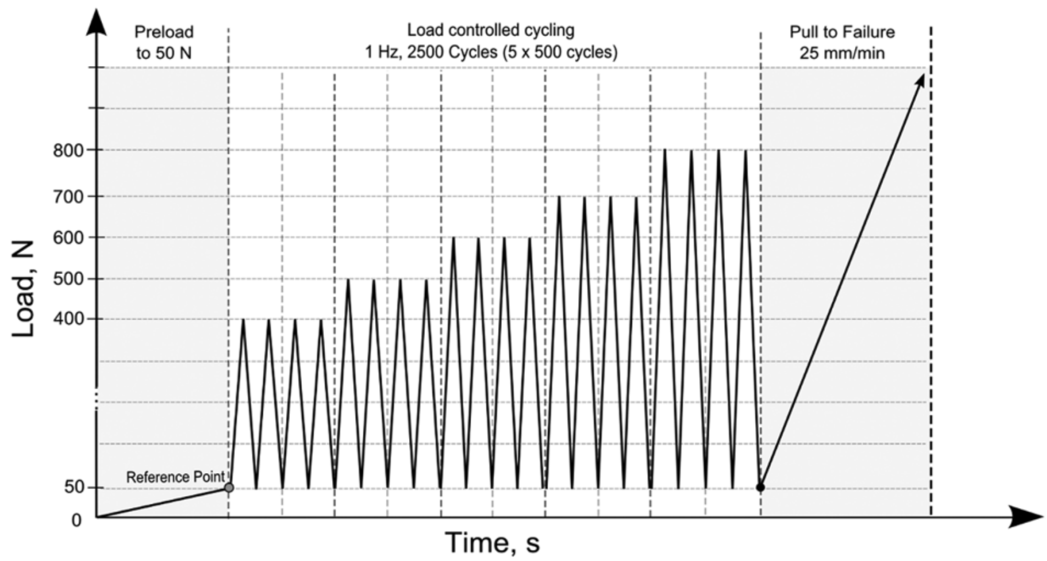

Figure 3. Schematic graph of the test protocol, showing load (N) over time (s). Each specimen underwent cyclic loading via a Locati approach, starting from 50 N to 400 N for 500 cycles. The upper load limit was subsequently increased in 100-N steps until 800 N was reached. Finally, a static pull-to-failure test was performed.

from 50 N to 400 N for 500 cycles at 1 Hz. The 400-N load level was based on a previous study by Caldwell et al[1] and simulates a straight-leg rise against gravity of a 70-kg person. To replicate the rehabilitation process, the load was subsequently increased by 100 N wherein a further 500 cycles were undertaken. This process was repeated sequentially until 800 N was reached (2500 cycles in total). The 800-N load limit was based on mechanical loads at the knee during walking for a 70-kg person.[8] Optical tracking was performed at every load level during the first of every 100 cycles by capturing the spatial position of the markers at 25 Hz. Specimens that survived cyclic loading were pulled to failure at 25 mm/min, as demonstrated in Figure 3.

Parameters

During cyclic loading, failure of the 2 techniques was defined when the gap of the osteotomy reached 50% of the initial distalization length, which was based on our clinical observations. In the present study, this was to a displacement of 7.5 mm and was comparable with clinical failure, defined by Warner et al.[13] Tubercular fragment displacement was evaluated after every load level and at the end of cyclic testing. Ultimate load-to-failure (F_{max}) and the modes of failure were recorded during the pull-to-failure test.

Data Analysis

Data were analyzed using Matlab (MathWorks), and statistical analysis was performed using SigmaPlot Version 13.0 (Systat Software). A regression analysis was used to analyze the distribution and relationship of the data points among the load levels and to display the displacement trend of the 2 groups. The samples were tested for normal distribution using the Shapiro-Wilk test. A 2-tailed t test was used to compare the mean values of the standard group and augmented group on statistical differences regarding displacement after the load levels during cyclic loading and ultimate failure load. The significance level was set to $P < .05$ with a desired power of 0.8 to detect statistical significance. A post hoc power analysis was performed to validate the chosen sample size of 5 pairs of knees for cycling loading.

RESULTS

Cyclic Loading

The augmented group exhibited less tubercular fragment displacement after cyclic loading when compared with the standard group within each matched pair, as demonstrated in Figure 4 and Table 1.

Specimens 2 and 5 from the screw group experienced high fragment displacement after cyclic loading (11.33 mm and 15.26 mm, respectively) and surpassed the predefined failure limit before the end of the first (400-N) load level (7.92 mm and 10.83 mm, respectively). All other specimens showed a total displacement of <50% of the distalized length (failure limit) after 2500 cycles. Therefore, for further illustrations and statistical comparison of the cyclic displacement data, specimens 2 and 5 from the screw group were excluded.

A 2-tailed t test was used to compare the mean displacement values after each load level between the 2 groups. Statistically significant lower displacement values for the suture tape augmentation were found at each load level with $P < .05$ and a power of 0.80 (except for the 400-N load level: power, 0.77), as demonstrated in Table 1.

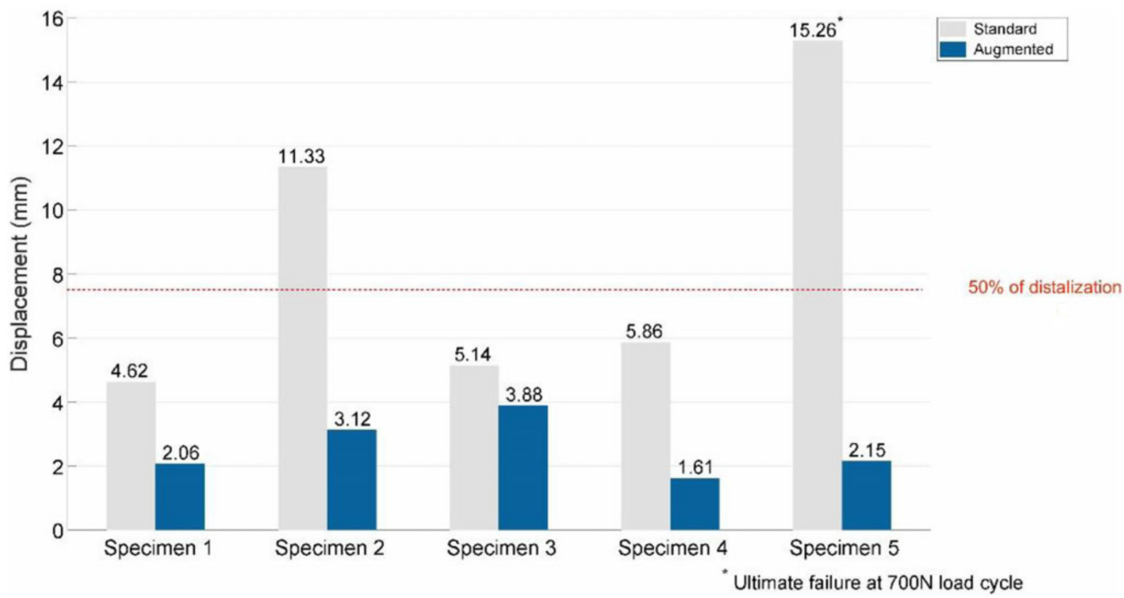

Figure 4. Graph of total tubercular fragment displacement (mm) after cyclic loading for the standard screw group vs the suture tape augmented group.

TABLE 1
Total Displacement (mm) of the Tubercular Fragment at the End of Each Load Level

	400 N		500 N		600 N		700 N		800 N	
Specimen Pair	Standard	Augmented	Standard	Augmented	Standard	Augmented	Standard	Augmented	Standard	Augmented
1	0.89	0.43	1.47	0.79	2.19	1.24	2.93	1.68	4.62	2.06
2[a]	–	0.64	–	1.21	–	1.84	–	2.46	–	3.12
3	0.56	0.36	1.39	0.84	2.29	1.63	3.71	2.58	5.14	3.88
4	0.94	0.10	1.47	0.29	3.01	0.54	3.65	0.98	5.86	1.61
5[a]	–	0.10	–	0.14	–	0.40	–	0.78	–	2.15
Mean (±SD)	0.80 (±0.17)	0.33 (±0.21)	1.44 (±0.04)	0.65 (±0.39)[b]	2.50 (±0.37)	1.13 (±0.57)[b]	3.43 (±0.35)	1.70 (±0.74)[b]	5.21 (±0.51)	2.56 (±0.82)[b]

[a]Specimen of the standard screw group failed the predefined limit during 400-N cyclic loading (displacement >50% of distalization). Dashes indicate unavailable data.
[b]Significantly lower compared with the standard screw group ($P < .05$; power 0.80).

Bipolynomial regression curves of the displacement data independent of the associated load levels revealed a coefficient of determination of $R^2 > 0.99$ for both groups. SDs were also fitted over the load levels and showed the area of distribution of the samples. The suture tape augmentation area was beneath the standard screw group for every load level and showed a less steep increase of fragment displacement for higher load levels, as demonstrated in Figure 5.

Pull-to-Failure Testing

The load-to-failure data showed higher values for the suture tape augmented specimens than the standard screw fixation, as demonstrated in Figure 6. Mean ± SD load to failure of the augmented group was 2475 ± 554 N, whereas the standard group failed at 1475 ± 280 N. A statistically significant difference between the groups was not detected because of low power of the t test ($P = .037$; power, 0.62), as 3 specimens could not be considered for the pull-to-failure test. One specimen of the standard screw group failed during cyclic loading, and for 1 matched pair, the patella fractured at the force entry point while the TTO fixation was still intact. The failure mode for all other specimens was fracture of the tubercular fragment, starting from the screw holes toward the distal edge of the fragment. One suture tape augmented specimen showed additional knot failure.

DISCUSSION

The most important finding of the present study highlights that the suture tape augmentation showed significantly

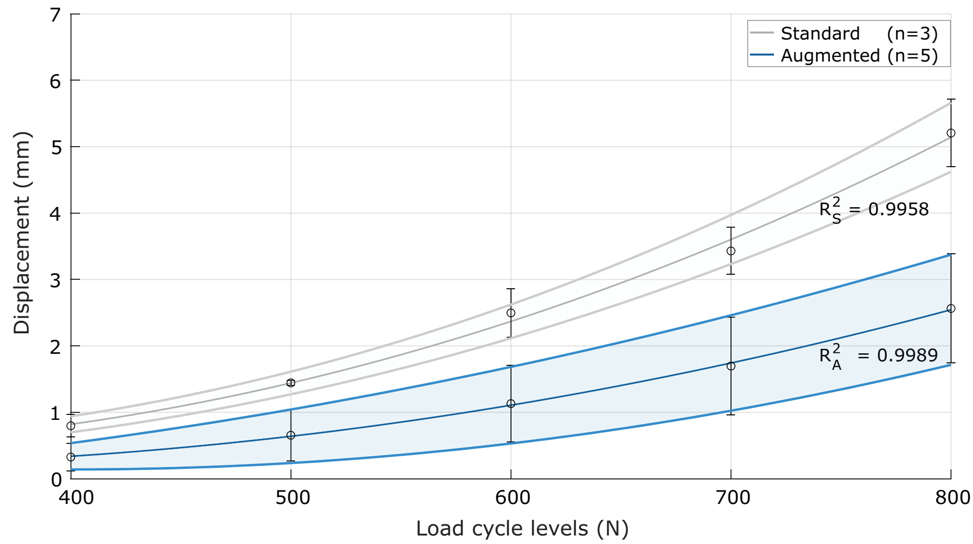

Figure 5. Regression curves of tubercular fragment displacement means of both groups during cyclic loading, including the SD to display the distribution area of the fragment displacement. The suture tape augmented group shows less displacement than does the standard screw group for all load levels. Two specimens of the standard screw group had to be excluded because of clinical failure. S, standard; A, augmented.

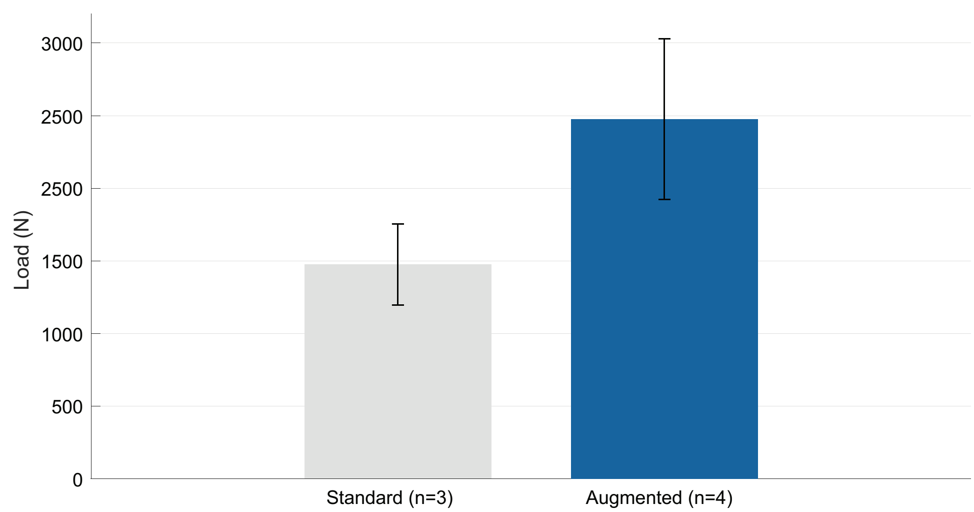

Figure 6. Pull-to-failure data. The suture tape augmented group showed higher values than did the standard screw group (mean ± SD, 2475 ± 554 N vs 1475 ± 280 N).

better values than did the standard screw technique with regard to displacement and ultimate failure load, even when removing the 2 outliers in the cyclic test. The slope of the linear regression was less steep, especially for higher load levels. The 2 outliers showing high initial displacement were both from the standard screw group, but the matched suture tape augmented technique behaved within expected limits. The augmentation seemed to be able to compensate for weaker fixation and could potentially increase the treatment success of a TTO.

We believe this is the first biomechanical study assessing TTO screw fixation augmented by a suture tape fixation. There have been several related studies performed in recent years that have provided relevant data as a gauge for this study. Caldwell et al[1] compared TTO 4.5-mm bicortical screw fixation alone with identical TTO fixation augmented with cerclage steel wiring for revision knee arthroplasty. They used a force of 400 N to evaluate cyclic displacement, demonstrating 1.38 ± 0.87 mm and 1.29 ± 0.51 mm for the screws and wire fixation after 500 cycles, respectively. Those values can be compared with the displacement data after the 400-N load level in the present study. The suture tape augmented group showed considerably less displacement (0.33 ± 0.21 mm), while the displacement values of the standard screw group lay within the SD of those values reported by Caldwell et al (0.80 ± 0.17 mm). After cyclic loading, Caldwell et al performed a pull-to-failure test and demonstrated an F_{max} of 1429 ± 348 N and 1072 ± 260 N, respectively.

Warner et al[13] performed a study comparing TTO fixation with bicortical 3.5-mm screws vs 4.5-mm screws. They performed 350 cycles sequentially from 50 N to 400 N and reported mean displacement values after cyclic loading of 3.21 mm and 1.98 mm, respectively. Subsequently, they undertook a pull-to-failure test, demonstrating a mean F_{max} of 1360 N and 1459 N, respectively.

Nurmi et al[9] performed a study comparing TTO fixation with bicortical 4.5-mm stainless steel screws versus 4.5-mm biodegradable screws. They performed 1500 cycles sequentially from 50 N to 300 N and then undertook a pull-to-failure test, demonstrating a mean F_{max} for the stainless steel screw fixation of 1163 N. Cosgarea et al[2] performed a pull-to-failure study comparing flat and oblique TTOs fixed with 3.5-mm bicortical screws and demonstrated a mean F_{max} of 1639 N for flat osteotomies and 1166 N for oblique osteotomies. Davis et al[3] also performed a pull-to-failure study comparing osteotomies fixed with screws compared with osteotomies performed using bevel and step-cuts augmented with differing numbers of steel cerclage wires. In all cases, screw fixation had a statistically significant higher pull-to-failure mean F_{max}, which was 1654 N. A comparison with the results from the present studies is limited. However, the F_{max} of the standard screw group lay within the range of the aforementioned studies, whereas the augmentation technique showed higher values than those previously reported in the literature.

There have also been studies[9,11] comparing the strength of fixation of different screw configurations as well as 1 study by Stevens et al[12] that assessed the use of a one-third tubular plate augmentation to prevent tubercular migration and bring about bony union. Many of the aforementioned studies used stainless steel cerclage wire as either a primary or an augmented fixation system. We anticipate that because suture tape is a soft, inert material in comparison with stainless steel cerclage wire, there will be less soft tissue irritation and a reduction in the requirement for surgical removal. A further benefit over stainless steel cerclage is the possibility of controlled progressive tensioning that can be optimized to each patient.[4]

We acknowledge that there were limitations within this study. The study had a small number of specimens, but a power analysis validated the chosen sample size. The study was both cadaveric and involved the dissection of much of the soft tissue supporting structures that surround the patella such as muscle and capsule. The nature of the dissection of the specimens reduced the comparability of the performance of the specimens to an in vivo knee. In addition, individuals experience pain that almost certainly confers some self-protective immobilization to the fixation, which obviously cannot be accounted for in cadaveric specimens.

The number of cycles undertaken in testing and the loading direction of the tibia were selected on the basis of a literature review of other similar studies[1,13] but may not have perfectly replicated the physiological loading direction and the number of cycles an in vivo knee would undergo during recovery and rehabilitation from a TTO procedure. However, a unique aspect of this study was that a stepwise rehabilitation process was simulated at all. A multistep loading approach with increasing force was implemented that correlated with movements of the knee, from a leg-raise against gravity up to full weightbearing walking.

The present study used matched pairs to compare the 2 techniques against each other. Dissection to the tibia allowed visual inspection of each specimen and verification of correct screw placement. However, bone mineral density measurements and radiographs would have allowed a more precise evaluation. We acknowledge that 2 of the specimens had very significant early tubercular fragment displacement. Specimens 2 and 5 in the screw group were outliers, and this very large displacement may have skewed the results. However, even when excluding these particular specimens or alternatively subtracting the initial displacement values to balance the groups, the suture tape augmented group still showed a significant statistical difference and may even highlight the effectiveness of the suture tape technique.

We acknowledge that clinical validation is required. The next step in advancing this technique is to apply this in vivo and collect outcome data on patient recovery (pain and satisfaction scores) as well as the degree of osteotomy displacement, time to union, and complication rates. We would also be interested in determining whether the increased stability provided by the suture tape system reduces the rate of nonunion, again because of increased stability at the site of fixation coupled with an augmented compressive force at the osteotomy site.

CONCLUSION

This study has demonstrated a significant statistical difference in tibial tubercular displacement over cyclic loading when assessing the current standard surgical technique of 2—bicortical screw fixation of the TTO compared with fixation with screws that is supplemented with a suture tape figure-of-8 construction.

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