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Biomechanical Assessment of Bicortical Suspension Device Fixation for Proximal Tibiofibular Joint Instability

Single Versus Double Device

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Background: Bicortical suspension device (BCSD) fixation treats proximal tibiofibular joint (PTFJ) instability in both the anterolateral and posteromedial directions. However, biomechanical data are lacking as to whether this technique restores the native stability and strength of the joint.

Purpose: To test (1) if BCSD fixation restores the native stability and strength and (2) if using 2 devices is needed.

Study Design: Controlled laboratory study.

Methods: Sixteen pairs of fresh-frozen cadaveric specimens were obtained. Six pairs were assigned to the control group and 10 matched pairs assigned for transection to model PTFJ and subsequent BCSD fixation (one specimen with 1-device repair and the other with 2-device repair). Joint stability and strength were assessed by translating the fibular head relative to the fixed tibia either anterolaterally or posteromedially. Control specimens received 20 cycles of 0- to 2.5-mm joint displacement tests (subfailure) and then proceeded to load to failure (5 mm). For the experimental group, cyclic tests were repeated after ligament resection and after fixation. Forces and stiffness at 2.5- and 5-mm displacement were recorded for comparisons of joint strength and stability at subfailure and failure loads, respectively.

Results: After repair of anterolateral instability, both the single- and double-device fixations successfully restored near-native states, with no significant differences as compared with the intact group for forces at subfailure load (P = .410) or failure load (P = .397). Regarding posteromedial instability, single-device repair did not restore forces to the near-native state at subfailure load (intact: 92.9 N vs single: 37.4 N; P = .001) or failure load (intact: 170.7 N vs single: 70.4 N; P = .024). However, the double-device repair successfully restored near-native posteromedial forces at both subfailure load (P = .066) and failure load (P = .723).

Conclusion: For treatment of the most common form of PTFJ instability (anterolateral), this cadaveric study suggests that 1 BCSD is sufficient to restore stability and strength. The current biomechanical results also suggest that 2 devices are needed for restoring PTFJ posteromedial stability and strength. Using 2 devices addresses both types of instability and provides more PTFJ posteromedial stability.

Clinical Relevance: The results suggest that 1 device should be used for treating anterolateral instability and 2 devices used for posteromedial instability based on the biomechanical study.

Keywords: proximal tibiofibular joint; tibiofibular instability; bicortical suspension device; biomechanics; strength

The proximal tibiofibular joint (PTFJ) connects the fibular head to the posterolateral side of the proximal tibia. PTFJ instability is a rare injury accounting for <1% of general knee injuries and up to 10% of all multiligament knee injuries.[4-6] Chronic or recurrent PTFJ instability generally needs to be treated; an unstable PTFJ disrupts knee external rotation and causes peroneal nerve symptoms and recurrent lateral knee pain. Restoring PTFJ stability helps relieve the related symptoms, including peroneal nerve symptoms. In the setting of multiligament injuries to the knee, the stability of the PTFJ is important for the proper assessment of the integrity of posterolateral corner injury and for the performance of a fibular-based, lateral-sided knee reconstruction.[5,6]

The PTFJ is stabilized by the thicker anterior ligaments and thinner posterior ligaments.[7] Anterolateral dislocations are most common, accounting for 77% to 90% of

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Figure 1. Clinical shuck test, which is often diagnostic for proximal tibiofibular joint instability. The test is performed by grasping the fibula between the thumb and index finger with translation of the fibula anteriorly and posteriorly. A positive test is indicated by asymmetrical translation versus the opposite side and/or reproduction of the patient's symptoms.[14]

Figure 2. (A) Axial and (B) coronal fat-saturated T2-weighted images showing acute rupture of the anterior tibiofibular ligament (thick arrow) and abnormal high signal and poor definition of the fibers of the posterior ligament (thin arrow) in panel A. In panel B, rupture of the posterior ligament (thin arrow) is seen; note the mildly displaced fibular head fracture (thick arrow).[5] Reprinted from Burke CJ, Grimm LJ, Boyle MJ, Moorman CT III, Hash TW II. Imaging of proximal tibiofibular joint instability: a 10 year retrospective case series. *Clin Imaging*. 2016;40(3):470-476; with permission from Elsevier.

PTFJ dislocations. In these injuries, the posterior ligamentous complex is disrupted, often due to a fall onto a flexed knee.[8] Posteromedial dislocation is relatively rare and results in a disruption of the anterior ligament complex. Examination of PTFJ instability is often performed with the patient in the supine position and knee flexed to 90°. The examination, as an anteroposterior shuck test, assesses the resistance when manipulating the fibular head to move in anterolateral and posteromedial directions (Figure 1).[9-11] This test is a bilateral examination in which the affected side is compared with the normal contralateral side because some patients may have congenital laxity of this joint. The instability can be further confirmed by evaluation of tibiofibular ligamentous integrity on magnetic resonance imaging scans (Figure 2).[12] After PTFJ injuries, nonoperative treatment with closed reduction and immobilization is often recommended. Injuries with persisting tibiofibular dislocation or subluxation require operative fixation, regarding which there is still no consensus. Reported operative treatments include internal fixation, arthrodesis, direct ligamentous repair, and ligament reconstruction using a bicortical suspension device (BCSD), autograft, or rerouted biceps femoris tendon.[13] Our experience suggests that BCSD can successfully stabilize the joint.[9]

Treating PTFJ instability with BCSD fixation has several advantages.[12,13] Fixation using suspension devices permits normal physiological joint motion to accommodate ligament healing. This technique also stabilizes the knee in both the anterolateral and posteromedial directions and allows for healing via scar formation at the site.[1,3] However, it is not clear how well the bicortical suspension fixation mimics the native PTFJ. Specifically, biomechanical data are lacking regarding the comparisons of biomechanical properties between the repaired and native intact joint. To our knowledge, 2 biomechanical studies have demonstrated that BCSD repair restores the translational stability of PTFJ.[2,3] However, they did not assess the strength of the tibiofibular construct after repair. In addition, a single device may not be strong enough, and a second device may be necessary to restore joint stability. However, using 2 devices to repair the joint has also been proposed but has not been biomechanically evaluated.[9] To address these questions, this study tested whether (1) the BCSD technique restores native stability and strength

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and (2) using 2 devices results in a more stable and stronger joint.

METHODS

Specimen Preparation and Operative Technique

Seventeen pairs (n = 34) of fresh-frozen lower limb (midfemur to toe-tip) specimens (17 left, 17 right; 7 male, 10 female; median age, 67 years [interquartile range (IQR), 60-69 years; range, 28-71 years]) with no history of PTFJ injury, previous surgery, or gross anatomic abnormality were procured from an accredited tissue bank (Research for Life, RFL). Specimens were maintained at −20°C and thawed at room temperature for 24 hours before testing. One sample was excluded because the ligaments were cut before testing, so we were unable to measure the intact joint. The second was excluded because the knee joint failed during preparation. Therefore, we included 32 knees in the testing.

Once thawed, the specimen was dissected free of skin, subcutaneous adipose tissue, and musculature. The femur was disarticulated from the tibia after careful excision of capsular and ligamentous structures. Next, careful dissection of the soft tissue surrounding the PTFJ was performed to expose, identify, and isolate the anterior and posterior tibiofibular ligamentous bundles. Throughout the dissection and testing, the ligamentous complexes were kept moist with physiological saline. The specimens were randomly assigned into 3 groups: control (n = 12; 6 pairs), single-device repair (n = 10; 5 pairs), and double-device repair (n = 10; 5 pairs). Each pair was randomized such that 1 specimen in each pair was tested in the anterolateral direction and the other tested in the posteromedial direction. For the 2 repair groups, anterior and posterior proximal tibiofibular ligaments were resected to simulate worst-case joint injury and instability.

The anteroposterior shuck test was manually performed to confirm the instability of the resected joint before initiating the repair (Figure 1). The repair was performed per manufacturer's recommended technical guidelines for insertion of the BCSD and also follows the technique previously published.[9] The entry and exit points of the suspension device were chosen to restore native joint stability of both the anterolateral and the posteromedial directions, without over- or underconstraint, based on the results of a finite element analysis computer simulation study.[15] For a single-device repair, entry and exit points 4 and 4 were selected; for a double-device repair, entry and exit points 3 and 6 and 5 and 8 were selected (Figure 3).

Biomechanical Testing

A custom apparatus was designed to replicate the anteroposterior shuck test used in clinical practice (Figures 1 and 4A). The apparatus could tilt the tibial and fibular structures to ensure that the loading direction was along the joint line in either the anterolateral or the posteromedial direction. A 0.5 inch (12.7 mm)–wide metal plate with a hook-shaped end was extended from the loading apparatus to reach the inferior part of the fibular head (Figures 4B&C). The pulling location was set to be 3.5 to 4.5 cm distal to the tip of the fibular head. Testing was initiated with cyclic loading at a subfailure load (0- to 2.5-mm displacement at 0.2 Hz for 20 cycles) for the intact joint condition in the predetermined direction (either anterolateral or posteromedial). For the repair groups, a second round of the same subfailure cyclic tests were performed for the resected joint condition. A third round was repeated after BCSD repair. A load-to-failure test was performed on the control group specimens for the intact joint condition; a load-to-failure test was conducted for the experimental groups after fixation and completion of the testing at subfailure load.

Data Analysis

Our main biomechanical outcome measurements were strength and stability. We measured the strength of the joint and fixation using force. We measured stability using stiffness (ie, force/displacement). Generally, a higher value for force represents a stronger construct, and a higher value for stiffness represents a more stable construct.

For each cyclic test, the force-displacement data were plotted. The plot often started with a toe region, which was followed by a linear ramp. Stiffness at 2.5 mm was calculated by linear fitting the curve to the 1- to 2.5-mm ramp region. Peak forces at 2.5-mm displacement were extracted for each of the 20 cycles, and the mean of the 20 peak forces was recorded. For the load-to-failure test, the force-displacement curve often had a linear upward ramp, followed by a yield plateau or a drop in force and then a second upward ramp after other structures such as the interosseous membrane were engaged. Most specimens did not yield or have a force drop before 5 mm of displacement, which was considered the clinical failure point and used as a threshold to determine the strength of the joint in this study. This failure displacement of 5 mm along the anterolateral or posteromedial direction was greater than a failure displacement of 3 mm (a failure strain of about 8%) along the ligament axis direction, which is estimated for PTFJ ligaments based on their ultimate load and stiffness values.[7] The force at 5 mm was recorded, and the slope of the linear ramp during 1- to 5-mm displacement was calculated as stiffness at 5 mm.

The normality of data distribution was assessed before performing any parametric tests. For the repair groups, the stiffness and force at 2.5-mm displacement (subfailure) were compared between anterolateral and posteromedial directions for the intact and resected joint conditions. Independent t test was used to compare stiffness and force values at both 2.5 mm and 5 mm between the intact (n = 16) and the single- or double-device repaired joint conditions (n = 5 each) and to compare stiffness and force values at both 2.5 mm and 5 mm between the single-device group and the double-device group. For the tests at subfailure (2.5 mm), the P value for statistical significance was set at $P < .017$ to adjust for multiple comparisons using Bonferroni correction. For the tests at failure (5 mm), the P value for statistical significance was set at $P < .025$ to adjust for multiple comparisons. In addition to the

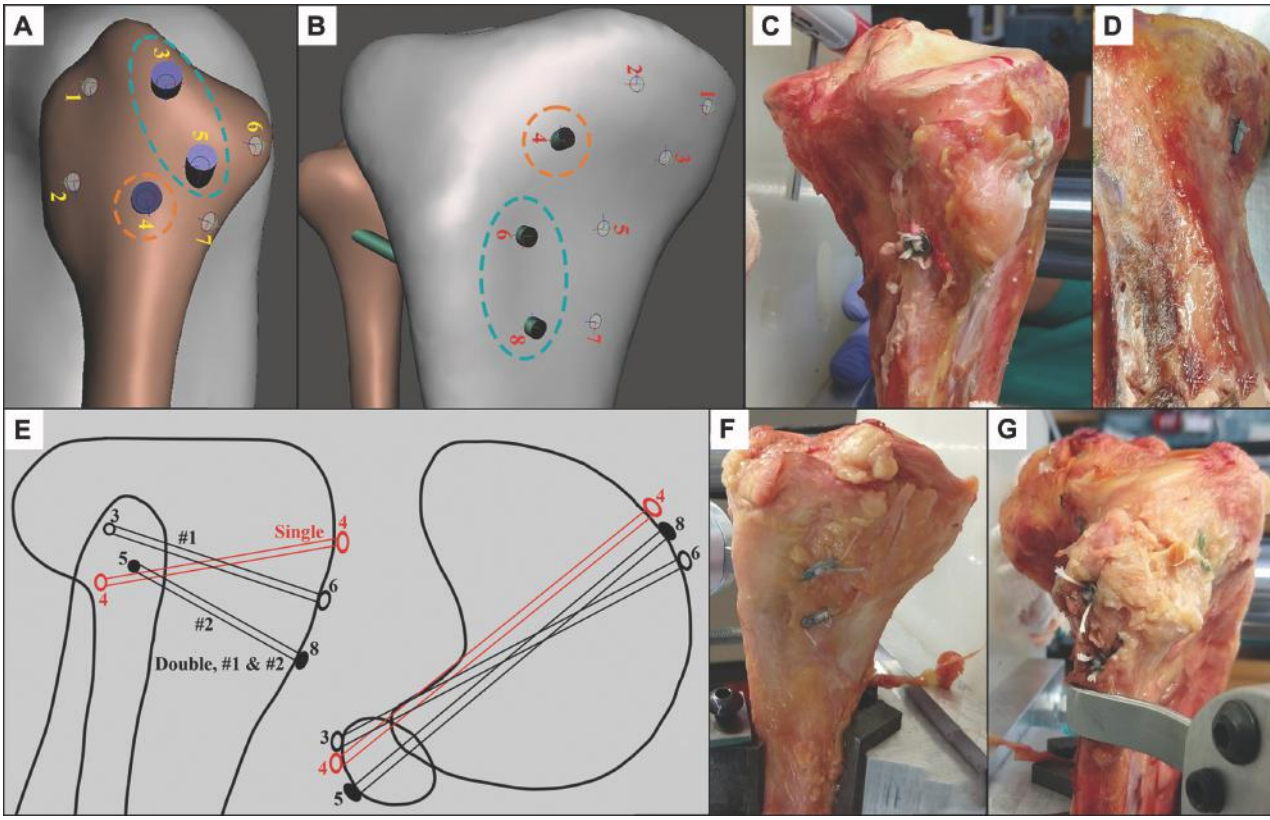

Figure 3. (A) Entry points for the 1-device (orange dotted lines) and 2-device (blue dotted lines) repairs on the fibular head. (B) Exit points for the 1-device (orange dotted lines) and 2-device (blue dotted lines) repairs on the anteromedial tibia. Placement of the 1-device repair on a cadaveric knee viewed from the (C) fibular side and (D) tibial side showing entry and exit points, respectively. (E) Schematic diagram of both 1-device repair (red) and 2-device repair (black) on both sagittal and transverse planes. Placement of the 2-device repair on a cadaveric knee viewed from the (F) tibial side and (G) fibular side showing exit and entry points, respectively. The numbers on the fibula and tibia indicate potential entry and exit points assessed.[15]

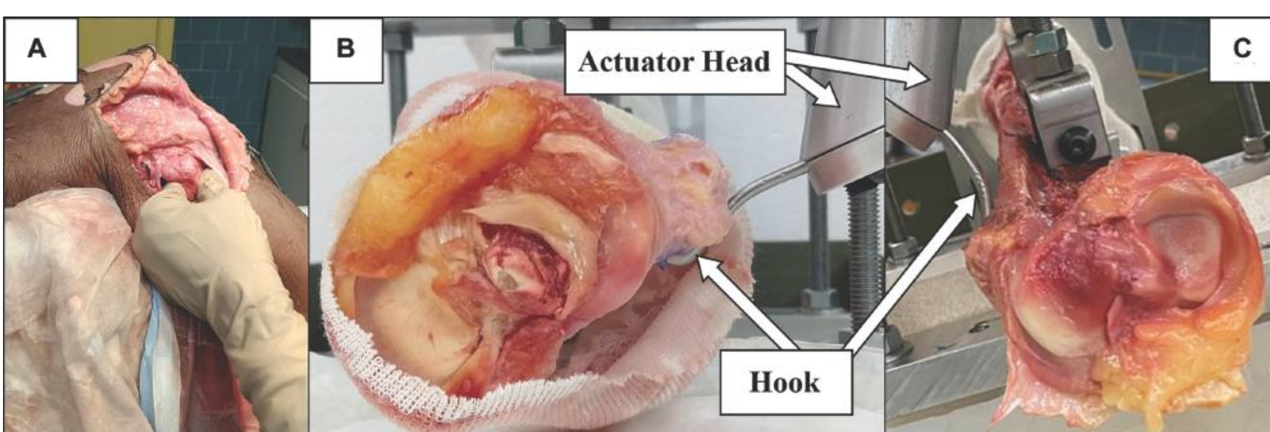

Figure 4. Setup for shuck test along anterolateral direction: (A) manual test, (B) biomechanical test composed of an extended hook (allowing for natural rotation) under the fibular head for anterolateral loading, and (C) biomechanical test for posteromedial loading.

TABLE 1
Load and Stiffness at 2.5 mm and 5 mm Between Groups and Direction[a]

	Subfailure				Failure			
	Strength		Stability		Strength		Stability	
	Force at 2.5 mm, N	*P* Value[b,c]	Stiffness at 2.5 mm, N/mm	*P* Value[b,c]	Force at 5 mm, N	*P* Value[b,d]	Stiffness at 5 mm, N/mm	*P* Value[b,d]
Anterolateral								
Intact, n = 16[e]	42.7 (22.7)	—	22.5 (10.9)	—	141.3 (64.9)	—	32.5 (15.4)	—
Resected, n = 10	20.8 (14.2)	**.006**	10.8 (8.1)	**.005**	—	—	—	—
Repaired: 1 BCSD, n = 5	38.4 (9.4)	.551	19.0 (4.8)	.336	132.8 (45.7)	.825	28.6 (13.2)	.684
Repaired: 2 BCSD, n = 5	34.6 (16.9)	.410	15.6 (8.9)	.191	110.1 (31.5)	.397	25.6 (7.9)	.433
Posteromedial								
Intact, n = 16[e]	92.9 (46.5)	—	47.1 (20.8)	—	170.7 (75.3)	—	35.5 (14.6)	—
Resected, n = 10	24.7 (16.6)	**<.001**	13.2 (10.8)	**<.001**	—	—	—	—
Repaired: 1 BCSD, n = 5	37.4 (18.3)	**.001**	17.4 (9.1)	**<.001**	70.4 (36.8)	**.024**	28.6 (13.2)	.028
Repaired: 2 BCSD, n = 5	54.8 (32.0)	.066	29.6 (18.7)	.121	184.2 (39.0)	.723	39.4 (9.8)	.815

[a]Data are presented as mean (SD). Boldface *P* values indicate statistical significance. BCSD, bicortical suspension device. Dashes indicate not applicable.
[b]*P* values are for comparisons with the intact joint condition.
[c]Adjusting for multiple comparisons, the *P* value for statistical significance was set at $P < .017$ (for 2.5 mm).
[d]Adjusting for multiple comparisons, the *P* value for statistical significance was set at $P < .025$ (for 5 mm).
[e]n = 6 for force and stiffness at 5 mm.

independent *t* test, paired *t* test was used for each experimental group comparison.

RESULTS

PTFJ Stability and Instability

The intact PTFJ condition had greater stiffness and force at 2.5 mm along the posteromedial direction (47.1 N/mm and 92.9 N) than along the anterolateral direction (22.5 N/mm and 42.7 N) (both $P < .001$). The differences between the 2 directions for the stiffness and force became insignificant at 5 mm (anterolateral: 32.5 N/mm and 141.3 N; posteromedial: 35.5 N/mm and 170.7 N; both $P > .346$). Ligament transection successfully modeled an injury pattern, with both force and stability in both the anterolateral and posteromedial directions decreasing significantly as compared with the intact joint condition (all $P \leq .006$) (Table 1). After ligament transection, the stiffness and force at 2.5 mm were similar between the posteromedial direction (13.2 N/mm and 24.7 N) and anterolateral direction (10.8 N/mm and 20.8 N) (both $P > .58$). Thus, the percentage decreases in posteromedial stiffness (80%; IQR, 74%-85%) and force (79%; IQR, 75%-85%) were significantly greater than the decreases in anterolateral stiffness (34%; IQR, 29%-70%; $P = .023$) and forces (35%; IQR, 30%-64%; $P = .014$).

Restoration of PTFJ Stability and Strength

Regarding anterolateral instability, both the single- and the double-device fixations returned forces to the near-native state at subfailure load and failure load (Table 1). Similarly, both the single- and the double-device fixations returned stiffness values to near-native states at subfailure load and failure load (Table 1).

Regarding posteromedial instability, the single-device repair did not restore forces at subfailure load or failure load, while the double-device repair returned the posteromedial forces to near-native states at both subfailure load and failure load (Table 1). Similarly, the single-device repair did not restore the posteromedial stiffness at subfailure load (intact: 47.1 N/mm; single: 17.4 N/mm; $P < .001$), but it did restore posteromedial stiffness at failure load (intact: 35.5 N/mm; single: 28.6 N/mm; $P = .028$). The double-device repair did return the posteromedial stiffness values to near-native states at subfailure load (intact: 47.1 N/mm; double: 29.6 N/mm; $P = .121$) and failure load (intact: 35.5 N/mm; double: 39.4; $P = .815$). The results of the paired comparisons (data not shown) were similar, with 1 device being sufficient to restore strength and stability in the anterolateral direction, but 2 devices required to restore strength and stability in the posteromedial direction.

For the failure modes of the 20 repaired joints, 15 constructs failed with the button(s) pulling through or into the tunnel of the fibular head, and 5 constructs failed with fibular fracture or severe dislocation (Figure 5).

DISCUSSION

In this study, we found that the BCSD fixation restored both strength and stability to the PTFJ comparable with the intact joint along both the anterolateral and the posteromedial directions. One device adequately restored the stability and strength to its native joint level for the most common injury pattern of anterolateral instability. The

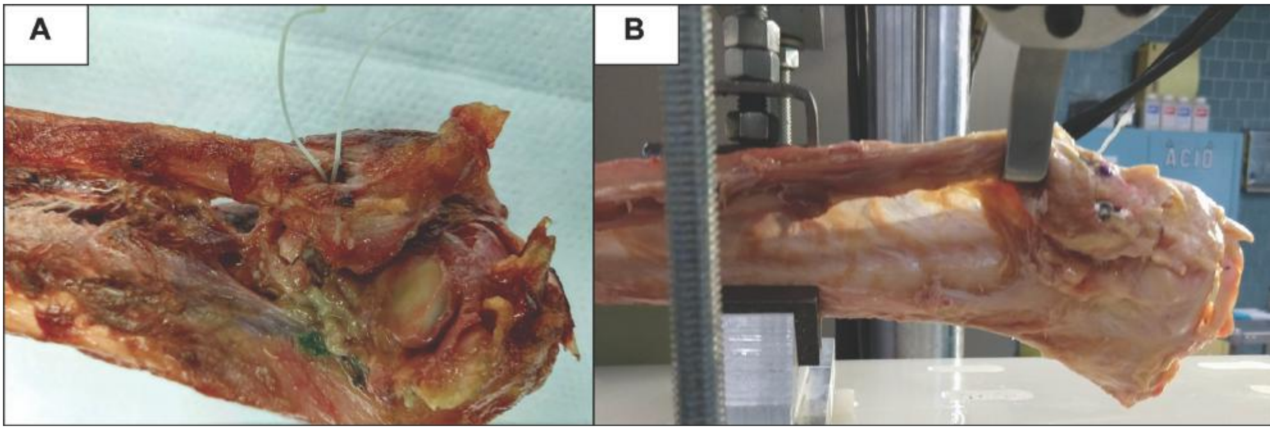

Figure 5. Photographs depicting failure modes after loading to failure. (A) The button was pulled into the tunnel of the fibular head, which was severely dislocated in 75% of cases. (B) Fracture or dislocation occurred in 25% of cases.

majority of PTFJ instability (77%-90%) is along the anterolateral direction.[13] Therefore, single-device BCSD fixation is a recommended fixation strategy for treating the most common cases of PTFJ injuries with anterolateral instability. For the less common posteromedial instability, 1 device was inadequate, and 2 devices were required to restore native joint strength and stability.

The stiffness of the ligaments stabilizing the PTFJ have been assessed in a previous study. The posterior ligament (109 ± 49 N/mm) has similar fiber-direction stiffness to that of the anterior ligament (133 ± 39 N/mm).[7] Similarly, we found that the anterolateral stiffness (32.5 N/mm) was similar to the posteromedial stiffness at 5 mm (35.5 N/mm) (P = .722). According to current literature, the strength of the posterior ligament bundle (322 N) is weaker than that of the anterior ligament bundle (517 N).[7] However, this study found that the anterolateral strength of the native PTFJ at 5-mm displacement (141.3 N) was not significantly different from the posteromedial strength (170.7 N) (P = .471). The disagreement is related to the differences in strength definition (ultimate failure in the referenced study vs 5-mm joint dislocation in the current study) and direction of strength testing (ligament fiber axis in the referenced study vs the anterolateral or posteromedial direction in the current study).

We confirmed that resecting both the anterior and the posterior ligaments at the PTFJ resulted in loss of stability along both the anterolateral and the posteromedial directions. This is consistent with several previous studies that simulated the PTFJ injury pattern by sectioning these ligaments.[1-3] The mean PTFJ displacement is reported to increase from 8 mm to 14 mm during manual joint gliding tests (shuck tests) regardless of the testing direction.[1]

Regarding anterolateral PTFJ instability, this study found that both single- and double-device fixation techniques effectively restored not only the joint strength and stability at small physiological joint motion but also the strength at displacement (ie, 5 mm, defined as clinical failure). A previous study also found that single BCSD fixation restored PTFJ anterolateral stability to normal even after the interosseous membrane was further injured.[3] These authors also found the tension force (40 N or 50 N) did not have a significant effect. We did not quantify the tension force applied, yet the tension force was assumed to be consistent by having the same surgeon (O.M.R.) perform all our device applications and tensioning. This study was the first to assess the anterolateral strength after BCSD fixation, and the findings support the use of a single BCSD fixation for treating anterolateral instability.

Although a previous study found that the posteromedial stability was restored by a single BCSD fixation, we found that only double-device fixation provides adequate restoration. This difference may be a result of their specimens retaining the whole knee.[3] Knee structures such as the lateral collateral ligament could provide additional stability to the PTFJ. In the context of this previous study, the posteromedial loads experienced by the joint are unclear; it is, consequently, unclear whether the single-device technique provides adequate stability and fixation strength needed for posteromedial instability. To the best of our knowledge, the current study was the first to assess the posteromedial strength after BCSD fixation, and the findings support the use of double BCSD fixation for treating posteromedial instability. Given that the failure mechanism was BCSD pulling through cortical bone and there is room in the fibula for 2 devices, our standard practice has been to use 2 devices. The findings from this study support this technique, as it produces the most stable construct and addresses both forms of PTFJ instability.

The device placement and the number of devices used can affect the restoration of PTFJ anterolateral stability according to a finite element study.[15] Pessoa et al[12] adopted a horizontal placement (fibular entry point 3 and tibial exit point 4 in Figure 3), ensuring that the center of the joint articulation was on the device's path. This study adopted a slightly superior-oriented placement with the same tibial exit point but a slightly inferior (distal) entry point on the fibular head. Although both placements restore anterolateral stability, the superior tilting provides additional anterolateral stability.[15] Using 2 devices is expected to provide additional stability and strength; this is especially valid for posteromedial strength. The double-device repair used in this study did not simply add one more device. The tracking was different between them, and both devices pointed inferiorly with more distal exit points compared with the single-device placement (Figure 3). The inferior orientation may partially explain why the double-device fixation did not provide additional anterolateral stability and strength.[15]

Although the BCSD fixation can restore PTFJ strength and stability to near-native states, caution may still be warranted in employing aggressive rehabilitation. This study found that 75% of the constructs failed via button(s) pulling through or into the tunnel of the fibular head under severe joint displacement (>5 mm), which constitutes clinical failure. At our institution, we routinely employ 2 devices for either form of instability as a safety measure.

There are limitations associated with this study. The sample size was relatively small, approximately 5 per repair subgroup, after accounting for the direction of instability and the number of devices. A larger sample size would strengthen the comparisons made in this study. When simulating ligament injury, we resected both the anterior and the posterior ligaments as opposed to 1 individually to simulate a worst-case scenario.[12] The femur was not left intact because the goal of this study was to address PTFJ instability directly rather than the effect of PTFJ instability on knee biomechanics.[2] As this was a cadaveric study, time-zero stability and strength of repair were investigated; the long-term behaviors of the repair, such as potential device creep and ligament healing, were not considered. Future clinical studies are needed to enhance the findings of this study.

CONCLUSION

Within the limitations of this biomechanical cadaveric model, both the single- and the double-device techniques effectively restored anterolateral stability and strength to the native joint level; only the double-device technique effectively restored posteromedial stability and strength to the native joint level.

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