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Locking Plate Fixation in a Series of Bicondylar Tibial Plateau Fractures Raises Treatment Costs Without Clinical Benefit

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Abstract

Objectives: To compare outcomes and costs between locking and nonlocking constructs in the treatment of bicondylar tibial plateau (BTP) fractures.

Design: Retrospective cohort study.

Setting: Level 1 academic trauma center.

Patients: All patients that presented with complete articular, BTP fractures (AO/OTA 41-C and Schatzker 6) between 2013-2015 were screened (n=112). Patients treated with a mode of fixation other than plate-and-screw were excluded. 56 patients with a minimum follow-up of 12 months were included in the analysis.

Intervention: Operative fixation of BTP fractures with locking (n=29) or nonlocking (n=27) implants.

Main outcome measurements: Implant cost, patient reported outcomes (PROMIS physical function and pain interference), clinical, and radiographic outcomes.

Results: There were no differences between the two groups with respect to demographics, injury characteristics, radiographic outcomes (change in alignment) or clinical outcomes (PROMIS, reoperation, nonunion, infection). Implant costs were significantly greater in the locking group compared to the nonlocking group (mean L \$4453; mean NL \$2569; $p<0.01$).

Conclusions: This study demonstrated improved value of treatment (less cost with no difference in clinical outcome) with nonlocking implants for bicondylar tibial plateau fractures when dual plate fixation strategies are performed.

Level of Evidence: Therapeutic III. See Instructions for Authors for a complete description of levels of evidence.

Keywords**:** tibial plateau fracture; locking implants; cost analysis; dual plate fixation; value of treatment

INTRODUCTION:

Bicondylar tibial plateau (BTP) fractures are often associated with severe osseous and soft tissue components of injury. Goals of operative treatment include articular reduction, restoration of alignment, and stable fixation. Literature from over twenty years ago described high rates of wound complications with open treatment, often through a single anterior incision, leading to unsatisfactory results. [1-4] Modern techniques that focus on less invasive approaches and minimizing soft tissue insult have reduced complication rates. [5]

Adjunctive medial plates are most commonly used in bicondylar proximal tibia fractures (1) to buttress previously depressed medial or posteromedial articular fragments and (2) to enhance stability of the medial metadiaphysis in an effort to maintain coronal alignment and resist varus. [5-7] Conventional dual plating of the proximal tibia offers the biomechanical advantage of buttressing both columns of the fracture. Lateral locked plating has gained momentum over the last decade as a less invasive construct with the potential to maintain alignment and resist varus collapse with similar efficacy as dual plating. However, biomechanical and clinical studies have reported conflicting results on the ability of a lateral locked plate to maintain appropriate alignment. [7-16]

There is ongoing debate on whether modern two-incision approaches lead to a higher rate of infectious complications than single lateral incision approaches. [5,9,12] There is also conflicting evidence surrounding the rate of coronal malalignment when lateral locked plating is performed in comparison to dual plating strategies. [6,9,12-17] As these fixation strategies have evolved, the use of precontoured proximal tibia locking plates has become commonplace, even including scenarios other than lateral locked plating to avoid dual plating. Most implant vendors offer medial and lateral locking plate options, but studies supporting clinical benefit to routine use of this more expensive technology are lacking. When a surgeon intends to use a dual plate construct for any reason, there are no data to suggest that locking implants convey clinical benefit compared to nonlocking implants.

There have been no investigations examining the difference in value (outcome:cost ratio) between locking and nonlocking proximal tibia implants in the treatment of BTP fractures. The objective of this study was to compare outcomes and costs between locking and nonlocking constructs in the treatment of BTP fractures. We hypothesize locking implants increase cost without affecting clinical outcomes.

MATERIALS and METHODS:

Following institutional review board approval, we performed a retrospective investigation of all complete articular, bicondylar tibial plateau fractures (AO/OTA 41-C and Schatzker VI) treated surgically at a Level 1 trauma center from 2013 through 2015. One of six fellowship-trained orthopaedic trauma surgeons performed all surgeries.

Exclusion criteria were age <18 years, pathologic fracture, ipsilateral tibial shaft fracture, treatment with any mode of fixation other than plate-and-screw, and follow-up less than twelve months. Demographic data, comorbidities, concomitant injuries, fracture characteristics, and clinical follow-up data were collected through electronic chart review.

Sequential radiographs from injury to final follow-up were reviewed by 2 fellowship-trained orthopaedic trauma surgeons to evaluate healing and alignment. Injuries were classified according to AO/OTA and Schatzker classification systems. [18,19] The following fracture and surgery characteristics were recorded: type of implant utilized (locking, nonlocking, lateral, medial), coronal alignment (normal medial proximal tibia angle 87 degrees), and sagittal alignment (normal posterior proximal tibia angle 81 degrees). Union was defined by surgeon documentation and confirmation of radiographic healing by independent review. Nonunion was defined by additional procedures (bone grafting, nonunion repair) undertaken to promote healing and/or absence of radiographic healing at six months postoperatively.

The primary outcome was treatment cost of locking (L) versus nonlocking (NL) implants. Implant costs were calculated using intraoperative inventory software and accuracy was confirmed with radiograph review. Any patient who had at least one locking plate and any number of locking screws implanted was included in the locking plate group. Secondary outcomes included union, reoperation, superficial infection (treated with oral antibiotics and local wound care), deep infection (requiring surgical debridement), post-traumatic arthritis, and PROMIS (Patient-Reported Outcomes Measurement Information System) physical function (PF) and pain interference (PI) scores.

Surgical management and implant choice was selected at the discretion of the treating surgeon. A standard anterolateral approach to the proximal tibia, with or without a posteromedial approach, was performed in all cases. Postoperatively, all patients were initially made touch-down weight-bearing. Patients were allowed to progressively weight-bear between 6 and 12 weeks postoperatively when the treating surgeon deemed appropriate based on clinical and radiographic evidence of healing.

Student's t-test and Fisher’s exact test were utilized in the analyses to compare the groups. A p-value of < 0.05 was considered statistically significant.

RESULTS:

Query of our institution’s billing database yielded 112 BTP fractures treated from 2013-2015. Ten patients were excluded due to use of implants other than plate-and-screw (six intramedullary nail and four ring fixator). Two patients underwent below knee amputation for a mangled extremity. Following application of exclusion criteria, 29 patients in the L group and 27 patients in the NL group had greater than 12 months clinical follow-up with functional outcome measures and were included in the analysis. There was no difference in implant usage in the 44 patients excluded for clinical follow-up less than 12 months (20 locking, 24 nonlocking). Mean follow-up was 24.3 months (range 12-41 months). There were no differences in patient demographics and comorbidities between the groups. (Table 1) The groups were similar in terms of injury characteristics including fracture classification, Injury Severity Score (ISS), open fracture, compartment syndrome, operative time, and use of bone graft or substitute. (Table 2) Twenty-nine (49%) patients had staged ORIF with previous spanning external fixator to stabilize the injury while soft tissue swelling improved. Greater than 95% of fractures in the cohort were complex complete articular fractures classified as AO/OTA 41-C3. Adjunctive medial plate fixation was utilized in 85% of fractures in the NL group and 62% of fractures in the L group. The nonlocking group had pre-contoured plates utilized in 21 of 27 cases and standard small fragment limited contact dynamic compression plates and recon plates were used in the remainder of the cases.

Implant costs were 73% higher in the locking group compared to the nonlocking group (mean L $4453; mean NL $2569; $p<0.01$). (Table 3) Functional outcomes as measured by PROMIS were similar between the groups. (Table 4) No difference was detected among clinical outcomes including superficial infection, deep infection, nonunion, malunion, reoperation, or post-traumatic arthritis between groups. (Table 4)

There were 11 reoperations in the L group and 6 in the NL group ($p=0.25$). Reoperations In the L group consisted of: surgical debridement for deep infection (n=5); aseptic nonunion repair (n=2), implant removal (n=3); total knee arthroplasty for post-traumatic arthritis (n=1). Reoperations in the NL group were comprised of: surgical debridement for deep infection (n=3); wound revision and skin grafting for superficial wound necrosis (n=2); total knee arthroplasty for post-traumatic arthritis (n=1). All deep infections went on to union and were infection free at the time of data collection.

DISCUSSION:

Lateral locked plating of BTP fractures has been shown in several studies to be effective in maintaining alignment, thus obviating the need for a medial incision and additional implant fixation. [9,12,14,15] However, several studies have shown lateral locked plating to be ineffective in stabilizing the posteromedial fracture fragment, which is present in up to 50% of BTP fractures. [5-7] Due to variable results in multiple studies, there is no definitive evidence that locking constructs are beneficial in the treatment of BTP fractures. Researchers have focused efforts on investigating whether isolated lateral locked plating can adequately substitute for dual plating. This is the first investigation comparing costs and clinical outcomes of locking versus nonlocking plate constructs independent of plate configuration. This investigation does not attempt to resolve the controversy of dual plate fixation compared to one-incision lateral locked plating for high-energy BTP fractures. It is possible that avoiding a second incision and the associated morbidity and OR time could increase value of treatment with lateral locked plating. However, our results suggest that when a medial plate is used for any reason in the treatment of BTP fractures, there is improved value of treatment (less cost without affecting clinical outcomes) with use of a nonlocking lateral construct as opposed to locking implants.

As stated above, literature review on this topic yields multiple biomechanical and clinical studies comparing lateral locked plating to dual plating that fail to answer the question of whether locked plating in general is beneficial for BTP fractures. There is conflicting published biomechanical evidence addressing the ability of a lateral locked plate to maintain appropriate alignment. [7-11] Two biomechanical studies of BTP fixation in cyclically loaded cadaveric models demonstrated less medial subsidence and inferior displacement with conventional dual plating compared to lateral locked plating. [8,9] Yoo, et al. demonstrated in a biomechanical model of BTP fractures with a posteromedial fragment that nonlocked dual plating was superior to lateral locked plating in resisting displacement. [7] In contrast, two other biomechanical analyses found no difference between lateral locked plates and conventional dual plating with respect to medial displacement. [10,11]

Similarly, there are conflicting clinical studies with respect to clinical and radiographic outcomes comparing dual plate fixation to lateral locking plates in the treatment of BTP fractures. Classic articles reporting high rates of infection with use of dual plates through an anterior incision are not currently applicable as soft tissue handling techniques have evolved. [1-4] Barei, et al. reported an 8.6% incidence of deep infection in AO/OTA 41-C3 BTP fractures through utilization of a two-incision approach with a focus on soft tissue preservation. [5]

Several studies have demonstrated no difference in alignment and malunion with lateral locked plating compared to dual plate fixation. [9,12,14,15] In a prospective study of 85 patients with BTP fractures, Yao, et al. reported no difference in final alignment when comparing treatment with a lateral locking plate versus dual nonlocking plates. [12] However, they excluded patients with a posteromedial fragment or medial comminution, thus limiting extrapolation of their results to more severe BTP fractures such as those included in this and other studies. [12] Separate investigations have reported higher rates of malalignment with lateral locking plates. [13,16,17] Gosling, et al. found a 26% rate of malreduction with use of a less-invasive locking plate, and Neogi, et al. reported 17% loss of alignment in the postoperative period with lateral locking plates in comparison to a 0% loss of alignment with dual plate fixation. [16,17] Jiang et al. prospectively compared 84 patients with BTP fractures and found a higher rate of malalignment in patients treated with a less-invasive lateral locking plate (15%) compared to those treated with traditional dual plates (2%). [13]

In this investigation, we found no difference among clinical and radiographic outcomes between the L and NL groups. (Table 3) Collectively, this study proposes there may be improved value with usage of nonlocking implants for BTP fractures when dual plate fixation is undertaken.

The difference in mean and median implant costs between the groups was $1884 and $1527, respectively. This amount may not initially appear to be a substantial percentage of overall hospitalization cost, however an in-depth look at modifiable expenses may suggest otherwise. A recent hospital revenue analysis of fracture care outlined major contributors to cost during an orthpaedic trauma patient’s inpatient stay. [20] Mean cost of inpatient care in the study was $21,200, which was comprised of direct variable expenses ($14,900; modifiable) and direct fixed expenses ($6,300; non-modifiable). [20] The second largest component of direct variable expenses was supplies, primarily attributable to orthopaedic implants, at a cost of $3800 (25% of direct variable expenses). [20] Although these exact costs cannot be extrapolated to a different trauma center, it demonstrates that significant cost saving measures can be undertaken by appropriate utilization of fracture implants.

When locking implants are deemed necessary by the treating surgeon, an alternative cost savings measure involves use of generic implants. McPhillamy, et al. demonstrated marked reduction in implant expenditures through utilization of generic locking implants without a compromise in clinical outcomes. [21]

Pre-contoured nonlocking proximal tibia plates were used in 78% of the cases in the NL group at our institution but this specific implant is not available at many institutions. Pre-contoured nonlocking plates were 76% of the cost of its locking counterpart. Accordingly, 86% of the cost savings realized at our institution was from locking screws and only 14% of savings came from the net difference between plates.

This investigation has several limitations. The retrospective nature of the study may lead to selection bias. The two groups were fairly well matched with respect to demographics, comorbidities, and characteristics of injury. (Tables 1 and 2) Ninety-six per-cent of the fractures included in the analysis were AO/OTA 41-C3. However, it is possible that the higher rate of initial external fixation (62% vs. 37%, p=0.11) and reoperation (38% vs. 22%, p=0.25) in the L group compared to the NL group, although not significantly different, may signify a greater degree of injury severity in patients that received locking implants. The limited number of patients studied increases the likelihood of type II error with respect to the clinical outcomes analysis. Although only fifty-six patients were included in the analysis, the homogenous nature of the injury studied may be considered a strength of the study. Osteoporosis and osteopenia are also considered relative indications for choosing locking implants in fracture surgery. Only three patients had underlying osteopenia in this study, and these results cannot be extrapolated to this unique population. Finally, to truly assess value, all the variables that account for quality of care and service would have to be included in the numerator, and all costs would have to be incorporated into the denominator. Technically, we are only estimating value as the ratio of final clinical outcomes to implant cost. Incorporation of additional factors may have led to different results including operative time and resource utilization.

CONCLUSIONS:

Although there have been significant advances in implant technology, benefits of locking implants remain unclear. This investigation found no clinical benefit to the use of locking implants in complete articular BTP fractures with a substantially larger cost incurred. This demonstrates improved value of treatment with nonlocking implants when dual plate fixation strategies are considered. Prospective studies may better define the clinical utility of locking implants in the proximal tibia.

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TABLE LEGENDS:

Table 1. Patient demographics and comorbidities.

Table 2. Injury and surgical characteristics.

Table 3. Cost comparison of locking and nonlocking implants.

Table 4. Clinical and radiographic outcomes.

Table 1. Patient demographics and comorbidities.

	Locking group (n=29)	Nonlocking group (n=27)	p-value
Age (mean)	51	49	0.61
Sex (M:F)	17:12	17:10	0.79
BMI (mean)	30	31	0.63
Smoker (%)	52	33	0.19
Diabetes (%)	21	19	1.00
Osteopenia (%)	7	4	1.00

Table 2. Injury and surgical characteristics.

	Locking group (n=29)	Nonlocking group (n=27)	p-value
OTA 41-C1/2 (%)	0	7	0.23
OTA 41-C3 (%)	100	93	
Injury Severity Score (mean)	9.1	8.3	0.67
Open fracture (%)	10	3	0.61
External fixation (%)	62%	37%	0.11
Compartment syndrome (%)	31	15	0.21
Operative time (mins)	210	182	0.25
Use of bone graft/void filler (%)	55	67	0.12
Adjunctive medial plate (%)	62	85	0.07

Table 3. Cost comparison of locking and nonlocking implants.

	Locking group (n=29)	**Nonlocking group (n=27)**	**p-value**
Mean implant cost (S.D.) (U.S. dollars)	4453 (2101)	2569 (957)	<0.01
Median implant cost (U.S. dollars)	3972	2445	

Table 4. Clinical and radiographic outcomes.

	Locking group (n=29)	Nonlocking group (n=27)	p-value
Reoperation (%)	38	22	0.25
Nonunion (%)	10	7	1.00
Superficial infection (%)	21	19	1.00
Deep infection (%)	17	11	0.71
Change in alignment >5 deg (%)	14	15	1.00
Post-traumatic arthritis (%)	14	15	1.00
PROMIS Physical Function	39	41	0.31
PROMIS Pain Interference	60	57	0.34