

Factors affecting stability after medial opening wedge high tibial osteotomy using locking plate: A cadaveric study

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ABSTRACT

Objectives: To investigate the effect of screw length, lateral hinge fracture, and gap filling on stability after medial opening wedge high tibial osteotomy (MOW HTO) using a locking plate.

Methods: Forty tibiae from fresh-frozen cadavers were randomly allocated into five groups. Group A was bicortically fixated, while Group B and Group C were unicortically fixated: 90% and 55% of drilled tunnel length, respectively. Group D was fixated using 90% length screws with a fractured lateral hinge. Group E was fixated using 90% length screws with gap filling using a bone substitute. Operated tibiae were tested under axial compressive load using a material testing machine. The medial gap changes under the serial axial load of 100–600 N and ultimate failure load were measured.

Results: Group D showed the biggest medial gap change and lowest failure load, while Group E presented the smallest gap change and highest failure load. The medial gap changes tended to increase with shorter screw length, but the difference was not significant between Groups A, B, and C. Group C and Group D showed greater medial gap change and lower failure load compared with Group E, while not differing from Group A and Group B.

Conclusions: Unicortical fixation in proximal screw holes of a locking plate was not inferior to bicortical fixation regarding axial stability in MOW HTO, although proximal screws that are too short should be avoided. Lateral hinge fracture decreased, while gap filling with bone substitute increased axial stability.

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1. Introduction

High tibial osteotomy (HTO) is an established surgical treatment for young, active patients with medial compartment osteoarthritis of the knee and varus deformity [1,2]. It is most often performed by either lateral closing wedge (LCW) or medial opening wedge (MOW) HTO [3,4]. Historically, LCW HTO is more popular, as direct bone-to-bone contact of LCW HTO is advantageous in earlier bone healing and allows earlier weight bearing compared with medial opening wedge (MOW) HTO, which creates a bony gap and frequently requires a bone graft or void filling [3,5]. To prevent correction loss and nonunion of the osteotomy site after MOW HTO, sufficient stability should be provided by the fixation device. Since the introduction of the locking plate system, which provides satisfactory mechanical stability [6,7], MOW HTO has been gaining popularity [4]. As optimal fixation is a prerequisite for favorable outcomes of MOW HTO, development of new superior implants is ongoing, especially focusing on biomechanical fixation strength [8–14].

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However, several factors may affect stability after MOW HTO using a locking plate, such as screw length [15], lateral hinge integrity [16–18], and gap filling [19–24]. While many biomechanical studies of HTO have compared the stability of different fixation devices [8–10,12–14,25,26], there is limited evidence regarding these specific issues in a same plate system. Owing to concerns of neurovascular injury, many surgeons prefer unicortical fixation on the proximal screw holes of the locking plate [27]. In several biomechanical studies, the proximal screws were bicortically fixed [10,13,20], while others did not comment on the length of the screws [14]. One study reported superior stability of bicortical fixation in a bicondylar tibial fracture model [15], so it is uncertain whether the unicortical fixation of proximal screws provides sufficient biomechanical strength in MOW HTO. In addition, unintended opposite-side cortical fractures of the lateral hinge may occur during MOW HTO [16,28–31]. Several clinical studies have reported the risk of lateral cortex fracture and correction loss, delayed union or nonunion, and reoperation [16–18]; however, the biomechanical effect of a lateral hinge fracture is rarely reported [32]. There is controversy regarding osteotomy gap management: leaving vacant or filling the defect with autograft, allograft or bone substitute [19,33,34]. However, the effect of bone substitute on initial axial stability has not been sufficiently investigated [20].

This study investigated the effect of screw length, lateral hinge fracture, and gap filling on stability after medial opening wedge high tibial osteotomy using a locking plate. It was hypothesized that unicortical fixation using 90% length of tunnel length would not be inferior to bicortical fixation, while screws that are too short (55% of drilled tunnel length) would provide unsatisfactory axial stability. It was also hypothesized that a lateral hinge fracture would reduce mechanical stability, whereas gap filling with bone substitute would reinforce it.

2. Material and Methods

2.1. Study design and specimen selection

This was an in vitro cadaver study. Ethics Committee approval was waived by the Institutional Review Board because it did not involve human subjects. Initially, 25 cadavers were assessed for eligibility. Computer tomography scans were performed on the proximal tibiae of all cadavers to screen for osteoporotic bones, as bone density may significantly affect mechanical strength. As the Hounsfield unit (HU) is a good indicator of bone density, the HU of the region of interest (ROI) in the trabecular region of the proximal tibiae was measured [35,36]. Four cadavers were excluded because the HU values of the trabecular region of the proximal tibiae were <50HU, far less than the cut-off value of lumbar spine or humeral head osteoporosis [35]. Forty tibiae from 21 fresh-frozen cadavers were harvested without fibulae and soft tissues attached. Two knees were excluded as they were replaced with implants, leaving 40 tibiae for the final experiment.

2.2. Experimental groups

The harvested tibiae were randomly allocated into five groups using a computer-generated randomization table. A single surgeon performed all surgical procedures. The MOW HTO was performed with uniplanar osteotomy and fixated using a locking plate (Tomofix®, DePuy Synthes, West Chester, PA, USA) and 5.0-mm self-tapping locking screws. The osteotomy started from the medial metaphysis, 4 cm below the joint line, and progressed obliquely to the upper point of proximal tibiofibular joint approximately 1.5 cm below the joint line. All of the opened medial gaps were targeted at 10 mm and maintained using a laminar spreader until the final fixation. The locking plate was applied to the best fitting position of the medial proximal tibia, typically one centimeter below the plateau. All screw holes were drilled full length to penetrate the far cortex using a locking drill sleeve, and the drilled tunnel length was measured. There was no between-group difference in the demographics, tibial plateau size, and drilled tunnel length (Table 1).

The five groups were treated differently in terms of length of proximal screws, integrity of lateral hinge (intact or fracture), and gap filling with bone substitute (Table 1). Group A was bicortically fixated without gap filling, while Group B and Group C were fixated using shorter screws without gap filling: 90% and 55% of drilled tunnel length, respectively (Figure 1 A). Group B was defined as the standard group, representing the most typical clinical setting. Group D was fixated using 90% length-screws without gap filling, while the lateral hinge was fractured (Figure 2A). Plate fixation was performed while the fractured lateral hinge was tightened using two towel clips (Figure 2B). The lateral hinge was intact in the other groups. Group E was fixated

Table 1
Demographics and group treatments.

Group	A	B	C	D	E	P
<i>Demographics</i>						
Age, years	71.0 (7.3)	72.0 (4.9)	74.3 (5.0)	75.3 (5.8)	75.3 (5.7)	0.312
Sex, men	7 (88%)	6 (75%)	5 (63%)	6 (75%)	5 (63%)	0.926
Side, right	3 (38%)	5 (63%)	3 (38%)	5 (63%)	4 (50%)	0.832
<i>Group treatments</i>						
Proximal screw length/drilled tunnel length	>100%	90%	55%	90%	90%	
Lateral hinge	Intact	Intact	Intact	Fracture	Intact	
Gap filling	No	No	No	No	Yes	

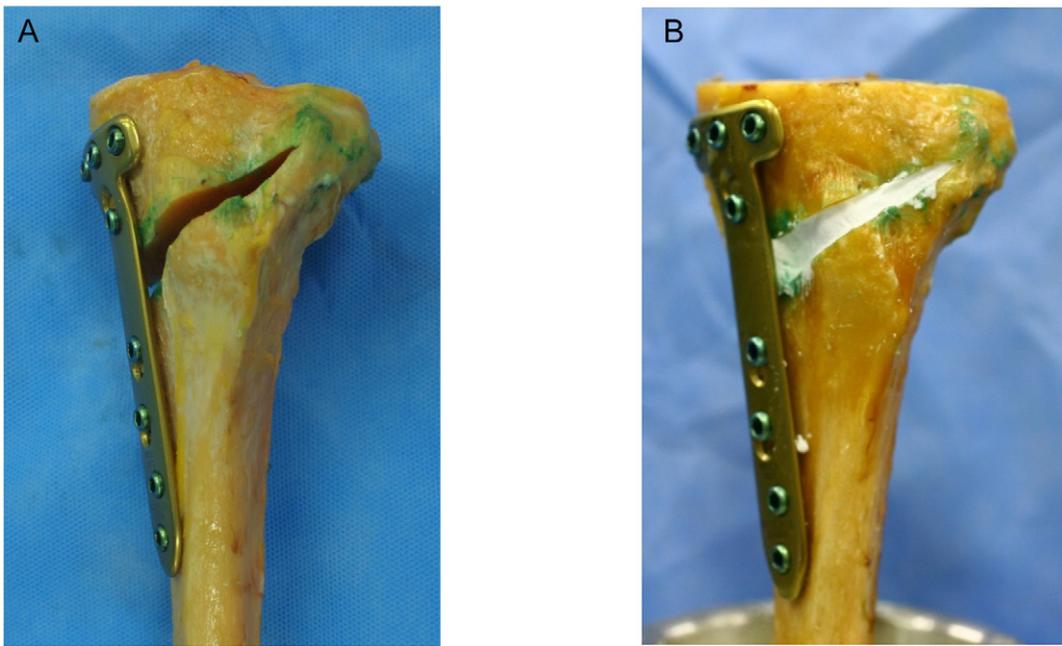


Figure 1. Operated tibia without gap filling (A), or with gap filling using bone substitute (B).

using 90% length screws with gap filling using bone substitute (geneX®; Biocomposites Ltd., Staffordshire, UK) (Figure 1B). The bone substitute contains β -tricalcium phosphate and calcium sulphate in a weight ratio of 1:1 [37]. The distal screws were bicortically fixated, except the most distal screw that was unicortically fixated with an identical length of 20 mm.

The hypotheses of this study were addressed by comparing each group with Group B, the standard group: effect of the screw length (B vs. A, C), lateral hinge fracture (B vs. D), and gap filling with bone substitute (B vs. E).

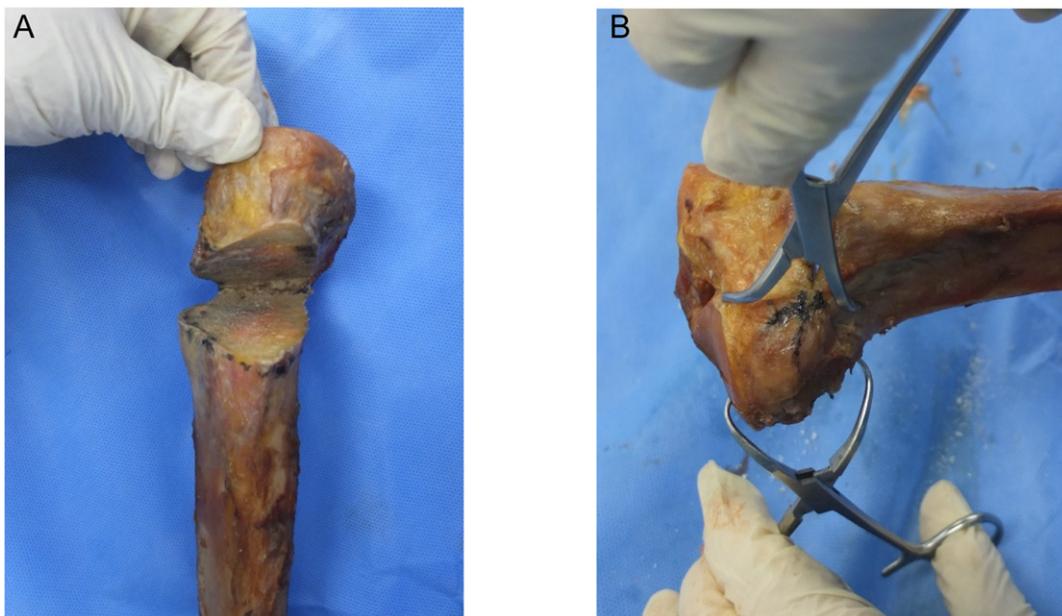


Figure 2. The complete osteotomy was performed in Group D to mimic the lateral hinge fracture (A). Plate fixation was performed while the fractured lateral hinge was tightened using two towel clips (B).

2.3. Biomechanical test setup

The distal portion of the tibiae was molded in a cylindrical metal bowl using polymethyl methacrylate (PMMA) and consolidated for 12 h in room air. The upper surface of the tibial plateau was flattened for full surface contact with a custom-made upper jig during the following biomechanical test. After solid consolidation was completed, the specimens were stored at -20°C until required and thawed at room temperature for 24 h before the experiments.

Biomechanical tests were performed using the Instron® universal test machine (model No. 5567, Instron, MA, USA), which has a position accuracy of 0.02 mm and a loading accuracy of 0.1 N. The cylindrical stainless bowl in which the specimens were embedded was mounted on the Instron™ universal test machine, and the custom-made upper jig was applied to the flattened upper surface of the tibiae. The compression loading axis was targeted to the center of the anteroposterior dimension and 62% of the mediolateral width of the tibial plateau (medial end 0% and lateral end 100%) with vertical direction to the ground in all specimens [27,38].

2.4. Biomechanical test protocol

Each specimen was subjected to three steps of biomechanical tests. First, cyclic loading tests were conducted with low loads of 10–200 N as preconditioning (Figure 3). After 60 cycles of loading, any failure during the cyclic loading test was recorded. Second, medial gap change was measured under serial axial compression loads of 100 N, 200 N, 300 N, 400 N, 500 N and 600 N, using an electronic internal caliper gauge (Model No. 54-554-622, Fowler Co., Newton, MA, USA) with a resolution of 0.0127 mm and accuracy of 0.02032 mm (Figure 4). Third, a load to failure test was applied by increasing the axial compression force. The ultimate failure load, defined as the point at which the first reduction in loading occurs in the load–displacement curve (Figure 5), and the mode of failure were recorded. The testing machine was operated at a constant speed of 20 mm/minutes for all tests.

2.5. Statistical analysis

All statistical analyses were performed using SPSS (IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY, USA). Null hypotheses of no difference were rejected if P -values were < 0.05 . Medial gap change under serial axial load, ultimate failure load, and mode of failure were compared. Inter-group differences were tested using Kruskal-Wallis test with post-hoc tests using Mann-Whitney U test for the continuous variables, and the McNemar's test for the categorical variables.

3. Results

3.1. Cyclic loading test

All specimens in each group tolerated 60 cycles of axial cyclic loading of 10–200 N without failure. Therefore, all specimens were subjected to the following steps of biomechanical tests.

3.2. Medial gap change under serial axial load

The medial gap changes increased as the axial load increased, and the gap in Group E changed the least among the five groups (Figure 6). In the post-hoc test, the Group E medial gap changed less than every other group under 300 N, 400 N, 500 N, and 600

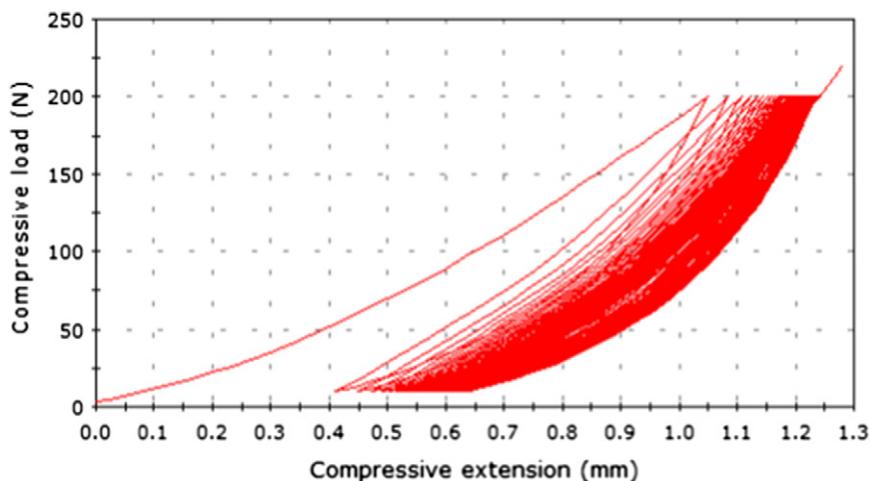


Figure 3. Change of specimen length after cyclic load test.

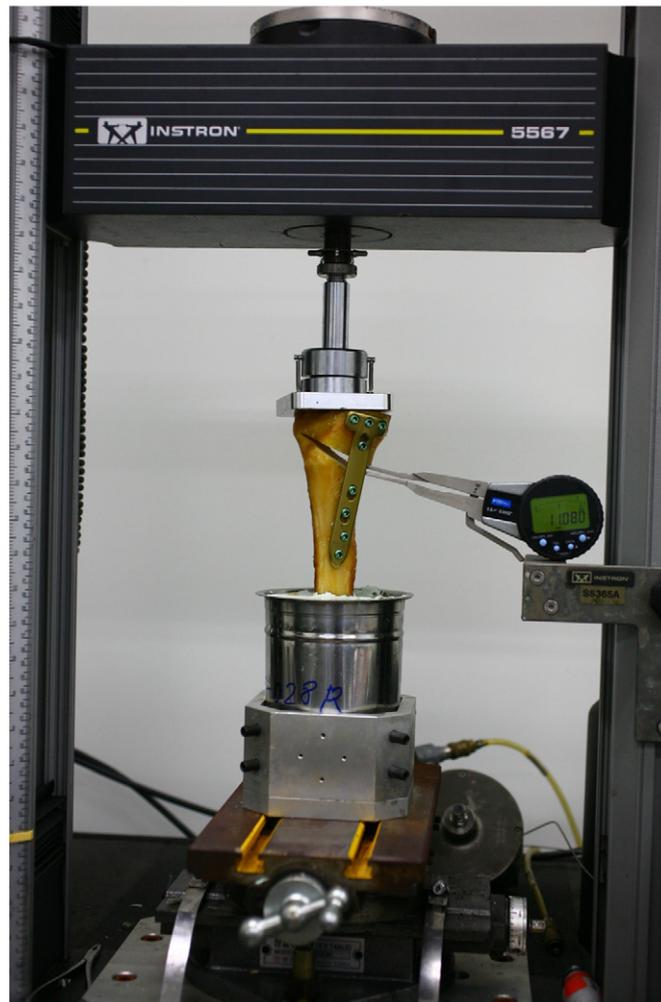


Figure 4. Biomechanical test setup for the medial gap measurement under serial axial compression load.

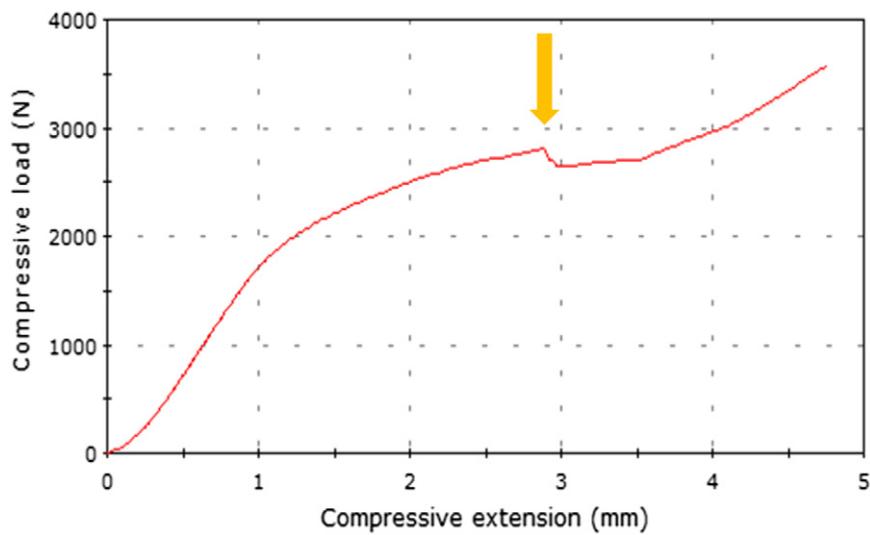


Figure 5. Ultimate failure load, which was defined as the point at which the first reduction in loading occurs in the load–displacement curve (yellow arrow).

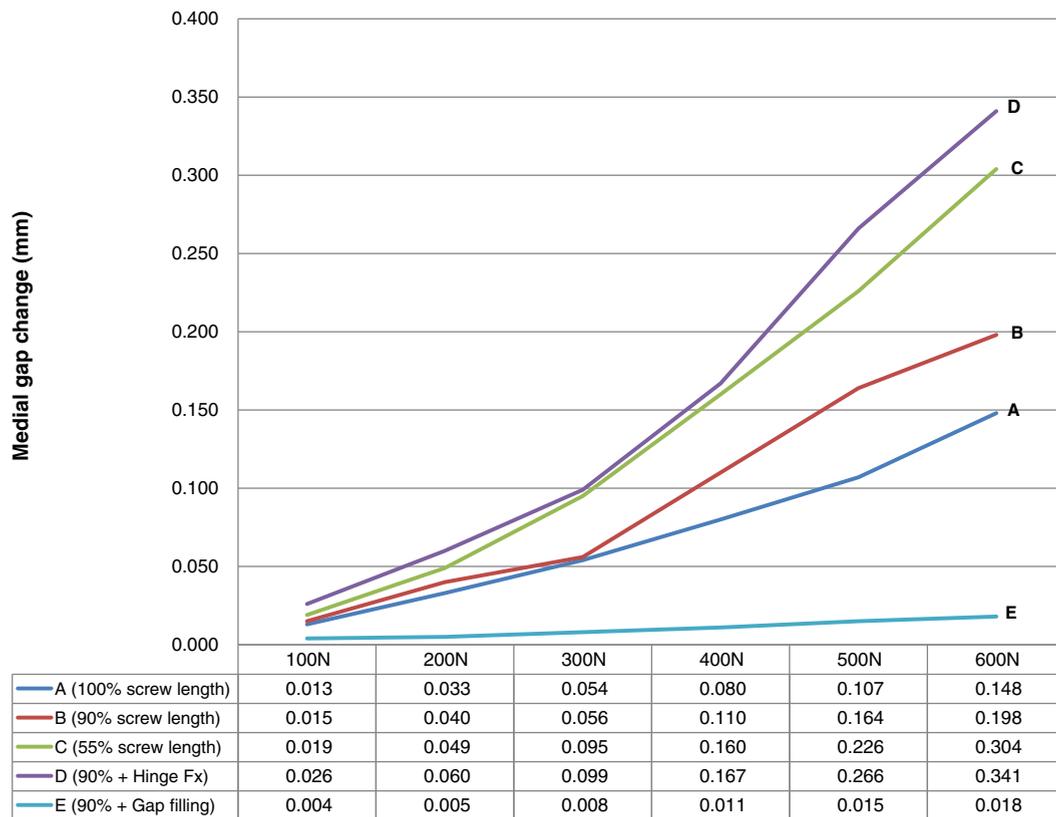


Figure 6. Serial medial gap changes according to axial load.

N. Group C and Group D gap changes were greater than Group E, even under lower loading: 100 N, 200 N and 300 N for Group C; 200 N and 300 N for Group D. There was no difference in the medial gap change between other group pairs.

3.3. Load to failure test

The failure load was highest in Group E among the five groups ($P = 0.027$) (Figure 7). In the post-hoc test, the failure load of Group E was higher than that of Group C (3005 N vs. 1862 N, $P = 0.003$) and Group D (3005 N vs. 1697 N, $P = 0.001$). There was no difference in comparison of all other pairs of groups. Interestingly, Group A showed lower failure load than Group B, but the difference was not significant (2032 N vs. 2275 N, $P = 1.000$).

3.4. Mode of failure

All failures during the load to failure test under axial compression load resulted in fracture at the lateral cortex, with the fracture line extended distally to the tibiofibular joint, like a type II lateral hinge fracture according to the Takeuchi classification (Figure 8) [16]. One specimen developed a fracture that reached both the lateral plateau and distal portion of the proximal tibiofibular joint. There was no failure of the plate or screws.

4. Discussion

The major findings of this study were that unicortical fixation using 90% length screws in the proximal screw holes was not inferior to bicortical fixation in MOW HTO, while screws that are too short weakened the mechanical strength. Lateral hinge fracture reduced mechanical stability, while gap filling with bone substitute could provide additional axial stability. These findings partially support the hypothesis that unicortical fixation using screws of 90% length of tunnel length is not inferior to bicortical fixation, and too short (55% length of the tunnel) screw fixation weakens the mechanical stability after MOW HTO using a locking plate. Although there was a tendency that bicortical fixation (Group A) reported less medial gap change than unicortical fixation using 90% length screws (Group B), the difference was not significant at any axial load from 0 to 600 N.

Interestingly, the mean of ultimate failure load was greater in Group B by 243 N than Group A, with no statistical significance. The peak axial load in the tibiofemoral joint during level walking is reported at about three times body weight [39–41]. As both groups showed ultimate failure load over 2000 N, a corresponding load in a person with 70 kg of body weight during walking, the

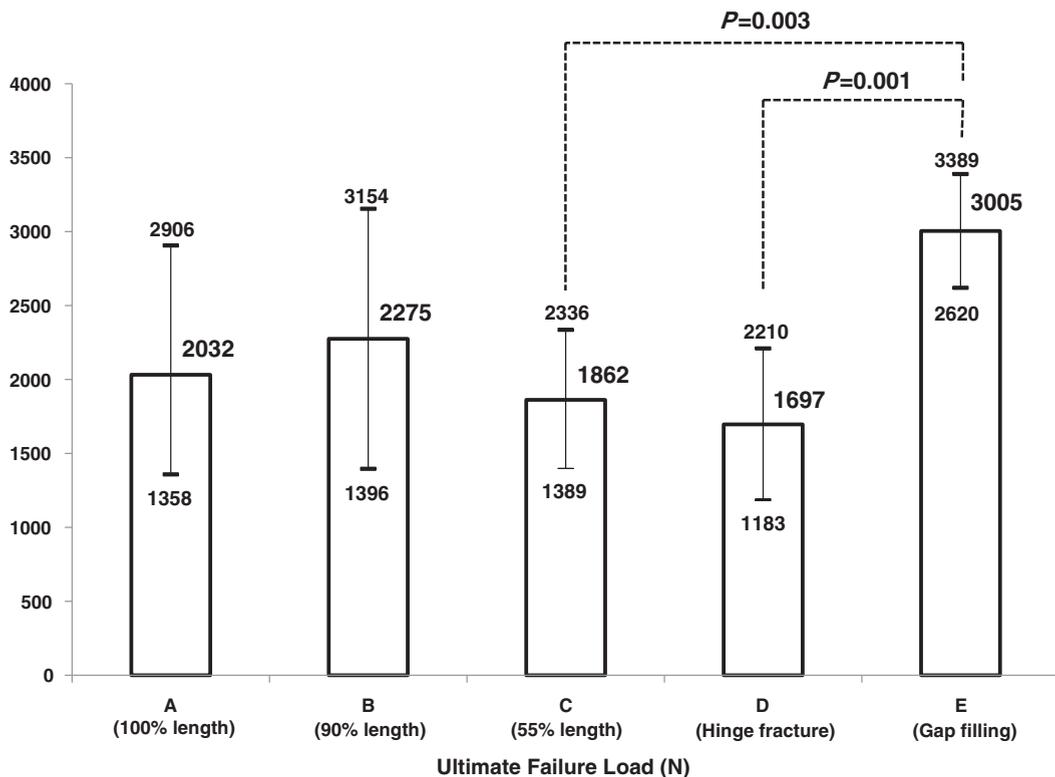


Figure 7. Ultimate failure loads are presented as mean values with 95% confidence intervals.

initial axial stability of the groups seemed to suffice for the majority of patients undergoing HTO. The current findings suggest that unicortical fixation is not inferior to bicortical fixation if the screw length is >90% of the tunnel length. As the far cortex of the proximal tibia is thin and the sense of drilling through the far cortex may be subtle, surgeons have to be concerned about possible neurovascular injuries when making a full length of drill hole for bicortical fixation [27]. Therefore, it is not recommended to try to insert the proximal screws bicortically, risking neurovascular injury during the drilling, for the sake of clinically insignificant additional stability compared with unicortical fixation with screws of sufficient length. Unicortical fixation for the proximal screws of a locking plate system is preferred in clinical practice and recommended in the manual provided by the manufacturer [10]. Biomechanical studies have performed bicortical fixation or not defined the fixation method of proximal screws [10,13,14,20]. Bicortical fixation has been reported to be superior to unicortical screw placement in an unstable proximal tibial bicondylar fracture model [15]. However, the unstable bicondylar fracture model is substantially different from high tibial osteotomy, as evinced by the profoundly low ultimate failure load compared to the current results (476.5 N in bicortical fixation vs. 258.9 N in unicortical fixation) [15]. The current study supports the biomechanical evidence of unicortical fixation in the proximal screw holes of a locking plate during high tibial osteotomy.

Although unicortical fixation with 90% length screws was comparable with bicortical fixation, placement of too short screws seemed to provide unsatisfactory axial stability. Ultimate failure load of Group C (screws with 55% length of drilled holes) was 1862.4 N, which was significantly lower than Group E (the most stable group), whereas Group B was not significantly lower than Group E. Considering the result of this indirect comparison and that the absolute value of failure load is <2000 N, 55% length screw fixation should be avoided. However, the cut-off value of acceptable screw length is neither reported in the literature nor presented in the current study.

The current findings supported the hypothesis that a lateral hinge fracture would diminish mechanical stability. Group D, which produced the lateral hinge fracture, presented greatest medial gap change and lowest ultimate failure load. The harmful effect of a lateral hinge fracture during HTO on the osteotomy site union has been reported in clinical studies [17,18,31,42,43], but there is controversy over the effect of a lateral hinge fracture in MOW HTO. Some researchers reported that they did not observe a lateral hinge fracture to be a risk factor of delayed union or nonunion [11,30], and others reported that additional fixation was rarely needed for union in an undisplaced fracture or certain types of lateral hinge fractures [16,29,31]. In addition, there are few biomechanical studies about lateral hinge fracture. Miller et al. reported that a lateral hinge fracture resulted in a 58% reduction in axial stiffness and a 68% reduction in torsional stiffness compared with control specimens [32], which was similar to Stoffel et al. [14] Although the lateral hinge fracture group showed inferior axial stability in the current study, the difference was not significant compared with Group B, which represented the standard clinical setting, and only significant compared with Group E (gap filling with bone substitute). Moreover, the ultimate failure load reached about 1700 N, which seems to not be very low



Figure 8. The typical mode of failure of the axial compression test. All the causes of failures were lateral cortical fracture with inferior extension (black arrow).

considering the reports of Miller et al. The different result of the two studies may be largely attributed to the locking plate mechanism of the TomoFix® in the current study, which provides angular stability [13,14]. This finding suggests that the clinical situation of lateral hinge fracture can be acceptably managed with cautious and delayed weight bearing, if the osteotomized tibia was fixated using a long, rigid locking plate, in agreement with Stoffel et al. [14]. Several clinical studies found that the TomoFix® plate (DePuy Synthes, West Chester, PA, USA) yielded better clinical outcomes than a short spacer non-locking plate or another type of locking plate for bone union and correction angle maintenance [31,44]. Nevertheless, as a lateral hinge fracture causes decreased stability after MOW HTO, intraoperative and early postoperative caution and clinical suspicion are essential.

When disruption of the lateral cortex is detected, choosing a long, rigid locking plate as the fixation implant is recommended, and rehabilitation protocol modification should be considered [16,29,31,44]. In a specific clinical situation of unstable lateral hinge fracture, such as Takeuchi type II, in which the fracture reaches the distal portion of the proximal tibiofibular joint, additional lateral fixation also should be in the possible list of management options [16,29,32]. However, this study could not completely address whether a lateral hinge fracture should be additionally stabilized on the lateral side or not, along with a medial long rigid locking plate, especially according to the fracture type.

The current findings also support the hypothesis that gap filling with bone substitute would reinforce mechanical stability in MOW HTO, in accordance with the only previous study that presented the mechanical effects of bone substitute in MOW HTO [20]. Group E (gap filling with bone substitute) showed the least medial gap change and highest ultimate failure load among the five study groups. Since the bone substitute was loaded, it shared the stress transmitted through the plate, which explains the findings [20]. However, the effect of bone substitute was not substantial compared with a previous report of about 1.7 times ultimate failure load of the group without void filling (4270 N vs. 2500 N) [20]. Bone substitute increased the ultimate failure load of 972.3 N and 729.3 N compared with Groups A and B, respectively. This difference may have mainly stemmed from the characteristics of the bone substitute. The current study used the geneX®, an injectable bone substitute that contains β -tricalcium phosphate and calcium sulphate, which is different from an earlier study that used β -TCP wedges [20]. Surgeons should be well-informed of the detailed information of the bone substitute they would use in void filling during MOW HTO, especially if the purpose is to provide additional stability.

This study had several limitations to be considered. First, it was an in vitro cadaveric biomechanical study, so caution should be exercised when extrapolating the results to the clinical situation. Second, this study was underpowered to determine the statistical significance of the mean difference of the intra-group measurements. A significant variation in test results was found

between the specimens, even in the same group. This individual variation may have stemmed from the different demographics, such as age and sex, and the bone density of the tibia. Although CT scans were performed to screen the osteoporotic tibiae for specimen preparation, there were larger differences in the test results among the specimens than expected. However, some significant differences were found in several comparisons, along with some marginal *P*-values. Third, the length of the drilled tunnel for screws can be changed according to the plate position. However, a single surgeon performed all procedures and applied the locking plate on the best fitting position on the medial proximal tibia, typically 1 cm below the plateau. There was no between-group difference in the drilled tunnel length of each screw hole. This study was designed based on several biomechanical studies that mostly used synthetic tibial models, not cadaveric specimens. These individual variations may reflect the clinical situation better than the studies of synthetic tibiae with identical mechanical properties. Fourth, lateral hinge fracture of Group D in this study represented type I according to Takeuchi classification [16]. The clinical result of each type of lateral hinge fracture was different, so the mechanical effect of each fracture type may also differ. Fifth, only tibiae were harvested for the experiment, other than the fibula and attached soft tissue. Considering the mode of failure was fracture of the lateral metaphysis or plateau, a fibula may affect the stability, supporting the lateral tibial plateau at the proximal tibiofibular joint. Sixth, the additional mechanical strength provided by a bone substitute is valid only at the time zero point, because it resolves with time. Depending upon the component of the bone substitute, the period that the bone substitute contains mechanical strength may differ. Seventh, the correction gap of osteotomy site was 10 mm in all specimens. Considering that the increased osteotomy angle is directly associated with loss of resistance to axial compression forces [25], greater or less correction than a 10-mm gap would present a different result from the current data. Finally, only axial stability was tested, and other components of mechanical stability such as torsional stability were not addressed. Further studies are warranted to address these limitations.

5. Conclusion

Unicortical fixation using 90% length screws in proximal screw holes of a locking plate was not inferior to bicortical fixation regarding axial stability in MOW HTO; proximal screws that are too short should be avoided. A lateral hinge fracture may cause unsatisfactory stability after MOW HTO, while gap filling with bone substitute can provide additional axial stability. These findings should be considered during MOW HTO to achieve satisfactory stability.

Authors' contributions

YGN conceived of the study, designed the study, performed the surgery on cadavers, and drafted the manuscript. SC participated in the design of the study and performed the surgery on cadavers. DSK participated in the design of the study, performed the surgery on cadavers, conducted the biomechanical experiment and collected data. TKK conceived the study and participated in its design and coordination and helped to draft the manuscript. All authors read and approved the final manuscript.

Declaration of Competing Interest

The authors declare that they have no competing interests.

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Each author certifies that his or her institution has approved the human protocol for this investigation, and that all investigations were conducted in conformity with ethical principles of research.

None of the material contained in the enclosed manuscript has been published or is under consideration for publication elsewhere. In addition, all the contributed authors have agreed to be so listed and have seen and approved the manuscript, its content, and its submission to *The Knee*.

This work was performed at the Joint Reconstruction Center, Seoul National University Bundang Hospital (166 Gumi-ro, Bundang-gu, Seongnam-si, Gyeonggi-do (13620), Republic of Korea).

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