Orthopedic Surgery and
Regeneration

RESEARCH ARTICLE Open Access

A Biomechanical Study of Norian® Calcium Phosphate Bone Cement Injecting Before and after Fixation of Lateral Split Depression Tibial Plateau Fractures: A Study on Cadaveric Tibia.

Daniel S. Chan[1], Ha V. Vo[2]*, Trung T. Le[2], Bich N. Nguyen[2], Edward C. Long[1]

[1]Orthopaedic Trauma Institute, Navicent Health Hospital, Mercer University School of Medicine, Macon, Georgia, USA

[2]Department of Biomedical Engineering, Mercer University, Macon, Georgia, USA

Abstract

Objective: To determine whether there is any biomechanical difference in technique of distributing calcium phosphate cement before or after fixation to repair lateral split depression tibial plateau fractures.

Methods: Lateral split depression tibial plateau fractures were created in ten cadaveric paired tibia specimens. Each pair had an identical fracture created, identical fixation constructs, and only differed by one specimen being repaired with the application of calcium phosphate bone substitute (Norian drillable) before fixation was applied, and one after. Each repaired specimen underwent computer tomography (CT) evaluation, and then biomechanically tested under cyclic compressive loading in intervals of 20,000 cycles at 2 Hz frequency, increasing stepwise loads representing 100%, 200%, and 300% weight bearing, then loaded to failure. The lateral plateau was loaded through a hemi-TKA/unicondylar femoral component. Articular fragment subsidence and condylar displacement were measured using a laser extensometer. The biomechanical characteristics of two groups (Before vs. after) were statistically compared for significance by using pair t-test ($p<0.05$).

Results: There was no significant difference between the two groups in all measurements. In the before group, the fragment subsided on average 0.65 ± 0.42 mm, 1.15 ± 0.41 mm, and 1.50 ± 0.50 mm at 100%, 200% and 300% bodyweight, respectively. Compared to the After group (0.59 ± 0.36 mm, 1.00 ± 0.48 mm, and 1.34 ± 0.52 mm), the differences were not significant (p-values 0.949, 0.649, 0.431, respectively). Similarly, the condylar displacement measured on average 0.85 ± 0.26 mm, 1.30 ± 0.41 mm, and 1.70 ± 0.49 mm in the before group, and was not significantly different to After (0.85 ± 0.27 mm, 1.34 ± 0.43 mm, and 1.79 ± 0.57 mm) (p-values 0.561, 0.294, 0.278, respectively). There were no differences at failure with regards to stiffness, yield displacement (p-values 0.911, and 0.297, respectively).

Conclusion: The order of calcium phosphate injection and implant fixation did not make a significant difference in the maintenance of reduction in the repair of lateral split depression tibial plateau fractures. The results of the fixation construct, regardless of order, in this study have demonstrated minimal subsidence of the articular fragment when simulated weight bearing was applied (0.65-1.7 mm).

Keywords:

Lateral split tibial plateau fracture; Norian calcium phosphate; Fragment subsidence displacement; Condyle displacement; Early weight bearing.

***Corresponding Author:** Ha Van Vo, Department of Biomedical Engineering, Mercer University, Macon, Georgia, USA, Tel. No: +1 478-301-2454; Email: hv_vo@mercer.edu

Received date: 4th January 2019,, **Accepted date:** 11th January 2019, **Published date:** 15 January 2019.

Introduction

A lateral split depression tibial plateau (Shatzker II) fracture is a very common pattern [1]. The surgical objectives in the repair of this injury are restoring the articular surface and stabilizing the fracture to enable the fracture to heal in the reduced position. The challenge is addressing the metaphyseal void that is left after reducing the depressed articular fragment.

Many techniques have been described in filling this metaphyseal void. Autogenous (iliac crest bone graft, ICBG) and allograft (structural and non-structural), have been reported as effective options [2,3]. However, between the post-surgical complaints or complications related to ICBG harvesting [4] or articular fragment subsidence [3,5,6] related to non-structural characteristics of the graft used to back fill the void, synthetic bone graft substitutes have become of great interest.

Synthetic osteoconductive biologics offer an easy to deliver solution that remodels into normal bone and has been shown to be structurally helpful in preventing articular subsidence [7,8]. A significant advantage in using these products is the ability to inject them into the metaphyseal void after fixation has been applied. This order of application inherently begs the question: is the material getting to the needed location to provide subchondral support and prevent subsidence? Or, is the injected material being impeded by the implant?

Injecting an osteobiologic before implanting fixation would be a reasonable solution to this concern about distribution; however, it is anecdotally well known that these ceramic materials fragment when drilled. Norian drillable (DePuy Synthes, West Chester, PA) was developed to circumvent this concern–as FDA approved product for drilling, it offers the ability to inject calcium phosphate into the void before implantation of fixation.

A recent publication investigated articular subsidence between these two groups in a saw bones model [9]; however, to our knowledge, there has not been a published study reporting the distribution of injected osteobiologic. The purpose of this study is to compare the difference in the distribution of the injected material before or after implantation of fixation, as well as compare the biomechanical characteristics.

Materials and Methods

Ten matched pairs of fresh-frozen cadaver tibiae (n=20) were acquired (United Tissue Network, Norman, OK), stored in the freezer, and each specimen underwent a 24 h thaw, preparation, fracture generation, repair and fixation, CT scan, and testing from start to completion individually to maintain homogeneity with regards to timing, temperature, and tissue conditions. Matched pairs were completed sequentially, and Group Before or After designation was completed at random so that there are equal specimens in each group (10 specimens/group).

After the 24 h thawing period, the tibial shaft was potted in epoxy acrylic resin (Paceline) in preparation for later biomechanical testing. Fracture generation, as well as repair, by a single surgeon. A thin blade sagittal saw was used to create the consistency fracture, and relative lateral compartment measurements were recorded to ensure that an identical fracture was created on the contralateral specimen. A 4-hole 3.5 mm LCP proximal tibial plate (DePuy Synthes, West Chester, PA) was placed to the lateral cortex for the best anatomical fit and position to plan the fracture creation. The split started at base of the imminence and exited just proximal to the kickstand screw in the plate. A 15 mm × 15 mm was determined between the most anterior and most posterior locking screws. A 15 mm × 15 mm articular fragment was created by using sagittal saw with a 5 mm subchondral thickness, and beneath it a 15 mm × 15 mm × 15 mm void was created.

An anatomic reduction of the fracture performed and provisional fixation applied using 1.6mm K-wires and pointed reduction forceps. At this point, for Group before specimens, a 5 cc Norian cement was prepared by the technique guide instructions (approximately 70 s for 70 revolutions with the rotary mixer), and transferred to the delivery syringe for injection within the next 3 min. Fluoroscopy was used during guided creation of hole for syringe into defect (Figure 1) and confirmation of the filling of the void.

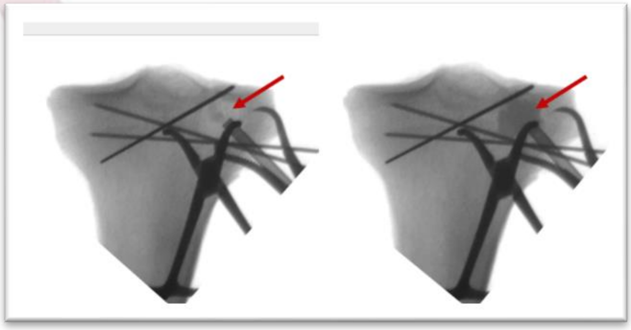

Figure 1: Fluoroscopy of the tibial plateau fixation construct (Before GROUP), before (left) and after (right) injected calcium phosphate (arrow).

Implantation of fixation proceeded with the placement of two 3.5 mm (titanium, to minimize scatter and optimize visualization of the distribution on CT) cortical screws in the middle of the void in the coronal plane and axially in thirds. The plate, in its best anatomically fit position, buttressed the split with a non-locked 3.5 mm screw placed in the shaft, and completed with locked screws at the kickstand, and the front and back positions in the proximal row of the plate. For group after specimens, the reduction and fixation were performed first, a hole for the delivery syringe was made using fluoroscopy guidance, and the Norian cement was prepared and injected as described above. Once again, the fluoroscopy was finally used to ensure the calcium phosphate bone cement was filled in the void both before and after groups (Figure 2).

Figure 2: Fluoroscopy of the completed tibial plateau fixation construct.

The completed tibial plateau specimen underwent CT scan to evaluate the calcium phosphate distribution inside the void (Figure 3). All the CTs were reviewed by the lead author to evaluate for the presence of calcium phosphate fully up against the subchondral bone of the entire restored articular fragment.

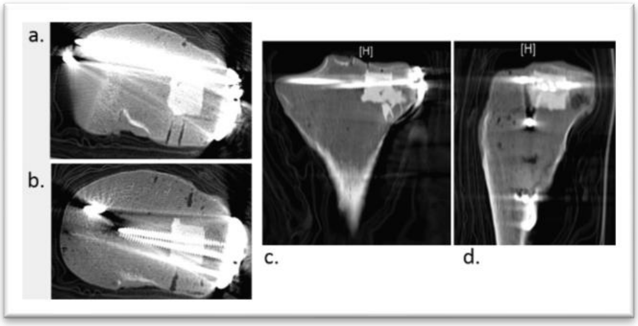

Figure 3: CT-Scan showing distribution of Norian calcium phosphate in the completed tibial plateau fixation construct: a and b. Axial scan superior to inferior, c. Coronal scan, d. Sagittal scan.

After the cement was confirmed to be fully cured within 24 h, the specimen was rigidly mounted to a custom made fixture of the MTS system with 25 kN load cell (MTS® Model Bionix 270.02 Axial/Torional, MTS Systems Corporation, Eden Prairie, MN), and secured laser extensometer gauges (LK-G157, Keyence, Itasca IL) for measuring fragment subsidence and displacement relative to the tibial condyle (Figure 4).

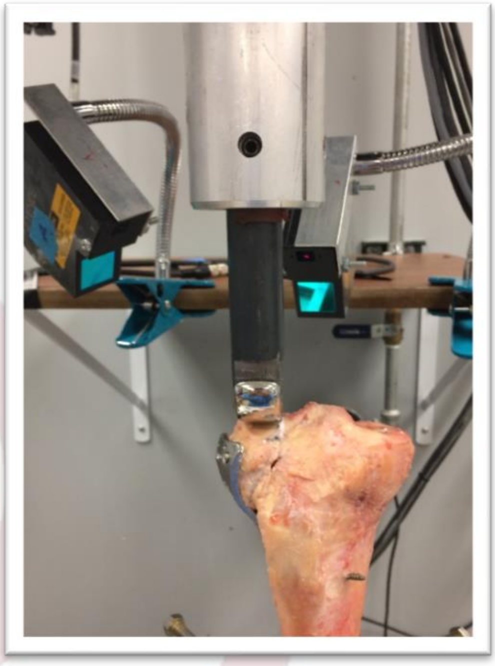

Figure 4: Biomechanical setup of the constructed tibial plateau fixation integrated with laser extensometer system.

The hemi-TKA/lateral unicondylar femoral component (Stryker, Kalamazoo, MI) is positioned to properly impact the lateral compartment of the proximal tibia. Stepwise cyclic compressive loads in vivo started at an applied load to the lateral compartment of 15% bodyweight (BW) for the first 20,000 cycles, which is equivalent to 100% BW total joint contact force. The following two 20,000 cycles increased to 30% and 45% BW applied load, equivalent to total joint contact forces of 200% BW and 300% BW, respectively. The literature derived stepwise scheme was based on: 1) single leg stance joint contact force is approximately three times BW [10]; 2) medial and lateral compartments of the tibial plateau experience a load distribution between 55% to 45% [11]; and 3) the hemi-TKA contact area is ~30% of the compartment [12,13]; therefore, the maximum loading of this stepwise scheme represents 1 to 3 times total BW or 33% to 100% weight-bearing. The maximum number of loading cycles (60,000) has been used in prior biomechanical experiments evaluating fixation treatment in tibia fractures [14] and simulates 12-14 w of post-operative weight-bearing [15,16].

BW of each specimen was determined by the donor demographic information provided by United Tissue Network. Cyclic loading was conducted at 2 Hz with a maximum of 60,000 cycles of until any of the failure criteria are met: 1) fragment subsidence or condylar displacement>10 mm vertically; and 2) screw fracture or bending. If a specimen survives the entire cyclic loading regimen, it will be destructively loaded to failure at 1 mm/s MTS run rate.

Subsidence of fragment and condyle will be measured at completion of every 20,000 cycle period. Primary biomechanical outcomes include stiffness, yield force, and yield displacement. Shapiro-Wilk test of normality was performed to show normal distribution of the data. Outcome parameters were then compared between matched specimens in Before and After group using a pair t-test. Analyses were performed with SPSS v2.0 (IBM, Armonk, NY) at a significance level of 0.05.

Results and Discussion

All cadaveric specimens were male, with average age 52 y (31 to 60 y), and an average weight of 111 kg (51 to 190 kg). The CT evaluation of all repaired specimens confirmed the distribution cement throughout the bone void space, as well as supporting the restored articular fragment equally for both groups regardless of order of fixation versus cement injection. Biomechanical testing revealed that the displacement of the articular fragment was not significant different between both groups as well. The average subsidence of the fragment in the Before group was 0.65 ± 0.42mm at 20,000 cycles, 1.15 ± 0.41 mm at 40,000 cycles, and 1.50 ± 0.50 mm at 60,000 cycles corresponding with 15%, 30%, and 45% bodyweight, respectively. Compared to the After group (0.59 ± 0.36 mm, 1.00 ± 0.48 mm, and 1.34 ± 0.52 mm), the differences were not significant (p-values 0.561, 0.294, and 0.278, respectively). Similarly, the condylar displacement measured on average 0.85 ± 0.26 mm, 1.30 ± 0.41 mm, and 1.70 ± 0.49 mm in the Before group, and was not significantly different to After (0.85 ± 0.27 mm, 1.34 ± 0.43 mm, and 1.79 ± 0.57 mm) (p-values 0.949, 0.649, and 0.431, respectively). There were no differences at failure with regards to stiffness, yield displacement (p-values 0.911, 0.297, respectively) (Table 1).

The use of calcium phosphate cement in tibial plateau fractures has been studied and shown to improve the ability to maintain the articular reduction, especially when compared to autograft [3]. The drillable nature of Norian cement has enabled surgeons to apply the calcium phosphate before fixation aiming to provide better support to the restored articular fragment. To our knowledge, there are no reported descriptions of the distribution calcium phosphate when used in tibial plateau fracture repair. The results of this study showed that the order of the fixation versus the application of cement did not make a significant difference in the distribution of the calcium phosphate cement; nor did it make a significant difference in a biomechanical comparison. Additionally, the biomechanical strength of the fixation construct revealed stability that implied for early weight-bearing post-operatively.

One of the concerns with the injection of calcium phosphate into the bone void created by the metaphyseal impaction of a lateral split depression tibial plateau fracture is that the fixation impedes its ability to reach the subchondral bone of the reduced articular fragment and support it effectively to prevent subsidence. Our investigation showed that this impedance should not be a concern; when Norian was injected after the 70 s and 70 revolutions in the rotary mixer and within the three-minute delivery timeframe, the viscosity of the calcium phosphate allows the substance to fill the entire void, most importantly above the screw fixation in middle of the void and approximately 2-3 mm apart from one another and the edge of the void. All CTs distinctly showed the presence of calcium phosphate fully filling the defect, above the screws, and fully supporting the subchondral bone. To our knowledge, this has not been reported previously in the literature.

A previous biomechanical investigation into using calcium phosphate in supporting the repair of depressed lateral compartment tibial plateau fractures in a saw-bones model reported lower displacement and high stiffness in the specimens that underwent CaP cement application before fixation [17]. Their fracture pattern, fixation construct, and synthetic model (saw-bones) differed from ours. Their fixation was comprised of two medial-lateral screws within the metaphyseal void and two anterior-posterior “raft” screws for subchondral support. Fluoroscopic evaluation during the injection of the bone cement showed incomplete filling of the void. This may be the explanation for their results of fragment subsidence during biomechanical testing. Our study resembles a more realistic and applicable testing model: 1) cadaveric specimens offer more realistic tissue-to-implant/calcium phosphate interaction and biomechanical results; and 2) the fixation construct used is for the lateral split depression pattern is clinically applicable. A CT scan was not performed in the saw bones study, so a complete description of the distribution of calcium phosphate cannot be made.

The biomechanical results are consistent with McDonald et al. [5] investigation into the calcium phosphate versus iliac crest bone graft used to address the metaphyseal bone void after the repair of lateral split depression tibial plateau fractures. They also cyclically loaded cadaveric specimens using the same stepwise scheme and found 1.8 mm of fragment depression in the calcium phosphate group after 210,000 cycles (4 Hz). Our interval cycles were 20,000 cycles conducted at 2Hz, with similar fragment displacement (1.50 ± 0.50 mm in the Before group, 1.34 ± 0.52 mm in the after group) (Figure 5). One difference was their fixation construct used a 3.5 mm non-locking lateral tibial plateau plate (Synthes) compared to our 3.5 mm locking proximal tibial plate (Synthes).

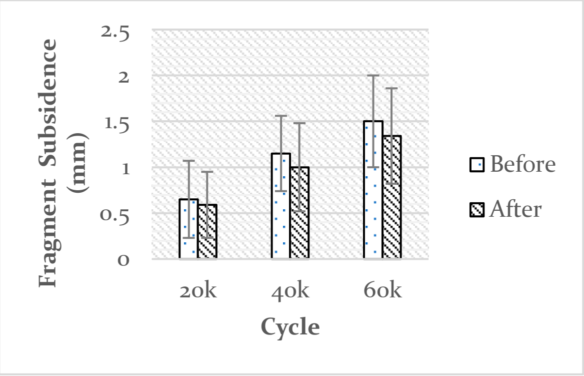

Figure 5: Total average fragment subsidence displacement during fatigue loading.

There are many recommendations regarding weight-bearing at fixation of tibial plateau fractures, ranging from non-weight-bearing [18], to partial [19], to immediate weight-bearing [20-22]. Segal reported allowing operatively treated lateral tibial plateau fracture patients to immediately weight bearing in a fracture brace, finding no fracture displacement greater than 2 mm radiographically. A recent investigation by Haak et al. [23] compared immediate full and delayed weight-bearing in operatively treated lateral tibial plateau fracture (AO 41-B) patients. Similar results were found with no radiographic fracture displacement in either group. These clinical reports suggest immediate weight bearing is tolerated post-operatively without complications; however, their lateral tibial plateau fractures are a mixture of splits, depressions, and split-depressions. Our biomechanical evaluation supports for the early weight bearing theory. The fixation construct using a locking proximal tibial plate and calcium phosphate augmentation applied to the repair of a lateral split depression fracture pattern with total weight-bearing can expect no more than 2 mm of displacement. Based on previous reports [24,25], this amount of displacement is acceptable and clinically well-tolerated. Previous mentioned similar biomechanical study [5] used a different fixation construct and reported condylar widening with fatigue loading. Our study using a locking plate is more consistent with the currently used fixation strategies and did not experience condylar widening with minimal condyle displacement at 1.70 ± 0.49 mm in Before group, 1.79 ± 0.57 mm in After group) (Figure 6).

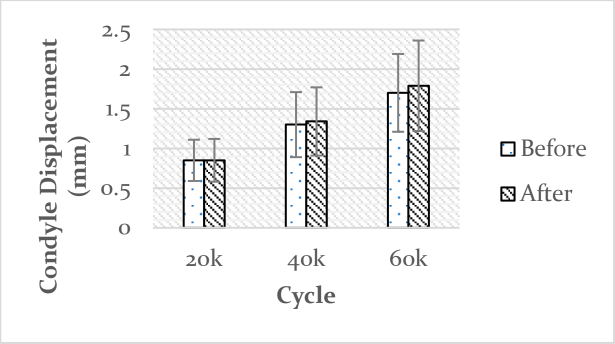

Figure 6: Total average condyle displacement during fatigue loading.

Although fracture creation using a saw produced consistency, which was consistent for comparative analysis, fracture behavior after repair and fixation may biomechanically be different. The split fracture line in the lateral cortex is variable; therefore, the shear forces on the lateral condyle also varies. The more vertical the split fracture line, likely the higher the risk of condylar displacement. A similar study limitation is the difference in the metaphyseal void that is created with joint reduction in situ versus the one that is created in the cadaveric specimens, and the way that calcium phosphate is distributed in an irregular shaped void versus a 15 mm cube: this difference may lead to differences in biomechanics as well.

There are several strengths of this study performing in in vitro condition. Ten cadaveric paired specimens provide an adequate sample size for biomechanical investigation. The fracture creation, repair and fixation, and calcium phosphate application, as well as review of CTs, were performed by a single orthopaedic trauma fellowship trained surgeon. Additionally, great attention was applied to reproduce identical timing and conditions related to preparation and testing of each specimen. This consistency minimized the variability in the data. Another strength is the loading biomechanical system and stepwise scheme used, as it mimics previously reported and accepted methods to imitate weight bearing testing. One merit enhancement was the laser extensometer integrated in our study measured vertical displacement of fragment subsidence to the microscopic level (0.5 µm) and provided more accuracy to the results.

Biomechanical outcomes	**Cycle**	**Before (n=10)**	**After (n=10)**	**t-test, P-value (p<0.05)**
Fragment subsidence (mm)	20 k	0.65 ± 0.42	0.59 ± 0.36	0.561
	40 k	1.15 ± 0.41	1.00 ± 0.48	0.294
	60 k	1.50 ± 0.50	1.34 ± 0.52	0.278
Condylar displacement (mm)	20 k	0.85 ± 0.26	0.85 ± 0.27	0.949
	40 k	1.30 ± 0.41	1.34 ± 0.43	0.649
	60 k	1.70 ± 0.49	1.79 ± 0.57	0.431
Stiffness at failure (N/mm)		1314.46 ± 529.85	1293.76 ± 404.17	0.911
Yield displacement at Failure (mm)		2.94 ± 0.79	2.67 ± 0.79	0.297

Table 1: Summary results of the biomechanical outcomes.

Conclusion

This study shows that the order of the application of calcium phosphate versus fixation does not impact the distribution of the injected bone substitute when used in the repair of lateral split depression tibial plateau fractures. Consequently, and not surprisingly, no significant differences were found when comparing the two groups in biomechanical testing. More interestingly, the results suggest that the fixation construct used, with injected calcium phosphate, and allows for early weight-bearing with minimal articular subsidence. Further investigation is needed into the clinical application of post-operative weight-bearing in lateral split depression tibial plateau fractures repaired in this way. Potential benefits may likely be quicker full range of motion attainment, faster return to function, and better overall outcomes and patient satisfaction.

Source of Funding

Investigator initiated grant from Depuy-Synthes, Inc.

Declaration of Interest

The authors report no conflicts of interest.

The lead author is a consultant for Smith and Nephew, and Globus Medical.

Acknowledgement

The authors acknowledge the momentary support and granted product received from DePuy Synthes. The work for this study was performed at NavicentHealth Medical Center and Biomedical Engineering Department at Mercer University.

References

1. Tornetta P (2015) Rockwood and greens fractures in adults (8th Edn.). Philadelphia: Wolters Kluwer Health.

2. Koval KJ, Helfet DL (1995) Tibial plateau fractures: evaluation and treatment. J Am Acad Orthop Surg 3: 86-94.

3. Russell TA, Leighton RK (2008) Comparison of autogenous bone graft and endothermic calcium phosphate cement for defect augmentation in tibial plateau fractures. A multicenter, prospective, randomized study. J Bone Joint Surg Am 90: 2057-2061.

4. Goulet JA, Senunas LE, DeSilva GL, Greenfield ML (1997) Autogenous iliac crest bone graft. Complications and functional assessment. Clin Orthop Relat Res 339: 76-81.

5. McDonald E, Chu T, Tufaga M, Marmor M, Singh R, et al. (2011) Tibial plateau fracture repairs augmented with calcium phosphate cement have higher in situ fatigue strength than those with autograft. J Orthop Trauma 25: 90-95.

6. Yetkinler DN, McClellan RT, Reindel ES, Carter D, Poser RD, et al. (2001) Biomechanical comparison of conventional open reduction and internal fixation versus calcium phosphate cement fixation of a central depressed tibial plateau fracture. J Orthop Trauma 15: 197-206.

7. Goff T, Kanakaris NK, Giannoudis PV (2013) Use of bone graft substitutes in the management of tibial plateau fractures. Injury 44: 86-94.

8. Greenwald AS, Boden SD, Goldberg VM, Khan Y, Laurencin CT, et al. (2001) Bone-graft substitutes: facts, fictions, and applications. J Bone Joint Surg Am 83: 98-103.

9. Hoelscher-Doht S, Jordan MC, Bonhoff C, Frey S, Blunk T, et al. (2014) Bone substitute first or screws first? a biomechanical comparison of two operative techniques for tibial head depression fractures. J Orthop Sci 19: 978-983.

10. Taylor WR, Heller MO, Bergmann G, Duda GN (2004) Tibio-femoral loading during human gait and stair climbing. J Orthop Res 22: 625-632.

11. ZhaoD, Banks SA, Mitchell KH, D'Lima DD, Colwell CW, et al. (2007) Correlation between the knee adduction torque and medial contact force for a variety of gait patterns. J Orthop Res 25: 789-797.

12. Lee SJ, Aadalen KJ, Malaviya LP, Lorenz EP, Hayden JK, et al. (2006) Tibiofemoral contact mechanics after serial medial meniscectomies in the human cadaveric knee. Am J Sports Med 126: 594-598.

13. Sdero R, Fenton PV, Rudan J, Bryant JT (2001) Fuji film and ultrasound measurement of total knee arthroplasty contact areas. J Arthroplasty 16: 367-375.

14. Gueorguiev B, Wahnert D, Albrecht D, Ockert B, Windolf M, et al. (2011) Effect on dynamic mechanical stability and interfragmentart movement of angle-stable locking of intramedullary nail in unstable distal tibia fractures: a biomechanical study. J Trauma 70: 358-365.

15. Schuller M, Weninger P, Tschegg E, Jamek M, Redl H, et al. (2009) Micromotion at the fracture site after tibial nailing with four unreamed small diameter nails-a biomechanical study using distal tibia fracture model. J Trauma 66: 1391-1397.

16. Gomez-Benito MJ, Fornells P, Garcia-Aznar JM, Seral B, Seral-Iñnigo F, et al. (2007) Computational comparison of reamed versus unreamed intramedually nails. J Orthop Res 25: 191-200.

17. Hoelscher-Doht S, Jordan MC, Bonhoff, C, Frey S, Blunk T, et al. (2014) Bone substitute first or screw first? A biomechanical comparison of two operative techniques for tibial-head depression fractures. J Orthop Sci 19: 978-983.

18. Whittle AP (2007) Fractures of the lower extremity. Campbells Operat Orthop (11th Edn.). Philadeliphia Mosby Elsevier 3085-3236.

19. Cole P, Levy B, Watson JT, Schatzker J (2008) Tibial plateau fractures. Skeletal trauma: Expert consultation (4th Edn.). Philadelphia: Saunders Elsevier 2201-2287.

20. Egol KA, Koval KJ (2001) Fractures of the tibial plateau. Chapmans Orthop Surg (3rd Edn.). Philadelphia: Lippincott Williams and Wilkins 737-754.

21. Eggli S, Hartel MJ, Kohl S, Haupt U, Exadaktylos AK, et al. (2008) Unstable bicondylar tibial plateau fractures: a clinical investigation. J Orthop Trauma 22: 673-679.

22. Segal D, Mallik AR, Wetzler MJ, Franchi AV, Whitelaw GP (1993) Early weight bearing of lateral tibial plateau fractures. Clin Orthop Relat Res 232-237.

23. Haak KT, Palm H, Holck K, Krasheninnikoff M, Gebuhr P, et al. (2012) Immediate weight bearing after osteosynthesis of proximal tibial fractures may be allowed. Dan Med J 59: 4515.

24. Barei DP, Nork SE, Mills WJ, Henley MB, Benirschke SK (2004) Complications associated with internal fixation of high-energy bicondylar tibial plateau fractures utilizing a two-incision technique. J Orthop Traum 18: 649-657.

25. Brown TD, Anderson DD, Nepola JV, Singerman RJ, Pedersen DR, et al. (1988) Contact stress aberrations following imprecise reduction of simple tibial plateau fractures. J Orthop Res 6: 851-862.