Can Electromagnetic Navigation for Distal Locking of Intramedullary Nail Reduce Procedure Time and Radiation Exposure?

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Background/Purpose: Distal locking screw insertion for intramedullary nails can lead to prolonged operation time, increased irradiation, and frustrations for those surgeons who treat tibial shaft fracture occasionally. Failure to insert distal locking screws can lead to malunion or nonunion. Electromagnetic navigation (E-navigation) was developed to provide surgeons with fast and easy technique for distal locking screw insertion. It provides 3-dimensional images and real time feedback of drill bit tip and locking holes location on the monitor without use of fluoroscopy. The purpose of this study was to compare the distal locking screw insertions using a conventional method (CM), and E-navigation. We hypothesized that the use of E-navigation would decrease the procedure time and fluoroscopy exposure time over all.

Methods: We conducted a multicenter randomized parallel group study at ten hospitals. Patients who underwent surgical fixation of tibia by intramedullary nail were recruited and randomized to one of two groups by method of distal locking: (1) CM such as free-hand technique or radiolucent drill technique and (2) E-navigation. The decision to use free-hand or radiolucent drill was according to surgeon's preference. Two distal locking screws insertion (SI) time starts at time of removing guide wire for nail and completion of two interlocking placement was recorded, and SI fluoroscopy time was also recorded. Statistical analysis was performed using the Tukey-Kramer method with significance set at a P value <0.05.

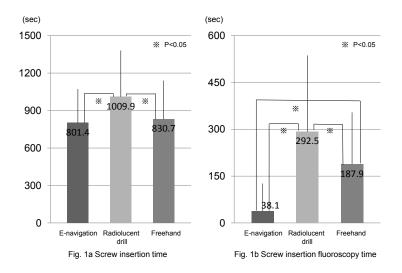
Results: From December 2011 to December 2014, 157 patients were recruited for the study. 79 patients were CM group (40 with free-hand technique, and 39 with radiolucent drill technique), and 78 were E-navigation group. SI time was 800 seconds in E-navigation, 1015.7 seconds in radiolucent drill, and 829.4 seconds in free-hand (Fig.1a). SI fluoroscopy time was 37.2 seconds in E-navigation, 289.2 seconds in radiolucent drill, and 173.5 seconds in free-hand (Fig.1b).

Discussion/Conclusion: There have been 5 publications about E-navigations used in distal locking procedure as far as we know. All but one concluded that use of E-navigations shortens the time of distal locking screw fixation time, but Maqungo et al reported that time to insert distal locking screws were not significant in both methods and concluded that the surgeons are well versed in the free-hand technique, that E-navigation was equivalent in speed. In our study SI time of E-navigation and free-hand also did not have significant difference. It might not be necessary to use E-navigation for experienced surgeons concerning speed,

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but all five articles and our study showed significant reduction in the radiation exposure. In our study, we were able to reduce about 80% of fluoroscopy time. That is a great advantage since radiolucent drill technique is the major technique used in our country. We believe E-navigation is a great option for quicker distal locking, and more in reducing the radiation exposure to patient and surgeons.



Suprapatellar Intramedullary Nail Technique Lowers Rate of Malalignment of Distal Tibia Fractures

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Purpose/Background: Distal tibia fractures are challenging to align anatomically with infrapatellar intramedullary nail (IMN) techniques with the knee in flexion. Vallier et al reported on radiographic outcomes following treatment with either IMN or plate fixation and found a 23% rate of malalignment in distal tibia fractures treated with an infrapatellar IMN. In a larger trial, Im and Tae identified an 11.7% incidence of angular deformity >5° in the infrapatellar IMN group. Suprapatellar IMN insertion enables the surgeon to maintain the leg in a semi-extended position, which eliminates the challenges associated with knee flexion of the limb required for instrumentation and fixation with infrapatellar IMN techniques. We hypothesize that use of the suprapatellar IMN technique results in lower rates of malalignment following surgical treatment of distal tibia fractures compared to infrapatellar IMN insertion.

Methods: A retrospective review of distal tibia fractures treated with an IMN from 2008 to 2014 at two Level-I trauma centers was completed. Demographic data for each patient were abstracted from chart review. Distal tibia fractures were graded according to the OTA classification scheme on injury radiographs. Patients were grouped into those who underwent either suprapatellar or infrapatellar IMN insertion in fractures located up to 5 cm from the tibial plafond. Anatomic alignment of the tibia was measured on postoperative radiographs on both the AP and lateral views. Acceptable radiographic alignment was defined as <5° in any plane. A trained reviewer not involved in direct care of the study groups graded each radiograph. Statistical analysis was completed using Pearson uncorrected chi-square test. P <0.05 was considered statistically significant.

Results: 266 patients meeting all inclusion criteria were identified. 132 patients underwent suprapatellar IMN, and 134 underwent infrapatellar IMN. The two treatment groups were evenly matched with respect to age, gender, fracture grade, and presence of open fracture. Within the suprapatellar group, the fibula was intact, fixed, and remained fractured in 6 (4.5%), 22 (16.7%), and 104 (78.8%) cases, respectively. The fibula was intact, repaired, and remained fractured in 9 (6.7%), 32 (23.9%), and 93 (69.4%) cases, respectively, in the infrapatellar group. There was no difference in the rate of fibular fixation between groups (P = 0.2). Primary angular malalignment >5° occurred in 35 patients (26.1%) with infrapatellar IMN insertion, and in five patients (3.8%) who underwent suprapatellar IMN insertion (P<0.0001).

Conclusion: This is the largest patient series directly comparing the suprapatellar to infrapatellar IMN insertion technique in the treatment of distal tibia fractures. Suprapatellar IMN technique results in a significantly lower rate of malalignment compared to the infrapatellar IMN technique.

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Clinical and Functional Results of 116 Patients with Knee Dislocations

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Purpose: Knee dislocations are rare injuries that may be limb-threatening and often associated with functional limitations. Treatment strategies vary among institutions, without consensus regarding timing, surgical tactic, and rehabilitation. Furthermore, high-energy and low-energy mechanisms are described that impact distinct patient populations with different risks. Our purpose is to describe the clinical results and functional outcomes of knee dislocations treated with a similar strategy and to identify risk factors for complications and poor outcomes.

Methods: 138 adult patients with knee dislocations (OTA 40A) over 14 years at one institution were reviewed; 22 had insufficient data, leaving 116: 74 (64%) male with mean age 36.9 years, mean body mass index (BMI) 30.7, and mean ISS 14.9. High-energy mechanisms occurred in 79 (68%), mostly motor vehicle (31%) and motorcycle (22%) collisions. 21 (18%) had popliteal artery injury requiring revascularization, while five others were observed. Eight patients (6.9%) had primary amputation; seven of them had vascular injuries. All others underwent initial closed reduction, and 38 patients (33%) with open injuries had urgent surgical debridement. 89% of all patients had provisional external fixation, retained for mean 6.8 weeks in 51%. Repair of medial and lateral structures and posterolateral corner occurred at mean 5.8 days (range, 0 to 26) after injury. Fixation of cruciate avulsion fractures (5 posterior cruciate ligament and 1 anterior cruciate ligament [ACL]) occurred concurrently. Due to residual instability, bicruciate reconstruction was performed in 4 patients at a mean of 29.4 weeks, while 1 other had ACL reconstruction, (4.6% with delayed cruciate reconstructions). Complications included deep vein thrombosis (DVT), pulmonary embolism, wound infection, heterotopic bone (HO), and arthrosis. Functional outcomes were measured with the Musculoskeletal Function Assessment (MFA) survey.

Results: After a mean 18 months follow-up, 63 early complications were noted in 45 patients (39%), requiring 31 (27%) to undergo 148 secondary operations, including 3 late amputations. Open knee dislocations resulted in more amputations (23% vs 1.3%, P <0.001). Popliteal arterial injuries were associated with more amputations (31% vs 4.3%, P <0.001), infection (39% vs 12%, P = 0.002), and DVT (23% vs 8.8%, P = 0.05). Open dislocations with arterial injuries were associated with the most complications: DVT in 77% (P = 0.005), infection in 54% (P = 0.066). Patients with wound infections were more likely to develop HO (39% vs 9.8%, P <0.001) and less knee motion (98° vs 115°, P = 0.14). Patients with ISS ≥20 had less knee motion at six months (86° vs 122°, P = 0.036) and one year (91° vs 120°, P = 0.016). 42 patients completed MFA surveys and had a mean score of 38.9 after a minimum of 12 months.

Conclusion: Few patients (4.6%) experienced functional instability requiring late cruciate reconstruction. However, early complications occurred frequently (39%), particularly in patients with open injuries and/or arterial injury. Limitations in knee motion were associated with high ISS, infection, and HO. Mean outcome scores are poor, and data collection is ongoing, which may provide valuable information to identify modifiable risk factors. Alternative treatment strategies could be more effective in promoting recovery and function.

Superior Outcomes after Operative Fixation of Patella Fractures using a Novel Cage Plate Construct: A Prospective Cohort Study

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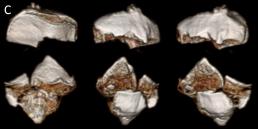
Purpose: Displaced patella fractures (OTA 34) traditionally have been treated with anterior tension band constructs and are associated with poor patient-reported and functional outcomes. To address these inferior outcomes, we have developed a novel fixation construct that provides multiplanar fixation through a low-profile mesh plate with minimal iatrogenic disruption to the patella vascularity. The purpose of this prospective cohort study was to determine if the new fixation construct resulted in improved outcomes compared to tension band techniques.

Methods: A prospective cohort study was performed on consecutive patients with isolated, unilateral patellar fractures. During the initial study period from 2008-2011, patients were treated with traditional tension band techniques using a combination of Kirschner wires, cannulated screws, figure-of-eight wires, cerclage wires, and/or nonabsorbable sutures. During the subsequent study period from 2012-2014, a novel cage plate construct was used that spans half of the patella circumference laterally and provides multiplanar fixation through a low profile plate (figure). Additional suture fixation of the patellar tendon to the cage plate was utilized to address inferior pole comminution. Thirty patients treated with a tension band and eleven patients treated with the novel cage plate construct were included in the study. Subjective clinical outcomes and objective functional and strength outcomes were collected at 3, 6, and 12 months postoperatively.

Results: The two cohorts had similar baseline characteristics, including average age (60.0 years and 65.5 years, respectively), gender (80% female and 82% female, respectively), body mass index (23.2. and 23.4, respectively), and medical comorbidities. Patients with the cage plate construct had clinically and statistically significant superior clinical outcome scores using the Activities of Daily Living Scale of the Knee Outcome Survey (ADLS-KOS) at both 3 months (58.7 vs 72.2, P = 0.016) and 12 months (74.9 vs 84.2, P = 0.024). Closed kinetic chain functional testing demonstrated significantly better forward lunge scores in the cage plate cohort compared to the tension band cohort at 3 and 6 months (P values <0.001-0.035). Open kinetic chain functional testing revealed significantly improved isometric, power, and endurance knee flexion in the cage plate cohort at 3, 6, and 12 months (P values 0.003-0.045). Thigh circumference difference was significantly decreased at 12 months in the cage plate cohort (1.31 cm vs 0.25 cm, P = 0.007). Anterior knee pain at final follow-up was significantly decreased in patients with the cage plate (80% vs 9%, P <0.0001).

Conclusion: Operative treatment of patella fractures using tension band constructs have resulted in impaired functional outcomes overall. In this prospective cohort study, the use of a novel fixation construct with multiplanar fixation and minimal disruption to patella vascularity has led to improved clinical and functional outcomes.





AP (a) and lateral (b) injury knee radiographs of a patella fracture in a 50-year-old woman. 3-dimensional CT reconstructions (c) reveal an AO/OTA34-C3 patella fracture. AP(d) and lateral (d) knee radiographs 12 months postoperatively.

Function and Knee Range of Motion Plateau 6 Months Following Tibial Plateau Fractures

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Purpose: Tibial plateau fractures are common and drastically affect patient quality of life. Adequate care and patient education are pivotal for patient recovery. The purpose of this study is to determine when function, range of knee motion (ROM), and pain levels no longer improve following tibial plateau fracture.

Methods: A consecutive series of patients who sustained a tibial plateau fracture were reviewed. Patients were evaluated postoperatively using the Short Musculoskeletal Function Assessment (SMFA), physical examination, and radiographic examination at regular intervals for a minimum of 12 months. Preoperative radiographs were reviewed, and fractures were classified based on the Schatzker classification. The cohort was divided into high- and low-energy fractures based on Schatzker classification. A Friedman test was run on each group to determine if there were differences in SMFA standardized scores, range of motion, and pain levels at 3, 6, and 12 months after surgery. Pairwise comparisons were performed with a Bonferroni correction for multiple comparisons.

Results: 84 patients with complete SMFA follow-up at 3, 6, and 12 months were identified. 78 (93%) had known ROM at all three time points. 74 (88%) had a known pain score at all three time points. Fifty patients (60%) had low-energy fractures (Schatzker 1-3). 34 patients (40%) had high-energy fractures (Schatzker 4-6). SMFA total score (P<0.0005) and knee ROM (P<0.0005) were significantly different when comparing all three time points following both low- and high-energy tibial plateau fractures. Pain level was not different at any time (High P = 0.718, Low P = 0.760) in either group. Post hoc analysis revealed significant differences in standardized SMFA total score, ROM, and most SMFA subscores between 3 and 6 months as

well as 3 and 12 months postoperatively in both groups. There was no statistically significant difference for any of the studied metrics between 6 and 12 months in the low-energy cohort. The mobility category (P = 0.046) and daily activities category (P = 0.033) were the only scores to show significant differences between 6 and 12 months in the high-energy cohort.

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Pairwise comparisons of SMFA scores between 6 and 12 months				
High Energy	Low Energy Adjusted p-value			
0.087	1.000			
0.118	1.000			
0.236	1.000			
0.033*	1.000			
	0.634			
0.046*	0.881			
0.974	1.000			
	High Energy Adjusted p-value 0.087 0.118 0.236 0.033* 0.046*			

* Indicates significance at p<0.05

Conclusion: In this cohort, no significant difference in function, ROM, or pain level exists between 6 months and 12 months after treatment of low-energy tibial plateau fractures. However, there are significant differences in mobility and daily activity between 6 months and 12 months after treatment of high-energy tibial plateau fractures. Patients can be counseled that 6 months after low-energy tibial plateau fractures patients should not expect significant changes in function or ROM. However, patients with high-energy tibial plateau fractures can be counseled that they can expect continued significant changes in mobility and ability to conduct daily activities up to 12 months after surgery.

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Is Early Total Care of Bicondylar Tibial Plateau Fractures Safe? *Florence Unno, MD*¹; *Kelly Lefaivre, MD*¹; *Georg Osterhoff, MD*²; *Henry Broekhuyse, MD*²; *Pierre Guy, MD*²; *Peter O'Brien, MD, FRCSC*²; ¹Vancouver General Hospital, University of British Columbia, British Columbia, CANADA; ²University of British Columbia, British Columbia, CANADA

Background/Purpose: The optimal treatment for bicondylar plateau fractures remains controversial. Contrary to popular practice, which favors staged protocols, we have used early single-stage open reduction and internal fixation (ORIF) to treat these injuries whenever possible. The purpose of this study was to determine the safety of this strategy.

Methods: We retrospectively reviewed all the patients who were treated with primary ORIF for AO/OTA type 41-C bicondylar plateau fractures in our Level I trauma institution. We selected patients for whom follow-up data were available for a minimum of 12 months. The primary outcome measurement was the reoperation rate within 12 months for repeat ORIF, irrigation-debridement (I&D) for infection or wound dehiscence, fasciotomies for compartment syndrome, treatment of malunion and nonunion, amputation, knee fusion, manipulation under anesthesia for stiffness, and hardware removal. For a subset of patients who were enrolled in a study with prospective data collection, we also evaluated functional outcome using the Short Form (SF)-36 and the Selected Functional Movement Assessment (SFMA), and analyzed the quality of fracture reduction using four radiographic criteria.

Results: 149 cases (145 patients) with AO/OTA type 41-C bicondylar plateau fractures were operated in our institution between 2005 and 2014. 80 patients were male and 65 female. The mean age of the patients was 50.8 years (range, 19-86). All but 14 fractures were closed (Gustilo I: three cases; Gustilo II: four cases; Gustilo IIIA: four cases; Gustilo IIIB: one case; Gustilo IIIC two cases). Primary ORIF was performed in 135 patients (90.6% of cases). Nine patients (6.0%) were treated with a staged protocol and five patients (3.4%) were transferred to our institution after initial treatment with an external fixator. Patients who benefited from primary ORIF were operated within 24 hours after admission in 60.0% of cases and within 48 hours in 89.7%. Eighteen patients (13.3%) who were treated with primary ORIF sustained repeat surgery within 12 months for complications. The reoperation rate was 10.4% if hardware removal was excluded. Eight patients developed a wound infection requiring I&D, 2 of them after open fractures. Three patients were reoperated for compartment syndrome requiring fasciotomies. Three patients underwent repeat surgery for nonunion and one patient for early fixation failure. Four patients were reoperated for hardware removal for pain or disturbance. No surgeries were recorded for malunion, amputation, knee fusion, or manipulation under anesthesia. Secondary outcome measurements were obtained for a subset of 39 patients who enrolled in a study with prospective data collection. For those patients, the SF-36 score changed from 56.2 for the Physical Component Summary and 51.9 for the Mental Component Summary at baseline to 52.4 and 46.0, respectively, at 12 months. In the same period, the normalized SFMA changed from 45.4 to 56.5 for Function, and 45.7 to 55.7 for Pain. In 82.1% of cases, three or four of the four radiographic criteria used to assess the quality of fracture reduction were met.

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.

Conclusion: Provided surgery is performed without delay by experienced orthopaedic trauma surgeons, a large proportion of bicondylar tibial plateau fractures can be safely treated with primary ORIF. Early surgery does not preclude good quality of reduction, and the reoperation rate within 12 months as well as functional outcomes are comparable when confronted to published results for surgical treatments using a staged protocol.

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A Novel PTH-Based Bone Graft Substitute Demonstrates Noninferiority to Autograft in a Large Phase IIb Study of Tibial Plateau Fractures *Tom Lyon, MD*¹; Francisco Baixauli Garcia, MD²; Andrzej Bohatyrewciz, MD³; Vicente Casa de Pantoja, MD⁴; Zoltan Detre, MD⁵; Klaus Dresing, MD⁰; Frederic Dubrana, MD′; Peter Giannoudis, MD, FRCS, MBBS, BS⁸; Andrzej Gorecki, MD⁹; Tibor Gunther, MD¹⁰; William Harries, MD¹¹; Peter-Michael Hax, MD¹²; Christian Krettek, MD, FRACS¹³; Krzystztof Kwiatkowski, MD¹⁴; Manuel Leyes Vence, MD¹⁵; Zoltan Magyari, MD¹⁶; Henry Mathevon, MD¹⁷; Peter Messmer, MD¹⁸; Khitish Mohanty, MD, FRCS¹⁹; Elvira Montanez, MD²⁰; Antonio Pace, MD²¹; Amratial Patel, MD²²; Stefan Piltz, MD²³; Anthony Pohl, MD²⁴; Angelo Rando, MD²⁵; Michael Raschke, MD²⁶; Xavier Roussignol, MD²⁷; Horst Stephan, MD²⁸; Endre Varga, MD²⁹; Jerzy Widuchowski, MD³⁰; Istvan Zagh, MD³¹; Jason Schense³²; ¹Lutheran Medical Center, Brooklyn, New York, USA; ²Hospital Universitario La Fe Valencia, Valencia, SPAIN; ³Pomeranian University of Medicine, Department of Orthopedics and Traumatology Szczecin, POLAND; ⁴Universitary Hospital La Princesa, Madrid, SPAIN; ⁵Szt Janos Hospital, Budapest, HUNGARY; ⁶Klinik fur Unfallchirurgie, Plastische und Wiederherstellungschirurgie, Goettingen, GERMANY; ⁷Chirurgie Orthopedique et Traumatologique CHU, Brest, FRANCE; ⁸Leeds General Infirmary, Leeds, GREAT BRITAIN; ⁹Department of Orthopaedics and Traumatology of Locomotor System, Centre of Excellence "TeleOrto", Me, Warsaw, POLAND; ¹⁰Orthopaedics and Hand Surgery Centre, Gyor, HUNGARY; ¹¹North Bristol NHS Trust, Cardiff, GREAT BRITAIN; ¹²Berufsgenossensch aftliche Unfallklinik, Duisberg, GERMANY; ¹³Hannover Medical School, GERMANY; ¹⁴Military Medical Institut, Warsaw, POLAND; ¹⁵FREMAP Hospital CEMTRO Clinic, Madrid, SPAIN; ¹⁶National Institute of Traumatology, Budapest, HUNGARY; ¹⁷Centre Hopitalier General de Dunkerque, Dunkerque, FRANCE; ¹⁸Hirslanden Klinik St Anna, Luzern, SWITZERLAND; ¹⁹University Hospital of Wales, Department of Trauma and Orthopaedics, Cardiff, GREAT BRITAIN; ²⁰Hospital Universitario Virgen de la Victoria Servicio de Cirugia Ortopedica y Traumatologia, Malaga, SPAIN; ²¹Fondazione Istituto San Raffaele, Cefalu, ITALY; ²²Norfolk & Norwich NHS Trust, Orthopaedic Deparment, Norwich, GREAT BRITAIN; ²³Ludwig-Maximilians-Universitat, Munchen, GERMANY; ²⁴Royal Adelaide Hospital, Department of Orthopaedic Trauma, Adelaide, AUSTRALIA; ²⁵Gold Coast Hospital, Southport, AUSTRALIA; ²⁶Universitatsklinikum Munster, Klinik und Poliklinik fur Unfall-Hand und Widerherstellungschirurgie, Munster, GERMANY; ²⁷Department d'Orthopedie, Traumatologie et Chirurgie de la Main, Rouen, FRANCE; ²⁸St Josef/Krankenhaus, Linnich, GERMANY; ²⁹University of Szeged, Department of Trauma Surgery, Szeged, HUNGARY; ³⁰Independent Public Hospital Provincial, Piekary Slaskie, POLAND; ³¹Karolyi Hospital, Department of Traumatology, Budapest, HUNGARY; ³²Kuros Biosurgery, SWITZERLAND

Background/Purpose: A novel formulation containing a modified, covalently linkable parathyroid hormone (TGplPTH1-34) in fibrin with hydroxapatite/tricalcium phosphate

(HA/TCP) granules has been developed for the treatment of tibial plateau fractures (TPFs) following open reduction and internal fixation. Efficacy and safety of the product was compared to the clinical gold standard, cancellous autograft.

Methods: An open-label, controlled, randomized, dose-blinded, phase IIb study was conducted in which patients with TPFs were treated with either cancellous autograft, high concentration (1.0 mg/mL) or low concentration (0.4 mg/mL) of TGplPTH1-34 in fibrin with HA/TCP granules. The primary end point was radiological healing at 16 weeks, as measured by an independent radiology panel. Additional secondary end points included measuring radiographic healing, clinical healing, and maintenance of reduction at both earlier (6 and 12 weeks) and later (6, 12, and 24 months) time points. 183 patients were treated in the study, based on the statistical requirement of showing noninferiority to autograft with a 15% noninferiority margin.

Results: The radiographic healing rate at 16 weeks for patients with the product at the high concentration (83.6%) was demonstrated to be both statistically noninferior to that for autograft (84.5%) and superior to that for the low concentration (66.1%). In the composite end point, which combined CT and clinical outcomes, 72.1% of the patients treated with the high concentration healed compared to 63% of those treated with autograft. Maintenance of reduction was evaluated as well, with minimal loss observed (<1 mm compared to postoperative radiographs) at all time points, out to the end of the study at 24 months. Long-term follow-up demonstrated that essentially all the patients were healed in both the high-dose and autograft groups. Finally, the measured safety parameters further demonstrated that the product was well tolerated.

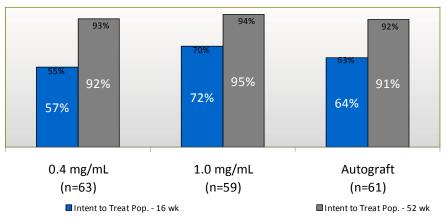


Figure: Outcomes from combined clinical and radiological healing assessment. The combined assessment for the intent to treat population at 16 wks and 52 wks is shown in the blue bars and gray bars respectively. Radiological assessment has been performed by an independent radiology panel while the clinical assessment has been performed by the investigator. At both timepoints, the healing rate following treatment with the high concentration of the PTH based product is higher than that for both patients treated with autograft as well as those treated with the lower concentration of TGpIPTH₁₋₃₄. This trend is confirmed in the per protocol analysis, which is shown in black at the top of each bar.

See pages 47 - 108 for financial disclosure information.

Conclusion: The authors have been developing a novel bone graft substitute based on the local retention of PTH in a fibrin matrix to induce bone healing. While the product has many potential applications, the initial development has been focused on the treatment of TPFs. In this study, it has been demonstrated that healing with the PTH-based product is as robust as that with autograft, throughout the entire healing process, Furthermore, at the early time points, where obtaining healing is more challenging, the product performed even better than autograft. Maintenance of reduction was measured, as this represents an important measure of the clinical outcome. Here, it was observed that the TGplPTH1-34-fibrin-granule composite provided a robust support, with no clinically relevant loss of reduction observed in the study. The combination of these data with the very clean safety profile provides a first clinical demonstration of the efficacy of the PTH-based product as a new powerful tool for fracture healing.

Functional and Clinical Outcomes of Nonoperatively Managed Tibial Plateau Fractures *Christian Pean, MS*; Anthony Christiano, BA; Sanjit Konda, MD; Roy Davidovitch, MD; Kenneth A Egol, MD; Hospital for Joint Diseases, New York, New York, USA

Background/Purpose: This study sought to assess and compare long-term functional and clinical outcomes in patients with tibial plateau fractures that are treated nonoperatively.

Methods: Over 8 years, 275 consecutive tibial plateau fractures were treated by two surgeons at a single institution and followed prospectively in an IRB-approved study. Overall, 28 patients (10%) were treated nonoperatively and followed for a mean 21 ± 15.5 months. All patients were treated similarly: kept non-weight-bearing for a minimum 10 weeks and prescribed a similar physiotherapy regimen. Patients were categorized into one of two cohorts based on the indication for nonoperative care: (1) minimal fracture displacement (MFD) defined as less than 2 mm of articular depression or 1 mm fracture gap or (2) surgery precluded (SP) by patient characteristics such as severe comorbidities at time of treatment or delayed presentation. Clinical follow-up included functional score, clinical examination, and radiologic evaluation. Student t tests for continuous variables and chi-square tests for categorical variables were used to assess differences between the groups. A multiple linear regression analysis of the entire cohort controlling for gender, age, smoking history, age-adjusted CCI (Charlson comorbidity index) and injury energy level was used to identify independent factors predictive of Short Musculoskeletal Function Assessment (SMFA) scores.

Results: 23 patients were available for long-term follow-up. The cohort was 48% male, 51.3 \pm 15.6 years of age, and had a mean age-adjusted CCI of 0.7 \pm 1.7. Overall, 57% of injuries were due to a high-velocity energy mechanism, and the fracture breakdown by Schatzker classification was as follows: 5 type I, 7 type II, 3 type III, 6 type IV, and 2 type VI. Average total SMFA at latest follow-up was 14.7 \pm 18.2 points and mean VAS (visual analog scale) pain score was 2 \pm 2.8. Overall, 65% (n = 15) of patients in this study attained good to excellent functional outcomes as defined by a total standard SMFA score of 15 or less. 22% (n = 5) had radiographic evidence of knee arthritis. Average knee range of motion (ROM) at latest follow-up for this cohort was 130° \pm 6.5°. In the patients in whom surgery was precluded, ROM (123° \pm 15.3° vs 132° \pm 3.8°, P = 0.03) and outcome scores (44.03 \pm 19.8 vs 10.4 \pm 13.6) were significantly poorer. To date, no patient had undergone total joint arthroplasty following index injury. Age was the only statistically significant predictor of total SMFA in a multiple linear regression analysis of the cohort, F(6,16) = 5.139, P = 0.007, adjusted R2 = 0.530.

Conclusion: A large proportion of carefully selected patients with minimally displaced tibial plateau fractures can expect good to excellent outcomes when managed nonoperatively. Patients with comorbidities precluding surgery for tibial plateau fractures at time of presentation have long-term sequelae from this injury including chronic pain and poorer functional outcomes.

See pages 47 - 108 for financial disclosure information.

Acute In Vivo Metrics of Joint Incongruity Following Articular Fracture Predict Posttraumatic Arthritis in Mice

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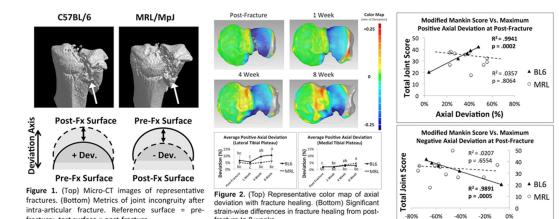
Purpose: Posttraumatic arthritis (PTA) occurs commonly after articular fracture. Joint degeneration may arise in part from surface incongruity after injury. Radiographic classification systems do not account for 3-dimensional (3D) geometry of the joint surface. CT-based measures of joint fracture severity have been used to predict ankle PTA development. Interestingly, the MRL/MpJ "superhealer" mouse strain is protected from PTA following articular fracture, thus providing valuable insight into the progression of PTA. Currently, the relationship between initial injury severity, articular displacement, and PTA development following articular fracture remains unknown. The objective of this study was to develop in vivo micro CT metrics of joint incongruity after articular fracture to further characterize the pathomechanism of PTA.

Methods: C57BL/6 and MRL/MpJ mice (n = 12/strain) received closed articular fractures (fx) of the tibia (Fig. 1). At 8 weeks, mice were sacrificed and assessed for arthritic changes (Mankin score). In vivo micro CT was performed pre- and post-fx, 1, 4, and 8 weeks post-fx. Displacements of the bone surface, or bone surface deviations (BSDs), were quantified for the lateral and medial tibial plateau (Fig. 1). Serum biomarkers of bone metabolism were measured pre- and post-fx to 6 weeks. BSDs were analyzed using analysis of variance and bone markers using nonparametric analyses.

Results: Temporal patterns in BSDs were significantly different between mice with larger average positive axial deviations found in C57BL/6 mice at 8 weeks post-fx (P = 0.01; Fig. 2). Mankin scores were correlated to all BSDs in both mouse strains. Acute BSDs showed the strongest correlations with PTA development. In C57BL/6 mice, axial BSDs on post-fx day 0 were highly predictive of PTA severity at 8 weeks post-fx (Fig. 3). In contrast, MRL/MpJ mice post-fx day 0 BSDs did not predict PTA development. Serum PINP (procollagen I N-terminal propeptide), a bone formation marker, in the C57BL/6 mice was significantly lower than the MRL/MpJ mice post-fx (P = 0.005), indicating a less robust acute response compared with the superhealer strain.

Conclusion: Acute displacements of the bone surface following articular fracture were predictive of arthritis development in C57BL/6 but not MRL/MpJ mice. C57BL/6 mice also showed an acute drop in serum PINP compared to MRL/MpJ mice. These findings suggest that MRL/MpJ mice undergo a unique mechanism of fracture healing following articular fracture and that joint incongruities secondary to articular fracture do not predispose MRL/MpJ mice to PTA development, whereas PTA development in C57BL/6 mice is predicted by acute bone displacements and decreased bone metabolism. In vivo CT metrics of joint incongruity provide a method for quantifying bone surface incongruities that have traditionally been difficult to measure. The translational potential of our joint incongruity metrics is high, as they could readily be applied to full-scale clinical CT scans.

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fracture to 8 weeks.

fracture; test surface = post-fracture.

Figure 3. Correlations between total joint Mankin score for arthritis at 8 weeks post-fracture and post-fracture joint incongruity.

Axial Deviation (%)

See pages 47 - 108 for financial disclosure information.

Decreased Bone Density in Geriatric Patients Does Not Lead to Inferior Outcomes After Open Reduction and Internal Fixation of Tibial Plateau Fractures

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Purpose: Operative fixation of periarticular fractures in elderly patients with poor bone quality can be challenging. Studies suggest that these patients may experience a higher rate of implant failure and poorer clinical outcomes when compared to younger cohorts, which has led many surgeons to pursue nonoperative management when feasible. Fractures of the proximal tibia (OTA 41.A-C), however, often present with significant articular involvement and surgical intervention is necessary to restore joint alignment and congruity. The purpose of this study was to determine if geriatric patients with decreased bone density had worse outcomes after open reduction and internal fixation (ORIF) of tibial plateau fractures when compared to younger patients with greater bone stock.

Methods: A prospective clinical registry of operatively treated tibial plateau fractures by a single surgeon was queried. Procedures were performed between 2003 and 2013 and all patients had a minimum of 1-year clinical outcomes scores including visual analog scale (VAS), Knee Outcome Survey Activities of Daily Living Scale (KOSADLS), the Lower Extremity Functional Scale (LEFS), and Short Form (SF)-36. For patients with preoperative CT scans, Hounsfield unit (HU) measurements were calculated by two reviewers on a GE Picture Archiving and Communication System (PACS) by creating three regions of interest on consecutive axial slices within the metaphyseal region of the distal femur. Values were averaged to generate a mean HU measurement, which was compared to available bone mineral densities (BMDs) for the femoral neck and lumbar spine as determined by bone densitometry (DXA). Clinical outcomes and HU measurements were analyzed between geriatric (age 65 or older) and nongeriatric cohorts.

Results: 93 patients were included for study, including 28 geriatric patients with a mean age of 73 years (range, 65-85) and 65 nongeriatric patients, mean age 48 years (range, 20-64). Cohorts were similar with regard to Schatzker classification and medical comorbidities including diabetes, hypertension, a history of smoking or alcohol abuse, and peripheral vascular disease. The nongeriatric cohort did have a significantly greater body mass index (27 vs 24, P = 0.03). HU measurements demonstrated an almost perfect intraclass correlation (ICC = 0.97), a strong correlation with lumbar BMD (r = 0.5), and a very strong correlation with femoral neck BMD (r = 0.7). HU measurements for nongeriatric patients were significantly greater than geriatric patients (136.4 vs 101.1, P <0.005), and there was no significant difference seen between the two cohorts with regard to 1-year clinical outcome scores (Table 1).

Conclusion: Although our cohort of geriatric patients demonstrated significantly decreased bone density when compared with a younger cohort, there was no significant difference observed in subjective 1-year clinical outcomes after ORIF of tibial plateau fractures. Clinicians can use this information to counsel patient with regard to expected results postoperatively. Further, presumed inferior bone quality should not deter treating surgeons from operating on elderly patients with tibial plateau fractures as they can have similar results at 1 year.

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Table 1

One-year clinical outcomes comparing geriatric and
nongeriatric patients treated operatively for tibial plateau fractures.

	Geriatric	Non-Geriatric	p-value
VAS	1.51	1.1	0.3851
KOS	79.9	83	0.3901
LEFS	69.7	78.21	0.0514
SF-36 PCS	45.8	48.9	0.1361
SF-36 MCS	51.2	54.8	0.0824

PCS = Physical Component Summary; MCS = Mental Component Summary

Plateau Indicators for Intervention after Operative Treatment (PIVOT) Score Identifies Patients at Risk of Poor Functional Outcome After Tibial Plateau Fracture

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Purpose: The ability to predict postoperative outcomes following the surgical management of tibial plateau injuries would help identify patients at risk of diminished functional outcomes for whom aggressive interventions may provide benefit. This study seeks to develop a simple score that can accurately predict functional outcomes for patients following operative management of tibial plateau fractures.

Methods: 228 operative tibial plateau fractures treated at a single institution were prospectively followed and included in this study. Demographics, injury classification, radiographic measurements, and Short Musculoskeletal Function Assessment (SMFA) scores were collected at routine intervals. Since total SMFA scores were found to plateau 6 months postoperatively in our cohort, this time point was chosen as the predictive target. The diminished outcome cohort (DOC) was defined as any patient with a functional SMFA subdomain greater than 10 points above the mean. Logistic regression was used to build a predictive formula for cohort membership (PIVOT Score) (Figure 1). No outliers were removed. Odds ratios (ORs) were calculated and are reported as 95% confidence intervals. An area under the receiver operator characteristic curve (AUROC) value was calculated to define the overall predictive capacity.

Results: At the 6-month postoperative time point, significant predictors of poor outcome were male gender (OR = 0.09-0.75; P = 0.013), Caucasian race (OR = 0.03-0.36; P = 0.0004), smoking history (OR = 1.81-28.33; P = 0.005), age (OR = 1.02-1.11; P = 0.003), and fracture pattern involving the tibial spine (OR = 1.97-16.48; P = 0.001). The final formula (Figure 1), created through logistic regression, was found to be a significant predictor of poor outcome (Nagelkerke R Square = 0.45; Hosmer and Lemeshow = 0.39, AUROC = 0.86). After assigning every patient a PIVOT Score, we identified 2 cutoff values that divided the cohort into 3 groups. Below 25% (low risk), 7% of patients had a diminished outcome. Between 25% and 50% (intermediate risk), 46% of patients had a diminished outcome. Above 50% (high-risk), 72% of patients had a diminished outcome.

Conclusion: The PIVOT Score is a significant predictor of 6-month diminished functional outcome. Patients scoring >25% are considered either intermediate or high risk for a diminished functional outcome. Early interventions aimed at improving functional outcomes can be targeted to these patients.

Figure 1: Tibial Plateau Diminished Outcome Score
Probability of Diminished Outcome = $1 / (1 + exp(-(-3.38-1.38*MALE)$
2.27*WHITE+1.97*SMOKER+0.06*AGE +1.74*TIBIALSPINE)))

Male (dichotomous variable; 1- yes, 0 - no); White (dichotomous variable; 1- yes, 0 - no); Smoker (dichotomous variable; 1- yes, 0 - no); Age (continuous variable); Tibial Spine Involvement (dichotomous variable; 1- yes, 0 - no)

Objective Metric of Energy Absorbed in Tibial Plateau Fractures Corresponds Well to Clinician Assessment of Fracture Severity

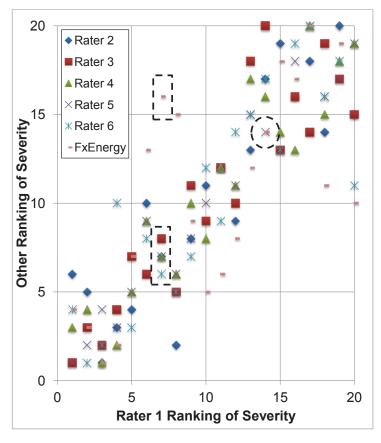
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Background/Purpose: Outcomes of intra-articular fractures are influenced both by acute mechanical damage and by residual chronic changes in joint loading. The extent of damage sustained in the acute setting reflects the energy absorbed in creation of the fracture; therefore, fracture energy can be expected to substantially influence clinical outcomes. Previous investigations have demonstrated that objective CT-based quantification of fracture energy in pilon fractures correlates with surgeon assessment of injury severity and 2-year radiographic outcomes. It is not clear whether these findings can be extrapolated to other articular fracture types. In this work, we explored whether this technique of fracture energy measurement could be used to stratify the severity of tibial plateau fractures. Specifically, we hypothesized that a CT-based measure of fracture energy would correspond to subjective surgeon assessment of fracture severity. We tested the hypothesis by comparing surgeon rank ordering of fracture severity for a series of tibial plateau fractures with CT-based measurements of fracture energy.

Methods: Twenty fractures were selected from a series of 50 tibial plateau fractures to span a full spectrum of severity. Fracture classification ranged from OTA 41-B1 to 41-C3. Six fellowship-trained orthopaedic trauma surgeons independently rank-ordered the fractures in order of severity using AP and lateral knee radiographs. The only instructions given to the raters were to rank the cases in order of least to most severely injured. Subjectively, they used the number and size of fragments, the amount and direction of displacement, percentage of articular surface involved, and whatever other features they felt were important based on their clinical experience. CT-based image analysis techniques were used to quantify the fracture energy. The software identifies all fracture fragments on CT imaging and calculates the amount of bone surface area liberated by the fracture. The previously validated algorithm incorporates fracture liberated surface area and bone density to provide the fracture energy measurement. The agreement between fracture severity assessments made by the surgeons and the ranking by fracture energy measurement was tested by computing their concordance. A pair of cases' injury severity rankings was deemed concordant if the case with the higher ranking of injury severity for one rater also had the higher ranking for a second rater. Simply put, the rate of concordance is the number of concordant pairs divided by the total number of possible pairings.

Results: Concordance between the six orthopaedic surgeons ranged from 82% to 93%. Concordance between surgeon severity ranking and fracture energy ranged from 73% to 78% (Fig. 1).

Figure 1: Representative rank-ordering of fracture severity by six orthopaedic trauma surgeons and by fracture energy. The y-axis represents severity ranking as assigned by raters 2-6 and according to the calculated fracture energy. The x-axis represents the rank ordering of rater 1. As an example, there was high agreement between rater 1 and raters 2-6 at rater-1 injury number 7, but this fracture's rank according to fracture energy calculation was much higher (black dashed boxes). At rater-1 injury number 14, the rank according to fracture energy was the same as the rank assigned by raters 1 and 5 (dashed circle).



Conclusion: There is a high level of agreement between surgeon assessment of tibial plateau fracture severity and CT-based measurement of fracture energy. In addition, agreement among six surgeons with extensive clinical experience judging injury severity was excellent. Taken together, these results confirm that a CT-based method of calculating fracture energy accurately portrays fracture severity as judged clinically for tibial plateau fractures and provides an objective way to quantify injury severity. In addition, it is likely this tool will be clinically useful as there was excellent surgeon agreement on fracture energy and clinical outcomes. Funding: Research reported in this abstract was supported by the National Institute of Arthritis and Musculoskeletal and Skin Diseases of the National Institutes of Health under award number R21AR061808. The research was also aided by a grant from the Foundation for Orthopaedic Trauma.

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The Effect of Soft Tissue Injuries on Clinical Outcomes Following Tibial Plateau Fracture Fixation

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Purpose: Tibial plateau fractures (OTA 41A-C) have a high incidence of soft-tissue injuries with rates of meniscal and ligament tears ranging from 47% to 99%. Previous studies have focused on injury patterns that are associated with these soft-tissue injuries. However, the clinical significance and the indications for surgical treatment of meniscal and ligament tears in the setting of tibial plateau fractures have not been established. The purpose of this study was to determine if soft-tissue injuries and subsequent secondary surgeries altered clinical outcomes following fixation of tibial plateau fractures.

Methods: A prospective database of operatively treated tibial plateau fractures by a single surgeon from 2004-2012 was used to identify patients. Inclusion criteria consisted of patients with injury radiographs, preoperative knee MRI, and a minimum of 12 months of clinical outcomes. MRI analysis was performed prior to operative fixation by a fellowship-trained musculoskeletal radiologist to detect tears in the medial and lateral menisci and complete ruptures of the anterior cruciate ligament (ACL), posterior cruciate ligament (PCL), medial collateral ligament (MCL), and lateral collateral ligament (LCL). Standard anterolateral and / or posteromedial approaches were used for fracture fixation as indicated by fracture pattern. Lateral meniscal tears were routinely repaired following lateral submeniscal arthrotomy, whereas other soft-tissue injuries were not addressed acutely. Clinical outcomes included the Knee Outcome Survey Activities of Daily Living Scale (KOSADLS), the Lower Extremity Functional Scale (LEFS), the Short Form (SF)-36, and knee range of motion (ROM) at the most recent postoperative visit. Subsequent secondary soft-tissue surgeries and arthroplasties were also recorded at final follow-up.

Results: 82 patients were included in the study. Average patient age was 54 years (range, 13-87), and 51% were male. 55 fractures (67%) were classified as Schatzker I or II, and the remaining 27 (33%) were classified as Schatzker IV, V, or VI. Postoperative clinical outcome scores were obtained at a mean of 31 months (range, 12-111). Using MRI to diagnose soft-tissue injuries, 49 patients (60%) had a lateral meniscal tear and 32 patients (39%) had a medial meniscal tear. MCL ruptures were seen in 23 patients (28%), LCL ruptures in 9 patients (11%), ACL ruptures in 8 patients (10%), and PCL ruptures in 2 patients (2%). 33 patients (40%) were diagnosed with injuries to multiple structures. Only four patients (5%) had a secondary soft-tissue surgery and one patient (1%) underwent total knee arthroplasty at final follow-up. Patient-reported outcomes (KOSADLS, LEFS, SF-36) and ROM assessments were not significantly different in patients with and without medial meniscal tears, in patients with and without lateral meniscal tears, and in patients with and without MCL ruptures. Patients with LCL, ACL, and PCL ruptures were too few for meaningful analyses.

Conclusion: While injuries to menisci and ligaments are common in patients with tibial plateau fractures, the clinical significance and treatment algorithms for these injuries have not been defined. In this cohort of patients with operative tibial plateau fractures, we confirmed a high frequency of soft-tissue injuries using MRI. With a minimum of 12 months of follow-up in these cohorts, meniscal and MCL injuries did not significantly affect clinical outcomes. Only five patients (6%) underwent a secondary soft-tissue surgery (4) or arthroplasty (1) at midterm follow-up. Given the small number of patients with other ligament injuries in this cohort, subsequent studies in larger cohorts will be important to pursue these results.