Fixed-Angle Versus Polyaxial Locking Plate Fixation Systems for Periprosthetic and/or Osteoporotic Distal Femoral Fractures

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Background/Purpose: Contemporary fixation of distal femoral fractures, especially in the presence of poor bone stock and/or of an ipsilateral knee arthroplasty, refers to the use of precontoured locking plating systems. They have evolved to include stainless steel or titanium alloy plates, with different thickness, shapes, external targeting jigs, and reduction tools for minimal invasive surgery, multidirectional or fixed-angle locking options. We hypothesized that the use of a plating system of newer design, adopting the concept of polyaxial technology and having options of insertion of different screw designs at the metaphyseal part, is equally effective in comparison to the first generation of periarticular distal femoral locking plates.

Methods: A prospective, concealed randomized clinical trial was conducted from 2010 between 4 UK centers, with selection criteria on osteoporotic and/or periprosthetic distal femoral fractures, excluding patients with dementia, loose femoral components, preinjury impaired mobility, or associated trauma influencing ambulation. The primary objective of the study was to test the hypothesis that the Polyax-BIOMET achieves similar union rates at comparable time frames with the LISS-DePuy/SYNTHES. The secondary objectives of this study included the comparison of intraoperative details (ie, closed vs open reduction, length of incisions, duration of surgery), the comparison of radiological characteristics of the plate/bone constructs (stiffness score, plate/screw density, plate span width, working length), the comparison to the incidence of nonunion, malunion, hardware failure, complications, secondary surgery, and the functional outcome according to the Oxford knee score, and the EuroQol (EQ)-5D. All fractures were classified according to the AO/OTA system, as well as the Rorabeck system, and bone density using the Singh score. The analysis of the accumulated data was a logistic regression of union on covariates that included use of either system with variables including: age, sex, smoking, mechanism, fracture type, Singh index, timing of ambulation progress, complication rates, quality-of-life score, and knee function. Statistical significance was set to the P value <0.05.

Results: In a 1:1 ratio, 40 patients were recruited following informed consent, and completed a 12-month follow-up. The overall union rate at 6 months was 73%, at 9 months was 90%. The 4 overall nonunions led all to revision surgeries, 2 exchanging to a retrograde femoral nail, 2 by using bone grafting without revision of osteosynthesis. Malunion was evident in 2 cases, one with 17° of recurvatum and 10° valgus, and one with 10° of recurvatum. The mortality rate at 1 year was 10%. Between the 2 plating systems statistical analysis verified

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no significant differences in regards to the demographics (mean age, 78 years (range, 58-99); gender 87.5% females), the mechanism of injury (falls from standing height 87.5%), the impact of comorbidities (Charlson score mean 5 (Range, 2-9), Singh score mean 2 (range, 1-4), the ratio of periprosthetic fractures (32%), the duration of surgery (mean 86 min; range, 55-192), the surrogate length of incisions (mean 15 cm; range, 7-33 cm), the stiffness score (mean 1; range, 0-3), the percentage of filled holes (mean 50.7%; range, 33.6-88.3%), the plate span width (mean 2.35; range,1.3-4.3), the working length (mean 135 cm; range, 46-227 cm), the ratio of working length/fracture length (mean 1.56; range, 0.75-3.27), the hospital stay (21 days; range, 10-43), and the ambulatory progress, as well as functional, quality of life and pain scoring at 6, 9, and 12 months. The number of open reductions (29% vs 19%) were more in the LISS group, although more complex fractures according to the AO/OTA system were managed in the later group (22.5% LISS 33.A1 vs 77.5% LISS 33.A2/3/B/C instead of 15% vs 85% POLYAX). Another significant difference favoring the POLYAX group was the minimal medial prominence of metaphyseal screws, which occurred in just 1 case versus in 6 cases of the LISS group, and led to secondary surgery in 3 of them.

Conclusion: The primary hypothesis was verified, with very good union rates for both systems, and limited implant-related complications. Good reduction, mechanically sound construct, and respect of the local fracture biology appears to be more important than the particular plate characteristics. The new generation of locking plates offer versatility, better use of locking corridors in poor bone stock, less screw-related soft-tissue impingement, and a short learning curve.

Δ The Effect of Knee Flexion Contracture on Outcomes of Distal Femur Fractures

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Background/Purpose: Injuries about the knee may result in stiffness. The development of a flexion contracture is common after distal femur fracture, yet the effect of a flexion contracture on outcomes has never been evaluated. The purpose of this study is to compare the demographics and validated outcomes of patients with and without a flexion contracture after operative treatment for distal femur fractures.

Methods: As part of a multicenter randomized trial of adult patients with A1-3 or C1 (undisplaced joint injuries) distal femur fractures, data on contractures were gathered prospectively. Patients were treated by intramedullary (IM) nail or locked plate. Demographic data, ambulatory ability, and validated outcomes including SMFA (Short Musculoskeletal Function Assessment), Bother Index, and EQ health index were obtained at 3,6, and 12 months postoperatively. Range of motion was tested at each interval. Flexion contractures were defined by a lack of full extension and were documented in degrees. A contracture was defined as 10° to account for measurement variation and be certain that a noticeable

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contracture was present. Comparisons were made using a Fisher exact test for categorical variables and t tests for continuous variables.

Results: 126 patients were enrolled and followed for >6 months. Of these, 98 were examined for contracture in person and had data at 3 months, 88 at 6 months, and 73 at 1 year. Patients who filled out outcome forms but were not examined in person were excluded. There were 55 men and 43 women aged 16 to 90 years (mean 51). The average ISS was 12.6 (range, 9-43) and 24 (24%) were open. A flexion contracture of 10° was present in 16% at 3 months and 14% at 1 year. Patients did not show improvement between 3 months and 1 year. There was no difference in contracture development between patients treated with nails versus plates (P = 1), open versus closed fractures (P = 0.24), or by gender (P = 0.5). Patients who developed a contracture were slightly older than those who did not, 65 ± 14 versus 52 ± 19 (P = 0.01). Outcome data are summarized in the table. Patients without a contracture had better outcomes; the SMFA score, walking distance, and stair climbing all reached statistical significance. Patients with contracture could walk less than 5 blocks and those without could walk more than 10 or were unlimited. Flexion contracture was not associated with a difference in flexion at any time point. Finally, patients with a flexion contracture did not show improvement in their SMFA score over time while those without a contracture showed steady improvement (bar graph: 3,6, and 12 months).

Conclusion: Flexion contracture after distal femur fracture occurs in approximately 15% of patients, is typically present by 3 months, and does not improve by 1 year. Outcomes for patients with contractures are worse than in those without contractures and minimal improvement is seen over the first year. Walking and stair climbing are substantially diminished.

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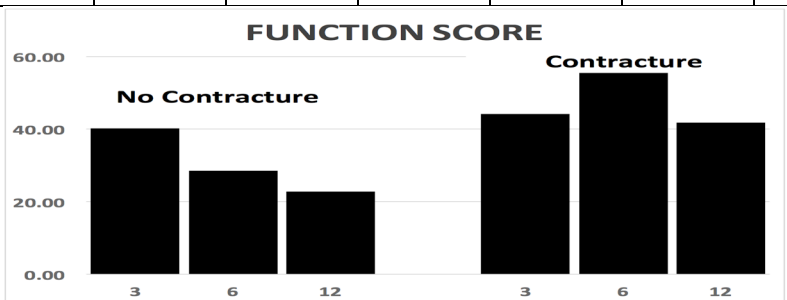
One Year Results

Group	SMFA	Bother Index	EQ-Health State	Avg. Flexion	Walking (1 – 6) 1 best	Stairs (1 – 5) 1 best
Contracture	41.8	35.8	0.6	107°	4.1	3.4
No Contracture	22.8	25.1	0.8	118°	2.6	2.4
P value	***0.038***	0.29	0.12	0.41	***0.007***	***0.017***



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.

Malalignment After Minimally Invasive Plate Osteosynthesis in Distal Femoral Fractures

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Background/Purpose: Minimally invasive plate osteosynthesis (MIPO) is a preferred operative treatment for distal femoral fractures. Although it has the advantage of excellent bony union, malalignment is a significant concern because of the indirect reduction of the fracture. The purpose of this study was to evaluate radiologic alignment after MIPO for distal femoral fractures.

Methods: Of 138 patients with unilateral distal femoral fractures who underwent MIPO in our hospital from 2005 to 2013, we enrolled 52 patients in whom bilateral rotational alignment could be assessed by CT. The patients included 32 men and 20 women, with a mean age of 53.4 years. Thirteen patients had femoral shaft fractures (according to the AO-OTA classification: 32-A, n = 2; 32-B, n = 6; 32-C, n = 5), whereas 39 patients had distal femoral fractures (33-A, n = 7; 33-C, n = 32). Coronal and sagittal alignments were assessed by using simple radiography, whereas rotational alignment was assessed by using CT. According to the difference between the affected and unaffected side, we divided the patients into 4 groups: excellent, good, fair, and poor. Thereafter, we determined which factors can lead to malalignment, including fracture location (distal femoral shaft fracture or metaphyseal fracture), fracture pattern (simple fracture, n = 15; complex fractures, n = 37 patients), coronal and sagittal alignment, and the presence of combined ipsilateral long bone fractures.

Results: Coronal and sagittal alignment were satisfactory in 96.2% (average 2.8°, 0.2°-10.3°) and 98% (average 2.2°, 0-8.1°) of the subjects, respectively, whereas the rotational alignment was satisfactory in 57.7% of patients. The leg length discrepancy was satisfactory in 92.3% of the patients (average 10.9 mm, -9 to 112 mm). Concerning rotational malalignment, an unsatisfactory result was obtained in 48.6% of subjects with complex fractures and 26.7% of subjects with simple fractures (P = 0.114, Pearson's chi-square test). No significant correlation was noted between the angular deformity in the coronal and sagittal planes and the degree of rotational alignment (P = 0.691, multiple regression analysis). Even if good alignment of the coronal and sagittal planes achieved after surgery, this does not guarantee good postoperative rotational alignment.

Conclusion: Regardless of the fracture pattern, rotational malalignment may develop at an extremely high rate after MIPO for distal femoral fractures, whereas a satisfactory alignment is obtained concerning coronal and sagittal alignment. Extreme caution should be taken to avoid rotational malalignment using this technique.

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Trochanteric Entry Femoral Nails Yield Better Postoperative Femoral Version and Lower Revision Rates than Retrograde and Piriformis Entry Nails: A Large Cohort Multivariate Regression Analysis

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Purpose: Intramedullary nailing (IMN) has become the standard of care for the treatment of most femoral shaft fractures. Different IMN options include trochanteric and piriformis entry as well as retrograde nails, which may result in varying degrees of femoral rotation. The objective of this study was to analyze postoperative femoral version between the three types of nails and to perform a regression analysis controlling for any potential confounding factors to delineate any significant differences in femoral version and revision rates.

Methods: 417 consecutive patients with femur fractures were treated with an IM nail at a Level I trauma and tertiary referral center. Of these patients, 316 met inclusion criteria and obtained postoperative CT scanograms to calculate femoral version and were thus included in the study. In this study, our main outcome measure was the difference in femoral version (DFV) between the uninjured limb and the injured limb. Femoral version was determined on postoperative CT scanograms by a trauma fellowship-trained orthopaedic surgeon. Statistical analysis included initial univariate regression followed by forward, stepwise multivariate regression analysis to compare DFV. Covariables included gender, age, body mass index (BMI), ethnicity, mechanism of injury, operative side, and open fracture.

Results: Total number included for analysis included 316 patients. Piriformis entry nails made up the majority (n = 141), followed by retrograde (n = 108), then trochanteric entry nails (n = 67). Univariate regression analysis revealed that a lower BMI was significantly associated with a lower DFV (P = 0.006). Controlling for possible covariables, multivariate analysis yielded a significantly lower DFV for trochanteric entry nails than piriformis or retrograde nails (7.9° ± 6.10° vs 9.5° ± 7.4° vs 9.4° ± 7.8°, P <0.05). Using revision as an end point, trochanteric entry nails also had a significantly lower revision rate, even when controlling for all other variables (P <0.05).

Conclusion: Comparative, objective comparisons of DFV between different nails based on entry point revealed that trochanteric nails had a significantly lower DFV and a lower revision rate, even after regression analysis. However, this is not to state that the other nail types exhibited abnormal DFV. Translation to the clinical impact of a few degrees of DFV is also unknown. Future studies of more in-depth study of the intricacies of femoral version may lead to improved technology in addition to potentially improved clinical outcomes.

Tables

Table 1. Cohort demographic and injury data (n=316)

Parameter	Value
Mean Age (SD), yrs	31.1 (13.6)
Gender (%)	
Male	261 (82.6)
Female	55 (17.4)
Mean BMI (SD)	27.2 (5.2)
Ethnicity (%)	
Black	181 (57.3)
White	65 (20.6)
Hispanic	59 (18.7)
Asian	1 (0.3)
Other	10 (3.2)
Injury Side (%)	
Left	144 (45.6)
Right	172 (54.4)
Mechanism of Injury (%)	
MVA	133 (42.1)
GSW	64 (20.3)
Pedestrian Struck	39 (12.3)
Fall	34 (10.8)
MCA	33 (10.4)
Crush	9 (2.8)
Assault	4 (1.3)
Open Fx (%)	43 (13.6)

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Table 2. Mean DFV for piriformis, trochanteric and retrograde femoral IMN along with univariate regression analysis results identifying any significant factors for each corresponding femoral IMN with lower and upper bound CI (95%). No significant impact was noted for any of the variables on mean DFV on any of the nails except a significantly correlated DFV with BMI in trochanteric start nails.

Nail Type	Mean DFV, Degrees (SD)	Variable	p value	95% CI Lower Bound	95% CI Upper Bound
Piriformis		**Gender**	0.48	-2.51	5.28
n=141	9.5 (7.4)	**Age**	0.83	-0.09	0.12
		BMI	0.78	-0.35	0.26
		Ethnicity	0.50	-2.05	1.00
		Mechanism of Injury	0.51	-0.48	0.96
		Operative Side	0.70	-2.17	3.22
		Open Fx	0.68	-3.30	5.02
Trochanteric		**Gender**	0.12	-8.75	0.99
n=67	7.9 (6.1)	**Age**	0.16	-0.037	0.23
		BMI*	***0.006***	***-0.94***	***-0.16***
		Ethnicity	0.27	-2.73	0.77
		Mechanism of Injury	0.08	-0.11	1.64
		Operative Side	0.80	-2.69	3.46
		Open Fx	0.18	-1.64	8.45
Retrograde		**Gender**	0.051	-0.03	8.57
n=108	9.4 (7.8)	**Age**	0.18	-0.05	0.25
		BMI	0.79	-0.35	0.46
		Ethnicity	0.35	-0.91	2.54
		Mechanism of Injury	0.80	-0.78	1.01
		Operative Side	0.42	-1.92	4.61
		Open Fx	0.53	-6.18	3.19

***p<0.05**

Table 3. Multivariate regression comparison of mean DFV between piriformis entry, trochanteric entry, vs retrograde femoral nails controlling for gender, age, BMI, ethnicity, mechanism of injury, operative side, and open fracture.Trochanteric entry nails had significantly lower mean DFV than piriformis start and retrograde nails.

Nail Type	Mean DFV, Degrees (SD)
Piriformis (n=141)	9.5 (7.4)
Trochanteric (n=67)	7.9 (6.1)*
Retrograde (n=108)	9.4 (7.8)

***p<0.05**

Table 4. Trochanteric entry nails had a significantly lower rate of revision than piriformis entry and retrograde nails, however, this significant difference becomes close, but not significant when analyzing via ordinal regression analysis controlling for gender, age, BMI, ethnicity, mechanism of injury, operative side, open fracture and entry point. Significant negative predictors for revision included associated open fracture.

				95% CI	
		Variable	p value	Lower Bound	Upper Bound
Revision[γ] (%)	**n (%)**	**Gender**	0.53	-1.17	2.27
No	304 (96.2%)	**Age**	0.27	-0.10	0.03
Yes	12 (3.8%)	**BMI**	0.76	-0.10	0.13
Piriformis	9 (75%)	**Ethnicity**	0.38	-1.31	0.50
Trochanteric	**0 (0%)***	**Mechanism of Injury**	0.25	-0.13	0.51
Retrograde	3 (25%)	**Operative Side**	0.97	-1.20	1.25
		Open Fx**	**0.03**	**-2.82**	**-0.11**
		Nail Entry	0.05	-1.61	0.01

[γ]Revision was defined as reoperation. All piriformis revisions were indicated for clinically significant malrotation; 2/3 retrograde nails were revised for malrotation, the other for non-union requiring an exchange nail.
*p=0.005 via chi-square analysis.
**p<0.05 via ordinal regression analysis.

Table 5. Subgroup analysis of IMN revisions secondary to malrotation

Nail Type	Piriformis (n=9)	Retrograde (n=2)
Mean DFV (SD)	21.9 (7.8)	19.1 (22.2)
Number Proximal Fragment Malrotation (%)	3 (33)	0 (0)
Number Distal Fragment Malrotation (%)	5 (56%)	1 (50)
Number Both Fragment Malrotation (%)	1 (11)	1 (50)

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Sagittal Femoral Bow Is Dependent on Bone Density

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Background/Purpose: Despite implant modifications to better match the sagittal bow of the femur, anterior cortical perforation and abutment remain prevalent with intramedullary nail fixation of proximal femur fractures. Prior femoral bow analyses have demonstrated an association between femoral bow, gender, age, and length but none with bone density. We tested the hypothesis that femoral bow is dependent on bone density.

Methods: 167 patients with a positron emission CT scan and a DXA (dual xray absorptiometry) scan within 1 year of each other were analyzed. The sagittal radii of curvature (ROCs) of the outer and inner anterior cortical boundaries of the femur were determined with a novel custom MATLAB script. Associations between age, gender, femoral length, World Health Organization (WHO) T-score class, and femoral ROC were determined with regression analyses.

Results: Study included 138 females and 29 males, mean age 59 years (standard deviation [SD] = 15). Mean femur length was 42.7 cm (SD = 27.0). Average time between CT and DXA was 174 days (SD = 108). Mean outer and inner anterior ROCs were 149.5 cm (SD = 56.7) and 147.5 cm (SD = 54.4), respectively. 68, 81, and 18 patients had normal, osteopenic or osteoporotic hips, respectively, while 79, 60, and 23 had normal, osteopenic or osteoporotic lumbar spines, respectively. Five lumbar spines were too degenerative for bone density assessment. The ROC of the outer, but not the inner, anterior cortical boundary of the femur depended on WHO bone density classification at the hip ($P = 0.034$ for outer, $P = 0.114$ for inner). Femoral ROC was not dependent on lumbar spine bone density. In addition to bone density, femoral length was associated with ROC ($P = 0.015$ for outer, $P = 0.049$ for inner) while age and gender were not.

Conclusion: The sagittal bow of the femur depends on bone density. Caution should be taken during guide wire introduction, reaming, and intramedullary nail insertion in low radii of curvature femurs due to their low bone density, or alternative treatment options should be considered.

Immediate Weight Bearing as Tolerated has Improved Outcomes Compared to Non-Weight Bearing after Intramedullary Fixation for Subtrochanteric Fractures

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Background/Purpose: Subtrochanteric femur fractures are commonly managed with operative fixation; however, they have a high complication rate including malunion, nonunion, and implant failure because of cortical comminution and stress concentration during stance. While the angled blade plate has been the gold standard for treatment, the last decade has seen a rise in the use of intramedullary fixation with new biomechanical data. Previous studies demonstrated satisfactory outcomes with a soft-tissue-friendly approach and avoiding varus malreduction; however, these studies utilized protected weight bearing for 6 to 8 weeks. The literature clearly demonstrates the benefit of early weight bearing in trauma patients and the safety of statically locked intramedullary nails in highly comminuted femoral shaft fractures. The literature has limited data to support immediate postoperative weight bearing after intramedullary fixation of subtrochanteric femur fractures. Our hypothesis was that immediate postoperative weight bearing as tolerated (WBAT) for subtrochanteric femur fractures would result in decrease length of stay (LOS) compared to non-weight bearing (NWB).

Methods: After IRB approval a retrospective cohort study was conducted from August 2009 to November 2015 at two Level I trauma centers. Inclusion criteria were skeletally mature patients with a subtrochanteric femur fracture (OTA 31A3.3 and 32A1.1-32A3.3). Exclusion criteria was presentation GCS (Glasgow Coma Scale) below 8, orthopaedic injury affecting weight bearing, thoracic or abdominal injury requiring surgery, periprosthetic fracture, and bisphosphonate-related atypical subtrochanteric femoral fractures. 69 patients met the inclusion criteria and underwent intramedullary fixation. These cohorts were compared using Wilcoxon rank sum test for statistical significance. Patients were evaluated regarding age, sex, mechanism of injury, implant type, implant size, degree of comminution, and fracture type. Primary outcome was total LOS, with subgroup analysis of high-energy cohort.

Results: The mean patient age was 55.7 years (range, 19-95) with a bimodal distribution of 36.5 (range, 19-66) and 73.4 (range, 59-95) for high and low-energy, respectively. Implant choice was predominantly cephalomedullary nail (83%, n = 57), followed by reconstruction (13%, n = 9) and standard piriformis entry (4%, n = 3). The nail diameter was predominantly 10 mm (75%, n = 52) followed by 11.5 mm (13%, n = 9). Overall the WBAT group had a decreased LOS compared to the NWB group (5.9 vs 4.5, P = 0.01). While the high-energy group had a longer overall LOS compared to the low-energy group (5.3 vs 4.4, P = 0.01),

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a subgroup analysis of high-energy patients with highly comminuted fracture patterns (Winquist-Hansen grade 3 or 4) had a decreased LOS when allowed WBAT as compared to NWB (5.1 vs. 7.0, P = 0.01). There was no statistical difference in the union rates or implant failures between groups.

Conclusion: This study demonstrates that immediate postoperative weight bearing of subtrochanteric femur fractures decreased length of stay and does not appear to increase the risk of implant failure or nonunion. Our data also suggest that in a high-energy cohort with highly comminuted subtrochanteric fracture patterns, immediate WBAT protocol may lead to decreased LOS and has similar safety with implant sizes of 10 mm. We plan to continue studying the effect of early WBAT on subtrochanteric fractures and the effect on patient-reported outcomes.

Δ Do We Really Understand the Patient Populations in Database Research: A Comparison of Femoral Shaft Fracture Patients in Three Commonly Used National Databases

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Purpose: Use of national databases has increased dramatically in the field of orthopaedics and orthopaedic traumatology. However, with the multitude of databases now being used to draw clinical conclusions, there has been little study of the differences in populations contained in various databases. The aim of the current study is to compare the populations of patients with femoral shaft fractures, a common high-energy orthopaedic injury, in three commonly used national clinical databases, in terms of age, comorbidities, and adverse events.

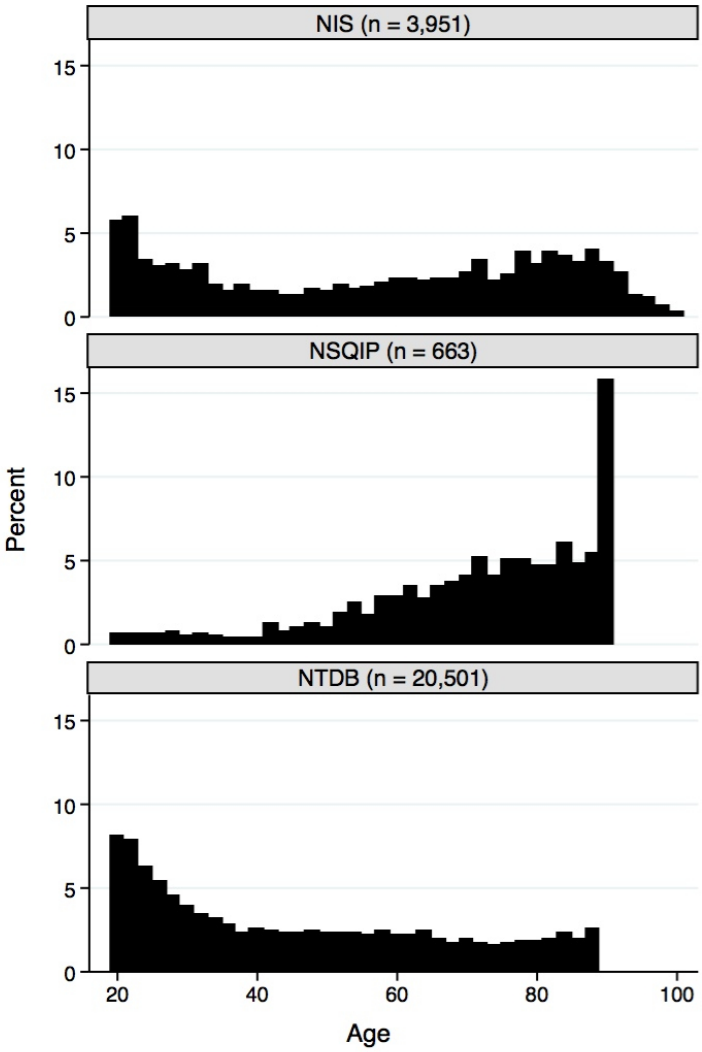
Methods: Patients with surgically managed femoral shaft fractures were identified in the Nationwide Inpatient Sample (NIS), National Surgical Quality Improvement Program (NSQIP), and National Trauma Data Bank (NTDB). Age, Charlson comorbidity index (CCI), individual comorbidities, and inpatient adverse events were compared between databases.

Results: The distributions of age (Figure) and CCI suggest a predominantly older population with more preexisting comorbidities in NSQIP (age [mean ± standard deviation] = 71.5 ± 15.6, CCI = 4.9 ± 1.9), and a younger population with fewer preexisting comorbidities in NTDB (age = 45.2 ± 21.4, CCI = 2.1 ± 2.0). Bimodal distributions in the NIS population suggest it includes a more mixed population (age = 56.9 ± 24.9, CCI = 3.2 ± 2.3). Differences in age and CCI were all statistically significant ($P < 0.001$). Differences in outcomes were also observed in the different database populations. In fact, the rate of adverse events varied from 21.6% in NIS to 9.1% in NSQIP ($P < 0.001$). Further, the rate of serious adverse events (death, cardiac arrest, myocardial infarction, stroke, thromboembolic event, or surgical site infection) varied from NTDB (7.4%) to NIS (5.1%); $P < 0.001$. Considering individual adverse events, the rate of thromboembolic events ranged from 4.2% in NTDB to 1.1% in NSQIP ($P < 0.001$). The rate of pneumonia ranged from 4.3% in NTDB to 1.5% in NSQIP ($P < 0.001$). The rate of urinary tract infection ranged from 12.1% in NIS to 2.8% in NTDB ($P < 0.001$).

Conclusion: Differences in populations contained in commonly used national databases are not always readily apparent. Care must be taken to fully understand these populations before performing or evaluating database research, as these differences clearly affect observed outcomes.

Δ OTA Grant

See pages 47 - 108 for financial disclosure information.



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.

Patient-Specific Injury Profiles Predict Organ Failure in Multiply Injured Patients

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Background/Purpose: Multiply injured patients (MIPs) sustain a composite of mechanical tissue damage, ischemic tissue damage, and hemorrhage-associated hypoperfusion that is specific to the individual injury. Metabolic response to injury is also highly variable and patient-specific. Collectively, individual injury and response characteristics affect complications and outcomes. While some MIPs demonstrate an uneventful recovery, other MIPs with seemingly similar injuries develop complicated clinical courses punctuated by wound problems (coagulopathy, infection, poor wound healing), systemic inflammatory response syndrome (SIRS), multiple organ failure (MOF), and death. Early identification of MIPs at risk for complicated clinical trajectories remains a diagnostic challenge. Current injury scoring systems are granular and do not account for patient-specific injury characteristics. In addition, these systems do not quantify patient response. They are of limited value in stratifying clinical trajectories and guiding treatment, including subsequent orthopaedic interventions. In this study, we explore a new paradigm by quantifying early (within 48 hours of trauma) individualized critical components of injury including mechanical tissue damage, magnitude and duration of shock, and acute metabolic response to establish a Patient-Specific Injury (PSI) score. We hypothesized that PSI scores would accurately stratify patient risk for MOF.

Methods: 72 consecutive adult (18-65 years) MIPs (ISS >18) admitted to the intensive care unit (ICU) for a minimum of 7 days were studied retrospectively. We collected vital signs and laboratory values during ICU admission, and accessed all admission imaging studies. Total body patient-specific mechanical tissue damage was quantified using a novel index (Tissue Damage Volume Score [TDVS]). TDVS calculates a volume (cm3) of every injury sustained by a patient based on measurements made from admission CT scans and radiographs. Total body TDVS was subdivided by tissue type and body region (head/neck, chest, abdomen, pelvis, extremities). Hypoperfusion was calculated by integrating elevated values of shock index (SI) (SI = heart rate/systolic blood pressure; SI >0.9 is a validated marker of hypoperfusion) over time to yield a patient-specific metric termed Shock Volume (SV). Patient-specific metabolic response was measured by calculating the difference of mean pH for the first 48 hours after injury from normal (7.40). TDVS, SV, and pH deviation were integrated into a PSI score. PSI scores were compared to Sequential Organ Failure Assessment (SOFA) scores with linear regression to determine correlation between PSI profiles and organ failure. The SOFA score is a validated outcome instrument that measures organ failure in trauma patients and was utilized as the primary outcome in this study.

Results: Total body PSI scores (Figure 1a) correlated well with organ dysfunction over the entire population. Pelvic PSI scores (Figure 1b) and abdominal PSI scores (Figure 1c) correlated more closely with organ dysfunction. Chest PSI scores corresponded to organ dysfunction, but the variability was greater (Figure 1d). There was minimal correlation between extremity and head/neck PSI scores and organ dysfunction (not shown).

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Conclusion: It has been postulated that the magnitude of mechanical and ischemic tissue injury and resuscitation dictate patient response and orchestrate clinical trajectories in MIPs. Our data demonstrated that patient-specific indices measured early during the injury period (mechanical tissue damage, hypoperfusion, metabolic response) collectively predicted subsequent organ dysfunction on an individual basis. PSI scores in patients sustaining axial trauma (chest, abdomen, and pelvis) were more accurate in predicting subsequent organ dysfunction. Such information could prove to be clinically relevant in timing interventions, including major orthopaedic operations. Although preliminary, this research offers a novel approach of applying personalized medicine to trauma patients.

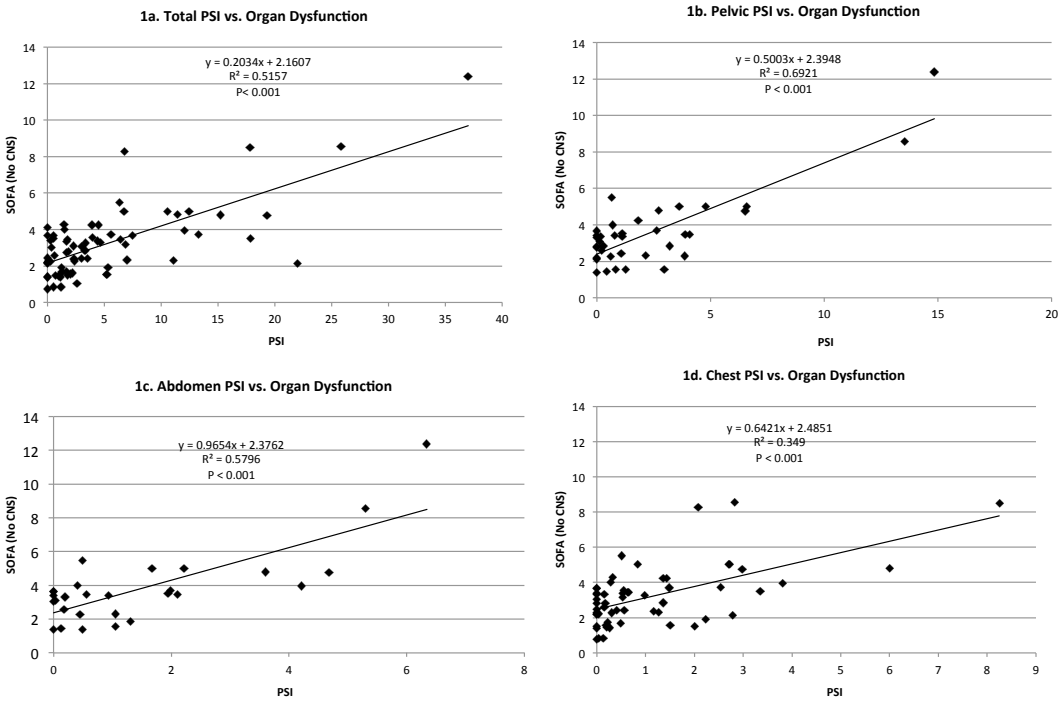

Figure 1: PSI Scores vs. organ dysfunction. Organ dysfunction was measured by SOFA scores. The CNS component was purposefully omitted from SOFA scores to improve clinical accuracy in an ICU patient population. Organ dysfunction correlated to PSI scores calculated from total body TDVS (Fig 1a), pelvis TDVS (Fig 1b), abdominal TDVS (Fig 1c), and chest TDVS (Fig 1d). PSI was most predictive of organ dysfunction in patients sustaining pelvic ($R^2 = 0.69$) and abdominal trauma ($R^2 = 0.58$).

Limb Salvage Versus Transtibial Amputation: A Comparison of Functional Gait Outcomes

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Background/Purpose: Several studies have compared outcomes of transtibial amputation patients and limb salvage patients with no clear advantage evident. With recent military conflicts resulting in significant numbers of lower extremity injuries, this debate has again come to the forefront. The recently developed Intrepid Dynamic Exoskeleton Orthosis (IDEO) has been shown to have superior functional results to other orthoses used with limb salvage. The purpose of this study is to determine if there is a difference in functional gait outcomes between patients with isolated traumatic below-knee single limb injuries treated with either a transtibial amputation or who use an IDEO and have undergone limb salvage procedures.

Methods: 24 IDEO and 99 transtibial amputation patients were studied in our instrumented gait lab from 2007 to 2014. Transtibial amputation patients with a gait study completed between 6 months and 1 year after walking without assistive devices were included, while IDEO patients were included if they had completed the "Return to Run" training program. Ten patients with amputations were matched by body mass index to the ten limb salvage patients. These two groups were then compared in regards to demographics and injury characteristics. Three-dimensional gait analysis data were collected with a 12-camera Motion Analysis Corporation system. Temporal spatial, kinetic (vertical ground reaction force), unified deformable (UD) power, work, and efficiency during walking at a self-selected speed were evaluated. A paired t test of the differences was utilized for statistical analysis.

Results: There were no significant differences between IDEO and amputation patients in regard to demographics or injury characteristics. IDEO patients walked with a significantly slower cadence ($P = 0.036$), spent less time on their affected limb in stance ($P = 0.045$), and more time in swing ($P = 0.019$) compared to transtibial amputation patients. Transtibial amputation patients and IDEO patients did not have significantly different vertical ground reaction forces. Transtibial amputation patients had significantly increased maximum positive power in the affected ($P = 0.004$) and unaffected ($P = 0.029$) limbs along with increased maximum negative power on the unaffected limb ($P = 0.035$) compared to the IDEO patients. There was significantly increased positive and negative work in the affected limb of amputation patients ($P = 0.0009$ and $P = 0.014$) and positive work in the unaffected limb ($P = 0.042$). There was no significant difference in the efficiency between the groups in either the affected or unaffected limb ($P = 0.174$).

Conclusion: Analysis of temporal spatial gait data showed statistically significant decreases in cadence, as well as diminished stance and increased swing times on the affected limb, consistent with a more antalgic gait pattern in IDEO patients. The UD power analysis demonstrated a more dynamic gait in transtibial amputation patients, with minimum and maximum peak values more closely resembling that of normative data. Thus in our sample of ten matched patients, those with a prosthesis had more dynamic functional outcomes compared to IDEO patients.

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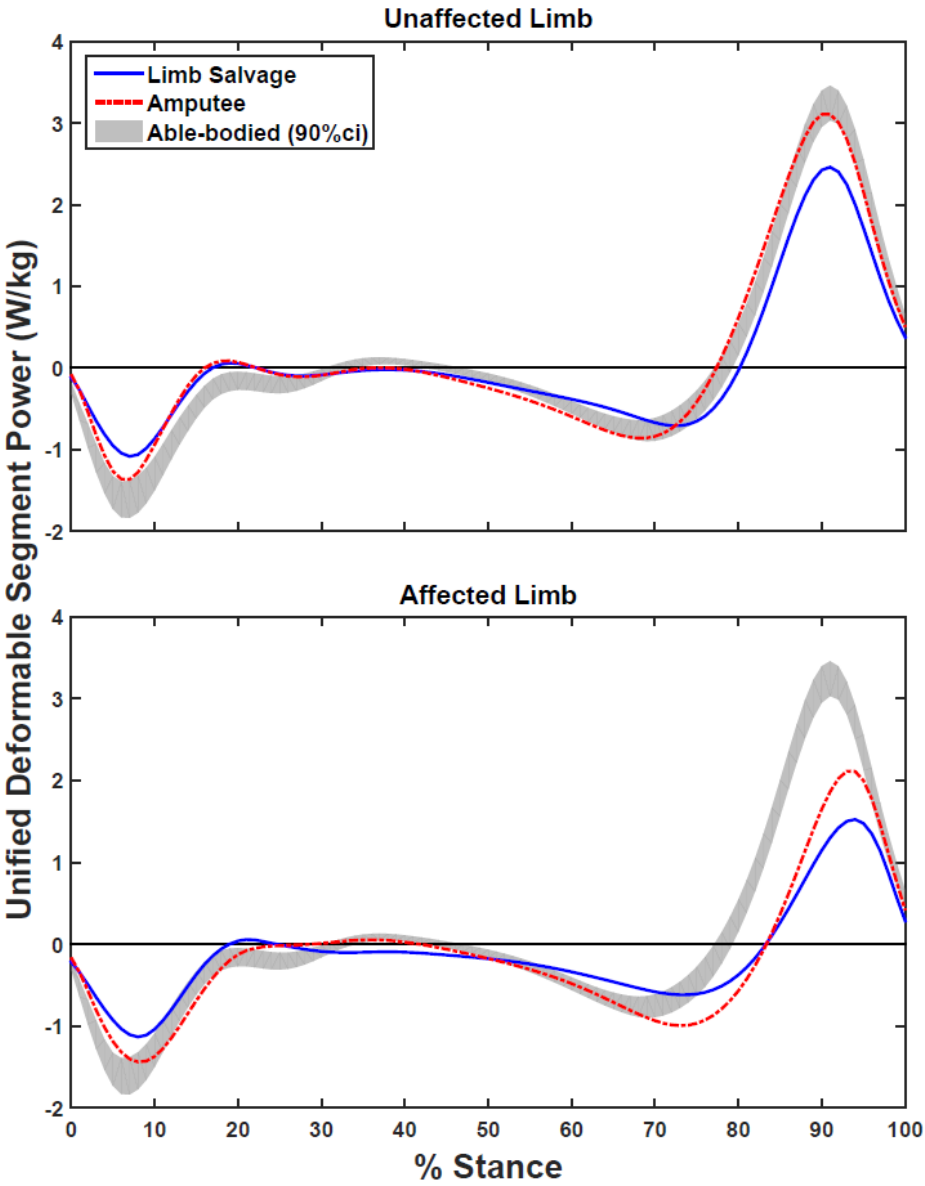

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Table 1. Temporal spatial gait parameters.

Parameter	Limb Salvage	Transtibial Amputation	*P*
Velocity (cm/sec)	1.26 ± 0.16	1.36 ± 0.10	0.071
Cadence (steps/sec)	104.72 ± 4.76	110.44 ± 6.86	**0.036**
Stride width (cm)	0.13 ± 0.03	0.12 ± 0.03	0.514
Stance time Aff (% gait cycle)	0.60 ± 0.01	0.61 ± 0.01	**0.045**
Stance time Un(% gait cycle)	0.63 ± 0.01	0.64 ± 0.02	0.696
Swing time Aff (% gait cycle)	0.40 ± 0.01	0.39 ± 0.01	**0.019**
Swing time Un (% gait cycle)	0.37 ± 0.01	0.37 ± 0.02	0.854
Stride length Aff (cm)	1.44 ± 0.14	1.48 ± 0.09	0.457
Stride length Un (cm)	1.44 ± 0.13	1.49 ± 0.09	0.340
Step length Aff (cm)	0.72 ± 0.07	0.76 ± 0.05	0.172
Step length Un (cm)	0.72 ± 0.07	0.72 ± 0.04	0.894

Aff: affected extremity, Un: unaffected extremity.

Table 2.Unified deformable segment power generation.

Segment power (W/kg)	Limb Salvage	Transtibial Amputation	*P*
Aff Max Positive	1.53 ± 0.38	2.14 ± 0.41	**0.004**
Un Max Positive	2.49 ± 0.53	3.21 ± 0.54	**0.029**
Aff Max Neg MS	-1.16 ± 0.37	-1.49 ± 0.55	0.128
Un Max Neg MS	-1.10 ± 0.31	-1.51 ± 0.59	**0.035**
Aff Max Neg LS	-0.64 ± 0.39	-1.04 ± 0.20	**0.005**
Un Max Neg LS	-0.77 ± 0.22	-0.90 ± 0.10	0.181

Aff: affected extremity, Un: unaffected extremity, Neg: negative, MS: mid-stance, LS: late stance.

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Increasing Severity of the Orthopaedic Trauma Association Open Fracture Classification (OTA-OFC) Correlates with Increasing Amputation Rate: A Prospective Multicenter Study

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Purpose: Open fractures are common and present unique challenges to orthopaedic surgeons. Most treatment decisions are based upon surgeon experience, estimated Gustilo-Anderson classification, and regional preferences. While widely used to describe open fractures in present practice, the Gustilo-Anderson system has demonstrated multiple flaws and was not originally described to be of prognostic use. The OTA Open Fracture Classification (OTA-OFC) represents a comprehensive classification system intended to be objectively obtained and of prognostic value. The OTA-OFC is a 3-level, 5-subclassification system that describes skin injury, muscle injury, arterial injury, bone loss, and contamination. The present study reports its utility in clinical practice and assesses its ability to guide treatment decisions and predict short-term outcomes at multiple centers.

Methods: After IRB approval, a prospective multicenter observational study was undertaken. Patient age, AO-OTA fracture classification, OTA-OFC, number of operative debridements, wound vac (vacuum-assisted closure) use, and antibiotic bead use were all recorded. Primary outcomes of amputation, infection requiring antibiotics, and wound healing were all recorded. A minimum of 90 days follow-up was required for study inclusion. Descriptive statistics were used to describe the study population. Logistic regression using forward conditional analysis was used to predict the impact of the OTA-OFC on short-term outcomes. All analysis was done using SPSS v21.

Results: 419 fractures in 373 patients across 10 trauma centers were enrolled in the study with minimum follow-up of 90 days. Of these fractures, 31 required amputation (7%), 101 developed infections necessitating IV antibiotics (24%) and excluding patients who went on to amputation for wound healing problems, 55 had not healed their wounds of compounding at the time of their 90-day follow-up appointment (13%). Logistic regression to predict amputation demonstrated that arterial and skin injury were statistically significant contributors to the prediction of amputation. Bone injury and muscle damage were significant contributors to the prediction of readmission for IV antibiotics. The OTA-OFC did not show correlation with wound healing at 90 days.

Conclusion: The OTA-OFC was designed as an objectively obtainable descriptive system that can be used at multiple locations with good interobserver reliability. It has been shown to have good prognostic value at one treatment center. The goal of this study was to determine its utility in clinical practice and to assess its ability to guide treatment decisions and predict short-term outcomes at multiple centers. The present data demonstrated that arterial and skin injury were statistically significant contributors to the prediction of amputation. Bone injury and muscle damage were significant contributors to the prediction of readmission

for IV antibiotics. The OTA-OFC did not show correlation with wound healing at 90 days. This study demonstrates the value of the OTA-OFC as a classification tool at multiple centers in modern practice, and is another step in the use of this system to guide open fracture management decisions.

		Skin			Total	
		1- edges approximate	2- edges do not approximate	3- extensive degloving		P Value
Amputation	No	274	45	34	353	
	Yes	2 (0.7%)	4 (8.2%)	25 (42.4%)	31	
Total		276	49	59	384	.000
		Muscle			Total	
		1- no necrosis	2-necrosis with intact unit	3- disruption of muscle-tendon unit		
Amputation	No	208	133	12	353	
	Yes	2 (1%)	12 (8.3%)	17 (58.6%)	31	
Total		210	145	29	384	.000
		Artery			Total	
		1- no major injury	2-injury with no ischemia	3- distal ischemia		
Amputation	No	332	15	6	353	
	Yes	9 (2.6%)	8 (34.8%)	14 (70%)	31	
Total		341	23	20	384	.000
		Contamination			Total	
		1- none	2- surface only	3- deep		
Amputation	No	233	83	37	353	
	Yes	7 (2.9%)	8 (8.8%)	16 (30.2%)	31	
Total		240	91	53	384	.000
		Bone Loss			Total	
		1- none	2- loss with cortical contact	3- segment loss		
Amputation	No	224	114	15	353	
	Yes	6 (2.6%)	10 (8.1%)	15 (50%)	31	
Total		230	124	30	384	.000
		Skin			Total	
		1	2	3		P value
Antibiotics	No	230	30	32	292	
	Yes	44 (16.1%)	19 (38.8%)	27 (45.8%)	90	
Total		274	49	59	382	.000
		Muscle			Total	
		1	2	3		
Antibiotics	No	185	89	18	292	
	Yes	24 (11.5%)	55 (38.2%)	11 (37.9%)	90	
Total		209	144	29	382	.000
		Artery			Total	
		1	2	3		
Antibiotics	No	267	12	13	292	
	Yes	72 (21.2%)	11 (47.8%)	7 (35%)	90	
Total		339	23	20	382	.007
		Contamination			Total	
		1	2	3		
Antibiotics	No	189	73	30	292	
	Yes	49 (20.6%)	18 (19.8%)	23 (43.4%)	90	
Total		238	91	53	382	.001
		Bone Loss			Total	
		1	2	3		
Antibiotics	No	199	75	18	292	
	Yes	29 (12.7%)	49 (39.5%)	12 (40%)	90	
Total		228	124	30	382	.000

See pages 47 - 108 for financial disclosure information.