

Δ A Randomized Controlled Trial Comparing rhBMP-2 Versus Autograft for the Treatment of Tibia Fractures With Critical Size Defects

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Purpose: The combination of recombinant human bone morphogenetic protein-2 (rhBMP-2) with allograft has been proposed as an alternative to iliac crest bone graft (ICBG) for tibia shaft fractures with large bone defects. Only 1 study compared rhBMP-2/allograft with ICBG in these patients. However, broad inclusion criteria complicated interpretation of the findings. This study's purpose was to determine if previous findings could be replicated in a randomized trial of open tibia fractures treated with an intramedullary nail (IMN) with bone defects. We hypothesized that radiographic union would be equivalent in the 2 treatment groups.

Methods: This multicenter, U.S. Food and Drug Administration (FDA)-regulated investigational device exemption (IDE) study randomized 30 patients aged 18-65 years with open tibia fracture to the use of either rhBMP-2/allograft (n = 16) or ICBG (n = 14). Inclusion criteria were: (1) circumferential bone defect of at least 1 cm in length and missing at least 50% of the bone circumference, (2) fracture stabilization with an IMN, and (3) bone graft 6-16 weeks following definitive fixation. The main study outcome was radiographic union within 52 weeks. Equivalence was evaluated by testing whether a 90% 2-sided confidence interval (CI) for the difference in the probability of radiographic union between rhBMP-2 or ICBG is contained with the interval -20% to +20%. Secondary outcomes included clinical healing, patient-reported function assessed using the Short Musculoskeletal Function Assessment (SMFA), major complications, and treatment cost.

Results: The status of radiographic union within 52 weeks was determined for 23 patients: 7 of 12 rhBMP-2 patients (58.3%) were judged as radiographically united compared to 9 of 11 ICBG patients (81.8%), resulting in a treatment difference of -0.23 (90% CI: -0.55, 0.10). 5 additional patients had radiographs at visits prior to 26 weeks (3 in the rhBMP-2 group, 2 in the ICBG group); 1 of the 3 rhBMP-2 and 2 of the 2 ICBG patients were judged to be united and were treated as united in a sensitivity analysis. Neither the primary nor the sensitivity analysis provided evidence to support the equivalence hypothesis. Compared with patients treated with ICBG, patients treated with rhBMP-2 had lower rates of clinical healing at 52 weeks (27% vs 54%), had higher SMFA scores (mean dysfunction score of 33.3 vs 23.7; mean bother score of 32.8 vs 21.4), and experienced more complications (5 vs 3). Mean treatment cost for rhBMP-2 was estimated at \$13,033 versus \$7535 for ICBG.

Conclusion: These data do not provide sufficient evidence to conclude ICBG and rhBMP-2 are statistically equivalent with regard to radiographic union. The data suggest ICBG may yield a higher union rate, fewer complications, and better functional outcomes within 1 year of bone graft.

Δ OTA Grant

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.

PAPER ABSTRACTS

Short Versus Long Cephalomedullary Nailing of Pertrochanteric Hip Fractures: A Randomized Prospective Study

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Purpose: The purpose of this study was to compare functional and clinical outcomes between patients with pertrochanteric hip fractures treated with either a short (SN) or long (LN) cephalomedullary nail.

Methods: 220 patients with intertrochanteric fractures were prospectively randomized to an SN (n = 110) or LN (n = 110). A total of 168 patients were followed for a minimum of 3 months (SN, n = 80 and LN, n = 88) with a mean follow-up of 8.5 months. 52 patients did not meet minimum follow-up with the majority of these lost to death. Demographics were similar between cohorts with respect to age, gender, diabetes, tobacco use, chronic kidney disease (CKD), body mass index (BMI), and AO/OTA fracture classification. The primary outcome measurement was functional outcome as evaluated by Short Form (SF-36) and Harris hip scores (HHS) at 3 months. Secondary outcomes included implant failure, peri-implant fracture, mortality, operative time, estimated blood loss (EBL), and reoperation.

Results: SN and LN cohorts were comparable in all aspects of the SF-36 and HHS subsections. There was a small, clinically insignificant difference in the HHS between the SN and LN cohorts (76 vs 71, $P = 0.02$). Patients treated in the SN cohort experienced shorter operative times (51 min vs 80, $P < 0.0001$), less EBL (70 cc vs 207 cc, $P < 0.001$), and shorter hospital length of stay (LOS) (5 vs 7 days, $P = 0.01$) but did not differ in tip-to-apex distance (TAD) (18.3 vs 18.8, $P = 0.51$) or subtrochanteric fracture extension (1.89 cm vs 2.15 cm, $P = 0.24$). There was no difference in lag-screw cutout (SN 3.75% vs LN 2.27%, $P = 0.67$), deep surgical site infection (SN 1.25% vs LN 2.27%, $P = 1.00$), and peri-implant fractures (SN 2.49% vs LN 2.27%, $P = 1.00$) with the SN patients successfully treated nonoperatively and both LN patients requiring open reduction and internal fixation.

Conclusion: Patients treated with a short or long cephalomedullary nail for pertrochanteric hip fractures experienced comparable functional outcomes with regard to SF-36 and HSS. Despite no difference in functional outcomes, patients treated with a short nail had shorter operative times, less EBL, and shorter hospital LOS with no difference in peri-implant fracture or lag-screw cutout when compared to the long nail cohort. Level of evidence: Therapeutic Level I.

Results of Operative Fixation for Femoral Neck Fractures in Patients Aged 18 to 59 Years: A Study of 16 Centers and 596 Cases

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Purpose: Femoral neck fractures in young adults are highly related to feared complications such as nonunion, failed fixation, malunion, and osteonecrosis. Despite a number of biomechanical and small clinical series, there has been no consensus on the best fixation method for this type of injury. The purpose of this study was to evaluate the results of fixation of these difficult fractures in a large multicenter cohort, including attention to differences between fixation using a sliding hip screw (SHS) and cannulated screws (CS).

Methods: This was a retrospective study of 956 patients from 16 trauma centers in North America aged 18 to 59 years old that were treated for a femoral neck fracture with operative repair during the study period. A retrospective review of medical records and radiographs was performed to evaluate injury and patient factors, details of fixation, and post-injury complications and secondary surgeries.

Results: 596 patients met inclusion criteria, including >6-month follow-up. 191 fractures were treated with a CHS and 405 were treated with CS. Uncomplicated healing occurred in 367 hips (62%; 115 CHS and 252 CS [$P = 0.90$]). Complications occurred in 38% of patients including nonunion in 17%, fixation failure in 16%, malunion in 10%, and osteonecrosis in 14%. Nonunion was seen in 18 CHS versus 35 CS ($P = 0.83$), fixation failed in 18 CHS versus 47 CS ($P = 0.47$), malunion in 12 CHS versus 28 CS ($P = 0.91$), and osteonecrosis occurred in 13 CHS versus 39 CS ($P = 0.28$).

Conclusion: 38% of patients 18 to 59 years of age treated with surgical repair for a femoral neck fracture had 1 or more significant complications in this large, multicenter study. There were no significant differences in complications rates between fixation using SHS or CS.

PAPER ABSTRACTS

Effectiveness of Various Vitamin D Protocols on Raising and Maintaining Blood Serum 25(OH)D3 Levels Over a 3-Month Period: A Randomized, Prospective Study

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Purpose: With heightened interest in the medical community regarding health benefits of vitamin D and vitamin D deficiency remaining commonplace, no standardized dosing strategies have been substantiated in patients with hypovitaminosis D. Our study aims to establish an optimal dosing regimen to elevate and maintain therapeutic 25-hydroxy vitamin D levels in patients with hypovitaminosis D.

Methods: A single hospital system performed this randomized, prospective study with approval through the IRB. Exclusion criteria included those 18 years of age or younger, certain medications and conditions that interfere with vitamin D absorption and metabolism, and serum vitamin D levels greater than 30.0 ng/mL. Subjects were randomized to 1 of 3 dosing regimens: Group 1, 100,000 IU vitamin D2 once; Group 2, 100,000 IU vitamin D2 weekly for 12 weeks; or Group 3, 50,000 IU vitamin D2 daily for 10 days followed by 2,000 IU vitamin D3 daily for 74 additional days. Serum vitamin D levels were drawn at time 0 and weeks 2, 6, and 12.

Results: Data from 48 patients were collected and analyzed; 68% of enrollees were vitamin D-deficient. No significant difference was found between groups with respect to age, race, and timing of blood draws. Group 1 did not show any statistical significance between time points, except for a decrease between weeks 2 and 12. Group 2 showed a significant increase in vitamin D levels between all time points except between weeks 6 and 12. Group 3 showed the greatest change in vitamin D levels between weeks 0 and 2, but had a significant decrease between weeks 2 and 6. No patients in any group reported severe symptoms related to hypervitaminosis D.

Conclusion: Group 2 (100,000 IU vitamin D2 weekly) provided expeditious correction and the greatest positive net change in vitamin D 25(OH)D3 blood levels for subjects with hypovitaminosis D, which was sustained at a satisfactory level over the 12-week course.

Operative Versus Nonoperative Treatment of Isolated Humeral Shaft Fractures: A Prospective Cohort Study

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Purpose: Nonoperative management of humeral shaft fractures has been considered the standard of care. There are little comparative data regarding functional outcomes between operative and nonoperative management. The purpose of this study was to prospectively compare plate and screw fixation (open reduction and internal fixation [ORIF]) and functional bracing (NO) regarding surgical and patient-based outcomes.

Methods: We performed a prospective comparative trial of ORIF versus NO of isolated humeral shaft fractures at 12 centers (Clinical Trials #16589). We excluded pathologic fractures, and those who could not follow-up, complete forms, or give consent. Surgeons counseled patients on treatment options and a patient-centered decision was made. Patients were followed at 2, 4, 8, 12, and 26 weeks clinically and with radiographs until united. The primary outcome was the Disabilities of the Arm, Shoulder and Hand (DASH) score. Complications included nonunion, infection, iatrogenic nerve palsy, and loss of range of motion (ROM).

Results: We enrolled 179 patients, of whom 6-month data were available for 104 (40 F; 64 M) aged 18 to 71 years (average 41). 45 were treated with ORIF and 57 NO. The groups were not different in OTA fracture class, body mass index, smoking, dominance of arm injured, or work-related injuries. At 3 and 6 months, the DASH score was 35 and 20 for the NO group and 28 and 18 for ORIF ($P = 0.24$ and 0.67). Union was present at 3 and 6 months in 64% and 98% of ORIF group and 65% and 86% of NO group without additional intervention. Radial nerve dysfunction (RND) was identified at injury in 6 (13%) of ORIF and 8 (14%) of NO group. An additional 6 patients (15%) of the ORIF group developed a postoperative iatrogenic RND. By 6 months, 7 of 12 RNDs in ORIF group resolved and 4 of 8 in the NO group. Of the 6 iatrogenic injuries, 5 (83%) were persistent at 6 months. There was 1 infection in the ORIF group. Visual analog scale (VAS) pain was higher in the NO group at 2 weeks (4.8 vs 3.7, $P = 0.056$) and 3 months (2.9 vs 1.9, $P < 0.05$). This difference was gone by 6 months (both groups 1.7). Narcotic use was lower at 2 weeks in NO group (56% vs 69%, $P = 0.01$), but not different at 3 months (23% vs 25%) or 6 months (both 9%). There was no difference in elbow motion between the groups (average 1° - 133°) or the number who went to physical therapy (both 63%).

Conclusion: We evaluated a prospective cohort with isolated humeral shaft fractures treated NO versus ORIF. We found no difference in the DASH, VAS pain, or elbow ROM at 6 months. However, 14% of the NO group developed nonunion. Complications in the ORIF group included a 2% infection and nonunion rate and 15% iatrogenic RND. 83% of these did not resolve by 6 months. VAS pain scores were lower at 2 weeks and 3 months in ORIF group, but they had greater narcotic use at 2 weeks. ORIF can be expected to result in higher union rates with the inherent risks of infection and RND. Finally, at 6 months, both groups demonstrated higher DASH scores than population norms, indicating a lack of full recovery.

See the meeting app for complete listing of authors' disclosure information.

**Operative and Nonoperative Treatment of Traumatic Arthrotomies:
A Prospective Observational Study**

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Purpose: Orthopaedic dogma dictates that traumatic arthrotomies (TAs) require formal irrigation and debridement to minimize septic arthritis risk, regardless of size. To date, there is no evidence for or against nonoperative (nonop) treatment of small TAs. The purpose of this study was to evaluate the incidence of adverse events (AEs) in patients undergoing operative and nonop treatment of TAs. We hypothesized that nonop treatment of small (<1 cm) TAs would have an extremely low rate of subsequent septic arthritis and surgery.

Methods: We prospectively enrolled all patients with a TA to a major joint diagnosed via saline load test, direct visualization, or intra-articular air on imaging. Patients were treated in the operative group (OG) or nonop group (NOG) based on the preference of the treating surgeon. Nonop patients received bedside irrigation, primary closure in the emergency department, and discharge on an oral antibiotic regimen. Primary outcomes were AEs including septic arthritis (SA) and other complications.

Results: 104 patients met inclusion criteria, 27 in the NOG and 77 in the OG. Mean age was 36.4 years for the NOG and 33.3 years for the OG. 96% of NOG patients returned for at least 1 follow-up visit and 88% of the OG. 81% and 55% of NOG and OG TAs were <5 cm, while 11% and 21% of the NOG and OG TAs were 5-10 cm. Mechanism of injury included abrasions, lacerations, punctures, and high and low-energy gunshot wounds. All NOG TAs had minimal to no contamination compared to 49% of OG TAs ($P < 0.05$). There was 1 SA case and no other complications in the NOG compared to 4 SA cases and 8 complications in the OG, with no statistical differences between groups. Of the OG, indications for surgery were: 49% went to the operating room for an additional injury, 5.2% had an intra-articular fracture, 20% had heavy contamination, 34% had large TAs, and 3.9% had an intra-articular loose body.

Conclusion: This series demonstrated a low rate of AEs (3.7%) in nonop-treated TAs. These results suggest challenging the current dogma requiring formal irrigation and debridement in the operating room for all TAs. We believe that small (<5 cm), minimally contaminated TAs with no associated fracture may be safely treated with bedside irrigation, primary closure, and a short course of oral antibiotics. This may reduce unnecessary spending, free operative time, and prevent surgical morbidity.

RIA Versus Conventional Reaming Combined With Antibiotic-Loaded Cement Spacer: A Randomized Controlled Study of Femur and Tibia Intramedullary Nail Infection Treatment

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Purpose: Studies addressing the management of infected intramedullary nailing (IMN) are mainly retrospective and with a limited number of cases. Reaming can be performed either conventionally or using the reamer/irrigator/aspirator (RIA) system. Until now there have been no comparative studies between these 2 methods. We aimed to compare the efficacy of RIA with conventional reaming (CR), followed by insertion of antibiotic-loaded cement, for the treatment of intramedullary nail infection (IMNI) of long bones. We assessed the rate of remission and control of infection between the 2 groups after 2 years of follow-up and identified microorganisms using tissue cultures and sonication of explanted IMN.

Methods: A randomized clinical trial was carried out between October 2013 and August 2015 involving 44 patients of whom a locked IMN implant of the femur and/or tibia was retrieved and who all met the clinical diagnostic and radiological criteria for IMN-associated osteomyelitis. Patients were randomized into 2 groups: RIA alone and CR followed by antibiotic-loaded cement insertion. Both groups also underwent 6 weeks of antibiotic treatment that varied according to the results of the antibiogram. Patients were evaluated after 1, 3, 6, 12, and 24 months for radiological and clinical follow-up.

Results: After 24 months, the rate of infection remission was similar between the 2 groups, 87% in the RIA group and 95.5% in the CR group ($p = 0.60$). Among 4 patients who had recurrence of infection, the time to reappearance of symptoms varied from 20 days to 1 year and 10 months. *Staphylococcus aureus* and coagulase-negative Staphylococci were isolated in 23 (40.4%) and 13 (22.9%) patients, respectively. Interestingly, we identified 20% with polymicrobial infection.

Conclusion: This study concludes that the RIA system alone is as effective as conventional reaming followed by antibiotic cement spacer in the treatment of IMN infection.

Are All Nonunions Infected? Comparison of Culture Versus Bacterial DNA Presence

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Purpose: Previous work suggests the majority of culture negative nonunions may be infected based upon molecular diagnostics. It is unknown if this reflects greater accuracy/sensitivity of molecular methods over culture versus “over sensitivity” and detection of clinically irrelevant amounts of bacteria. This study compares traditional culture to molecular methods for detecting bioburden present in fracture nonunions by examining 3 groups of orthopaedic trauma patients. We hypothesized that molecular techniques would detect bacterial presence at similar rates in each group.

Methods: This was a prospective cohort study at an academic Level I trauma hospital. Using a priori inclusion criteria 3 groups of patients were enrolled: (1) closed fracture undergoing index surgery, (2) healed fracture undergoing symptomatic implant removal, and (3) fracture nonunion undergoing index nonunion procedure. Tissue from the fracture, implant removal, or nonunion site was collected during surgery and sent for culture using standard methodology or molecular analysis via detection of the 16S ribosomal RNA (present in bacteria but not humans). The chi-square test was used for categorical data and 1-way analysis of variance for continuous data with $P < 0.017$ considered statistically significant.

Results: A total of 111 surgical sites were included: 43 group 1, 41 group 2, and 27 group 3. Groups were similar with respect to age, body mass index, American Society of Anesthesiology class, gender, race, low/high-energy injury, presence of compartment syndrome, and whether preoperative antibiotics were given. The proportion of open fractures was different, with group 3 having significantly more. Cultures were positive in 2.3% of group 1 (1/43), 7.3% of group 2 (3/41), and 11.1% of group 3 (3/27) ($P = 0.32$). The 16S ribosomal subunit was detected in 23.3% of group 1 (10/43), 64.9% of group 2 (24/37), and 74.0% of group 3 (20/27) (significant, $P < 0.00002$). All positive cultures had detectable 16S ribosomal RNA.

Conclusion: As previously reported, we also found molecular methods identified bacterial presence more often than culture. However, the data show that while molecular methods detected bacteria more often in nonunions or implant removal compared to index fracture surgery, there was similar detection comparing nonunions to implant removal. It is possible that the increased frequency of bacterial detection by molecular methods is reflective of biofilm presence on metal and not clinically relevant infection responsible for nonunion.

Preoperative Nasal Povidone-Iodine Solution Effectively Reduces the Rate of Surgical Site Infection in Orthopaedic Trauma Cases

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Purpose: The purpose of this study was to determine whether immediate preoperative application of nasal povidone-iodine solution reduced postoperative surgical site infections in this cross-sectional observational study at a Level I trauma center.

Methods: We compared 2 groups of patients in order to determine the effectiveness of preoperative application of nasal povidone-iodine solution for infection prophylaxis. Group I, the treatment group, consisted of 1056 orthopaedic trauma patients who received immediate preoperative application of nasal povidone-iodine solution and were prospectively evaluated. Group II, the historical control group, consisted of a matched group of 1042 orthopaedic trauma patients who did not receive the application. We recorded the outcome measure of postoperative surgical site infection as defined by return to the operating room for infection or readmission for IV antibiotics. Results were compared in order to determine the effectiveness of preoperative application of nasal povidone-iodine solution for infection prophylaxis.

Results: There was a statistically significant difference in the rates of postoperative infection between the groups (treatment group 7/1056, control group 24/1042, $P = 0.002$). Patients in the treatment group were 71.7% less likely to develop postoperative infection compared to the control group (95% confidence interval [CI] 34.0%-87.9%). In subgroup analyses evaluating only open or closed fractures, there remained significantly decreased rates of infection between groups for both open (treatment group 1/226, control group 7/171, $P = 0.02$) and closed fractures (treatment group 6/830, control group 17/871, $P = 0.02$). Patients with open fractures in the treatment group were 89.6% less likely to develop postoperative infection compared to the control group (95% CI, 14.5%-98.7%). Patients with closed fractures in the treatment group were 65.5% less likely to develop postoperative infection compared to the control group (95% CI, 12.6%-86.4%).

Conclusion: Immediate preoperative application of nasal povidone-iodine solution significantly reduced the rate of postoperative surgical site infection in this cross-sectional observational study. Application was effective in cases of both open and closed fractures.

Systemic Absorption and Nephrotoxicity Associated With Topical Vancomycin Powder for Fracture Surgery

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Purpose: The topical application of vancomycin powder during fracture surgery has been proposed as a possible method to reduce surgical site infection in orthopaedic fracture surgery. It is unknown whether vancomycin powder used in this manner results in systemic absorption. Our hypothesis was that the use of topical vancomycin powder in fracture surgery would result in low levels of vancomycin in the serum and would not result in nephrotoxicity.

Methods: A sub-study was performed as part of the VANCO study, a multicenter randomized controlled trial of the efficacy of 1000 mg of topical vancomycin powder to reduce surgical site infection after fracture fixation of high-energy tibial plateau and pilon fractures. Patients at a single site were prospectively enrolled and had vancomycin levels checked from blood drawn in the recovery room and 6-8 hours later. Serum creatinine was obtained prior to surgery, the day after surgery and at 2 weeks post-surgery. The study group included 58 patients who had vancomycin levels drawn at both time points: 56 received IV cefazolin perioperatively and 2 received IV vancomycin. The study group had an average age of 44 years and was composed of 38 tibial plateau and 20 pilon fractures. Serum creatinine was obtained in 56 patients 6-8 hours after surgery and in 46 patients 2 weeks after surgery.

Results: 0 of 56 patients who received cefazolin perioperatively (0%, 95% confidence interval [CI]: 0-4.4%) had detectable ($>5 \mu\text{g}/\text{mL}$) serum levels of vancomycin powder at 1 hour and 6-8 hours. The 2 patients who received IV vancomycin had detectable levels that were either below or within the recommended therapeutic level of 12-15 $\mu\text{g}/\text{mL}$. One patient with a prior history of elevation of serum creatinine had a minor increase of serum creatinine but had undetectable vancomycin levels. None of the other patients at any of the time points had a clinically significant increase in creatinine.

Conclusion: Despite its relatively widespread usage, there are few data regarding the systemic levels and nephrotoxicity associated with the topical use of vancomycin powder in orthopaedic fracture surgery. These prospective data indicate that there appears to be little clinical concern for toxicity associated with systemic absorption of vancomycin powder in this specific clinical application.

Case-Match Controlled Comparison of Minimally Invasive Plate Osteosynthesis and Open Reduction and Internal Fixation for the Stabilization of Humeral Shaft Fractures*Kevin Tetsworth, MD; Matthew Randell, MBBS; Vaida Glatt, PhD*

Purpose: This study was undertaken to compare minimally invasive plate osteosynthesis (MIPO) to open reduction and internal fixation (ORIF) for humeral shaft fractures, to determine which technique minimized complications while optimizing clinical outcomes.

Methods: This was a retrospective case-match controlled cohort from a tertiary referral trauma center. All patients with humeral shaft fractures between April 2010 and September 2015 were identified, a total of 123 fractures. Of these, 31 were treated by MIPO and 54 by ORIF. Indications for surgical management included polytrauma, floating elbow, and failure of nonoperative treatment. A case-matched cohort was assembled according to fracture pattern, gender, age, and comorbidities, with a total of 56 patients (28 per group). The pooled complication rate was the primary outcome measure (radial nerve injury, nonunion, infection, prominent implants, and reoperation). Radiographic alignment and the Disabilities of the Arm, Shoulder and Hand (DASH) score were secondary outcome measures.

Results: Cumulative complication rates were 3.6% following MIPO and 42.9% after ORIF ($P = 0.0004$). The mean DASH score following MIPO was 17.0 ± 18.0 , and after ORIF was 24.9 ± 19.5 , but this difference was not significantly different ($P = 0.140$). The mean coronal plane angulation following MIPO was $1.8^\circ \pm 1.3^\circ$, and after ORIF was $1.0^\circ \pm 1.2^\circ$ ($P = 0.022$). The mean sagittal plane angulation following MIPO was $3.0^\circ \pm 2.9^\circ$, and after ORIF was $1.0^\circ \pm 1.2^\circ$ ($P = 0.002$). These radiographic findings were not considered clinically meaningful.

Conclusion: The cumulative complication rate was 12 times higher following ORIF of humeral shaft fractures compared to MIPO. MIPO achieved nearly equivalent radiographic alignment, with no clinically meaningful differences observed. Although the patient-reported DASH score was better after MIPO, this difference was not significant. This study demonstrates MIPO of humeral shaft fractures can achieve highly comparable clinical results with a dramatically lower risk of postoperative complications compared to ORIF. It is an attractive treatment option for those patients with humeral shaft fractures unsuitable for nonoperative management.