

A Prospective, Randomized Controlled Trial Comparing the Fibular Nail versus Standard ORIF for Fixation of Ankle Fractures in Patients Under 65 Years of Age

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Purpose: The technique of open reduction and internal fixation (ORIF) of ankle fractures with plates and screws has not changed substantially since the 1960s. Three principal complications are associated with this type of surgery. First, wound dehiscence and infection, with published rates of up to 30%, and higher rates in patients with diabetes and neuropathy. Second, there is a risk of construct failure, particularly in osteoporotic bone. Third, the scar or prominent hardware may cause later irritation and require further surgery. We have previously reported that fibular nailing in the elderly is associated with a significantly reduced complication rate and better cost-effectiveness when compared to ORIF. We hypothesized that fibular nailing in younger patients would result in comparable outcomes, with a reduced rate of wound and hardware problems.

Methods: 100 patients aged 18 to 64 years with unstable ankle fractures requiring fixation were randomized to undergo fibular nailing or standard stabilization using AO techniques. Immediate weight-bearing in cast was permitted. Outcome measures were assessed over 2 years postoperatively and included: the accuracy of reduction, development of wound complications or radiographic arthritis, range of movement, Olerud and Molander score (OMS), and patient satisfaction. The mean age was 44 years (range, 18-64) and 56 patients were women. 25% of patients were smokers, three were diabetic, and 35% had some form of comorbidity, most commonly hypertension or ischemic heart disease. 27 injuries occurred during sport and two after an assault; the remainder occurred after a simple fall from a standing height.

Results: Patient satisfaction with the surgical scar was higher after fibular nailing (visual analog scale mean 0.75; range, 0-5) than for ORIF (mean 1.5; range, 0-7). Superficial wound infections that resolved with oral antibiotics occurred in two patients in each group. Six patients requested removal of the nail, and five further requested removal of the locking screws. In the ORIF group, nine patients requested plate and screw removal. Patient-reported outcome scores were comparable for the two groups. Two failures of fixation occurred in the fibular nail group: one in a patient with neuropathy, and one in a patient who developed a postoperative pulmonary embolism and failed to attend follow-up. One failure of fixation occurred in the ORIF group. All other patients went on to an anatomic union without complication.

Conclusion: The fibular nail allows accurate reduction and secure fixation of ankle fractures, with comparable radiographic and patient-reported outcome at 2 years, and a greater patient satisfaction with the appearance of the surgical scars. Neuropathy should be a contraindication to early weight-bearing.

An Equivalence Randomized Controlled Trial Comparing Close Contact Casting (CCC) with Internal Fixation Surgery for Unstable Malleolar Fractures in Patients Over 60 Years

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Purpose: The decision to treat an unstable malleolar fracture by surgery in older adults is complicated by comorbidities, increased risk of infection, surgical wound problems, and inadequate fixation due to poor bone quality. Close contact casting (CCC), is a novel casting technique that may offer an alternative to open reduction and internal fixation (ORIF). We aimed to determine the clinical and cost-effectiveness of CCC compared to ORIF in adults aged over 60 years.

Methods: This was a pragmatic, multicenter, equivalence randomized controlled trial incorporating health economic evaluation. Recruitment was from 24 hospitals. Exclusions were: serious limb or concomitant disease or substantial cognitive impairment. Participants were randomized using computer allocation via a 24-hour telephone service. The primary outcome, Olerud and Molander Ankle Score (OMAS), was collected at 6 months by blinded assessors. A qualitative patient-experience study was embedded.

Results: We randomized 620 participants (309 ORIF, 311 CCC); mean age 71 years (74% female). Follow-up assessments at 6 months were completed by 593/620 (96%) participants. Per protocol analysis showed CCC resulted in equivalent functional outcome compared to ORIF (OMAS mean difference -0.65 [95% CI (confidence interval): -3.98, 2.68]); equivalence margin preset at ± 6 points. Intention-to-treat analysis demonstrated the same equivalence. There were no differences in secondary outcomes of quality of life (mental and physical), ankle range, pain, mobility, and patient satisfaction. Complications occurred in both groups; commonest for CCC group were loss of reduction and conversion to ORIF, and for ORIF group were wound breakdown and surgery for wound/implant problems. CCC showed mean cost savings to the universal health care service (mean difference -\$968 [95% CI -2,089, 114]) and society (mean difference -\$1,026 [95%CI: -2,782, 806]). Over common willingness-to-pay thresholds, the probability that CCC was cost-effective was very high (>95%). The experiences of the treatments were similar as both groups endured the impact of ankle fracture and uncertainty regarding future function and the necessity for further interventions.

Conclusion: CCC provides a clinically equivalent outcome to ORIF with a cost reduction to the universal health care service and society. Identifying a nonsurgical treatment evidenced to deliver the same patient outcome must now produce a shift in the approach of surgeons in advising older patients with unstable malleolar fractures.

Proximal Fracture of the Humerus: Evaluation by Randomization (ProFHER) Trial

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Background/Purpose: Proximal humeral fractures are common injuries, accounting for 5% to 6% of all adult fractures, with an estimated 706,000 having occurred worldwide in 2000. Around half (51%) of these fractures are displaced, the majority of which involve the surgical neck (40% of all fractures). Cochrane review has found, at each update, insufficient evidence from randomized controlled trials to inform practice, including whether surgical intervention, even for specific fracture types, produces consistently better outcomes, and well-designed trials are needed to answer this question. The ProFHER trial was designed to evaluate the clinical and cost-effectiveness of surgical versus nonsurgical treatment for adults with displaced fractures of the proximal humerus involving the surgical neck.

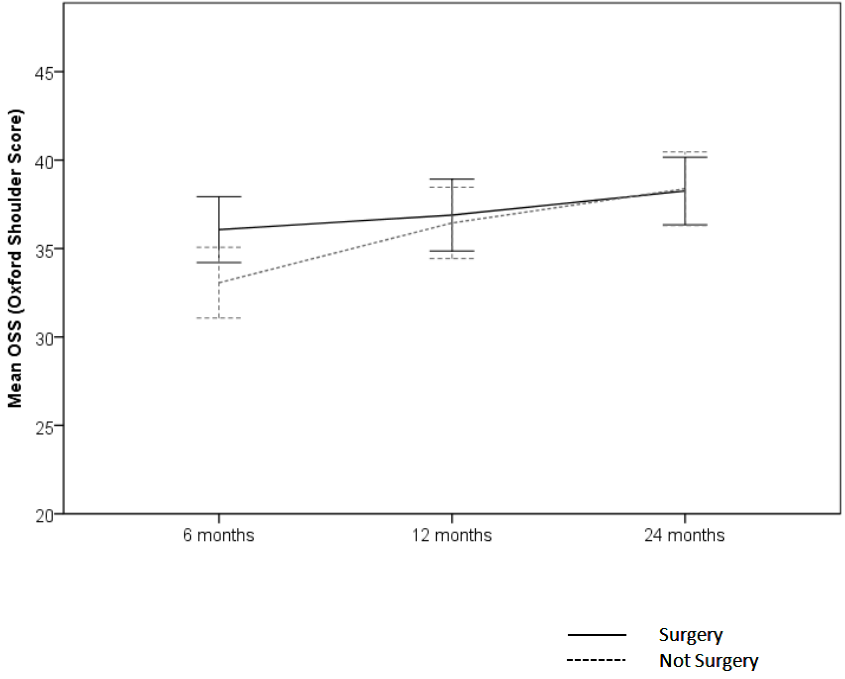
Methods: The ProFHER trial is a pragmatic parallel group multicenter randomized controlled trial, with an economic evaluation. Recruitment was undertaken in the orthopaedic trauma departments of 33 hospitals from September 2008 to April 2011. Surgeons used surgical techniques of fracture fixation or humeral head replacement with which they were experienced. Initial nonsurgical treatment was sling immobilization. Rehabilitation was standardized and included outpatient and community based rehabilitation. The primary outcome was the Oxford Shoulder Score (OSS; scale 0 to 48, higher scores indicating better outcome) assessed over 6, 12, and 24 months. The trial was powered to detect a clinically important difference of 5 OSS points. Secondary outcomes were the Short-Form 12, EuroQol-5D-3L, complications, subsequent therapy, and mortality.

Results: The 250 participants (125 randomized to each group), aged 16 years or older, presented within 3 weeks of sustaining a displaced fracture of the proximal humerus that involved the surgical neck. Of these, 215 participants (106 surgery, 109 not surgery) completed follow-up. There was no significant between-group difference in OSS over the 2-year period (0.75 points in favor of surgery, 95% confidence interval [CI] -1.33 to 2.84; P = 0.48), nor at individual time points. We found no statistically significant between-group differences in secondary outcomes, including surgical or fracture-related complications (30 vs 23 patients) and secondary surgery to shoulder (11 each group). Surgery cost significantly more over 2 years.

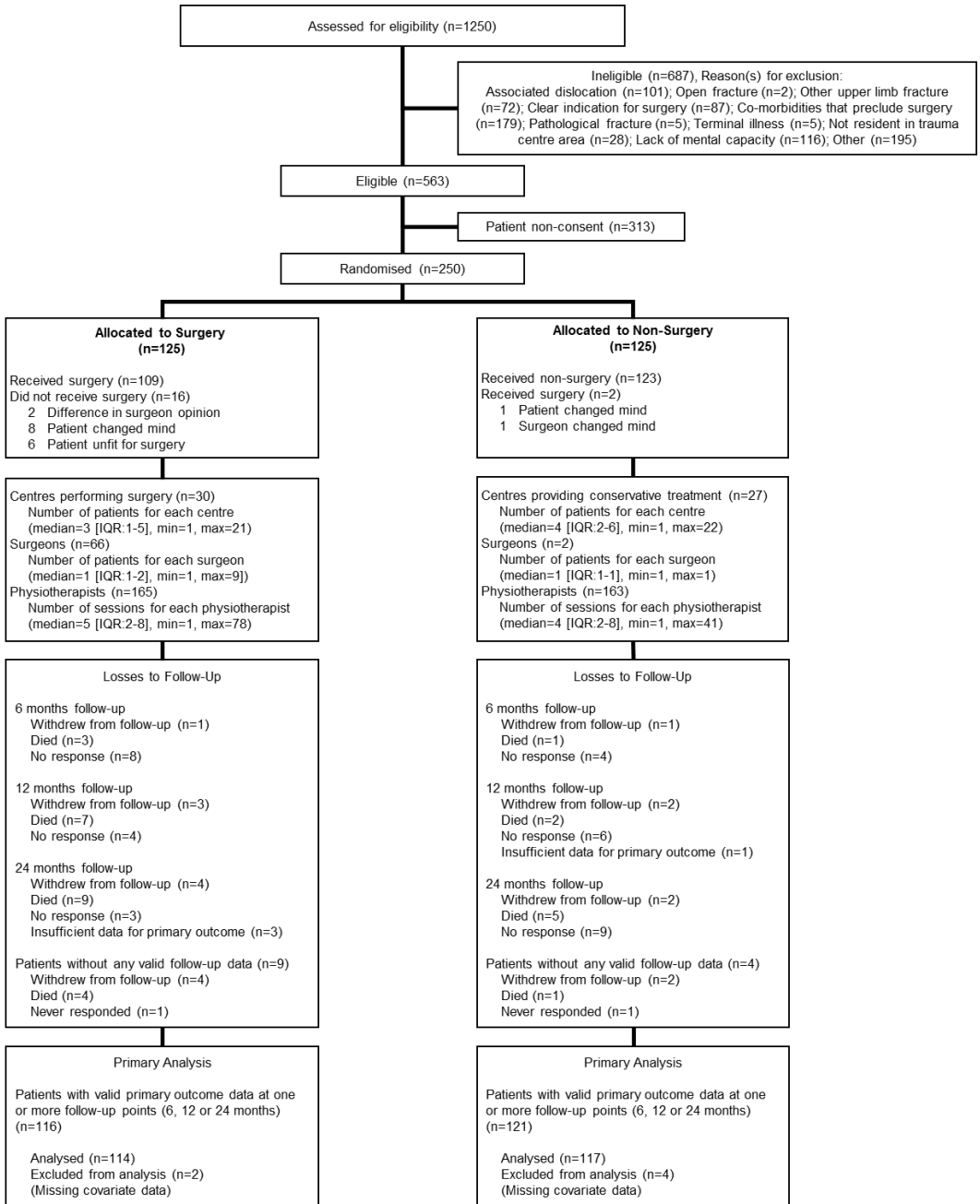
Conclusion: Current surgical practice does not result in a better patient-reported outcome for most adults with displaced proximal humeral fractures involving the surgical neck, and is not cost-effective in this setting.

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Comparison of OSS by treatment groups:



Participant Flow:



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A Multicenter RCT Comparing the InterTAN Device Versus the Sliding Hip Screw in the Treatment of Geriatric Hip Fractures: Results Depend on Preinjury Functional Level

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Background/Purpose: The benefit of intramedullary devices for the treatment of intertrochanteric hip fractures in the elderly is unknown. This may be related to the functional capacity of patients who sustain hip fractures, as incremental improvements in function may be difficult to appreciate. The InterTAN (IT) device was designed to allow earlier mobilization for patients with intertrochanteric fractures. Our objective was to determine whether the mechanical benefits of this device would translate into improved function for elderly patients with hip fractures, compared to a conventional sliding hip screw (SHS).

Methods: 249 patients aged 55 years or older were prospectively enrolled in an REB-approved multicenter study, and computer randomized to either IT (n = 123) or SHS (n = 126). Patients were followed for 12 months. The validated primary outcome measures were the Functional Independence Measure (FIM), to measure function, and the Timed Up and Go test (TUG), to measure motor performance. Secondary outcome measures included femoral shortening, complications and mortality. A preinjury FIM was measured by retrospective recall, and all outcomes assessed at discharge, 6 weeks, 3 and 6 months, and 1 year postoperative. 100 patients per group with complete data were required to have 80% power to detect differences in the FIM score of 7.8 points or greater using a two-sided ANOVA (analysis of variance) with a type I error rate of 5%.

Results: Fractures included 43 31A-1, and 199 31A-2 fractures. Age, sex, body mass index (BMI), living status, and comorbidities were similar between groups. The recalled preinjury FIM scores were similar between the SHS and IT groups and followed a similar pattern of recovery after discharge. The average FIM motor subscale at 12 months was 4.5 ± 1.1 points lower than preinjury. The proportion of patients able to complete the TUG, as well as the time, was similar between the SHS and IT groups at each time interval. Fewer patients who received an IT (17.2%) had limb shortening greater than 2.5 cm compared to those who received a SHS (42.9%) (P <0.001). There were no differences in secondary outcomes. To determine

the role of preinjury function, we analyzed the subgroup of patients with the ability to walk 150 feet independently preinjury (FIM walk score of 7) and a 31A-2 fracture. 70 patients met these criteria (36 SHS, 34 IT). Patients treated with SHS followed a bimodal distribution of outcomes, associated with radiographic shortening. In this subgroup, patients treated with SHS with greater than 2.5 cm of shortening demonstrated poorer FIM and TUG scores compared to patients treated with SHS without shortening, or patients treated with an IT.

Conclusion: Patients with intertrochanteric proximal femur fractures can expect similar results whether treated with an intramedullary or extramedullary device. However, our study demonstrates an advantage to the IT device in patients with superior functional capacity prior to their unstable intertrochanteric hip fracture. In these patients, treatment with a SHS complicated by shortening resulted in worse outcome. These results may help orthopaedic surgeons decide which surgical implant is most appropriate for individual patients in the treatment of intertrochanteric hip fractures.

The Suprapatellar Variant of the Semi-Extended Surgical Approach Improves Intramedullary Nail Position Compared with the Conventional Medial Parapatellar Surgical Approach

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Background/Purpose: Proximal third tibial shaft fractures remain a challenge to treat with intramedullary nails (IMNs) due to the risk of creating malunion by using the conventional medial parapatellar (CMPP) surgical approach. Although the lateral parapatellar approach reduces the incidence of valgus malunion, recurvatum is still a concern. To reduce malalignment, Tornetta and Collins postulated the semi-extended (SE) approach for IMN insertion since placing the knee in approximately 15° of flexion usually results in good proximal fracture alignment. Their original article described using an open approach involving reflection of the patella, but more recently, a less invasive modification of the SE approach that permits IMN insertion using a suprapatellar incision (SPSE) has been developed. We hypothesized that the SPSE surgical approach permits more accurate placement of the guidewire (GW) and the IMN compared with the CMPP approach.

Methods: A multicenter randomized controlled trial (RCT) was undertaken comparing the CMPP approach with the SPSE approach. 94 patients with isolated extra-articular tibial shaft fractures were recruited. Standardized AP and lateral perioperative and early postoperative radiographs were used to assess (1) GW and (2) IMN alignment with respect to the long axes of the tibia, (3) the starting point of the GW on the proximal tibia in both planes, and (4) the final position of the proximal end of the nail in both planes within the proximal tibia. One experienced assessor, blinded to the treatments, undertook all measurements. Statistical analysis was undertaken using a Mann-Whitney U test with significance set at $P < 0.05$.

Results: Overall alignment of (1) the GW and (2) the IMN with respect to the long axes of the tibia, (3) the GW starting point, and (4) the final position of the IMN in the proximal tibia were all improved by using the SPSE approach, although not all were statistically significant. The notable statistically significant results relate mainly to IMN placement and are as follows: overall IMN alignment in the coronal plane, $P = 0.0061$; overall IMN alignment in the sagittal plane, $P = 0.0032$; and final position of the proximal end of the IMN within the proximal tibia in the sagittal plane, $P = 0.0294$ --favoring the SPSE approach.

Conclusion: The results of this multicenter RCT confirms that GW and IMN position is improved when the SPSE approach is used compared with the CMPP approach. However, the most interesting findings relate to (1) IMN alignment with respect to the long axes of the tibia and (2) the final position of the IMN in the proximal tibia in the sagittal plane. In essence, while using a CMPP approach to insert an IMN, the initially acceptable GW position is lost following reaming of the canal. This presumably results from eccentric reaming though using protective sleeves that are displaced by pressure from the patella and the patellar tendon. This problem is not observed using the SPSE approach and infers that the SPSE surgical approach is the preferred one for treating proximal third and segmental tibial fractures where the potential for malunion is of great concern.

See pages 47 - 108 for financial disclosure information.

Low-Intensity Pulsed Ultrasound in Acute Tibial Shaft Fractures Treated with IM Nails: The Results of the TRUST Trial

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Background/Purpose: Tibial shaft fractures are one of the most common fractures treated by orthopaedic trauma surgeons and results of large trials have shown continued disability at 1 year. Additionally, functional outcome has been correlated with radiographic progression to union. The plateau period for functional outcome is between 6 months and 1 year for patients with fractures that heal without secondary intervention. Decreasing the time to union would likely hasten the recovery of patients. The use of low-intensity pulsed ultrasound (LIPUS) for acute tibial fractures has support in prior studies in animals and also in small series of tibial shaft fractures in adults. However, due to limitations of prior studies, the effect of LIPUS on promoting functional recovery for acute tibial fractures treated with IM (intramedullary) nailing remains uncertain. The purposes of this study were to evaluate the use of LIPUS on validated functional outcomes of patients with acute tibial fractures treated with IM nails and to evaluate healing using the RUST method (Radiographic Union Scale for Tibial fractures).

Methods: This trial was designed as a multicenter (43 centers) randomized, blinded, placebo/treatment controlled evaluation of the effects of LIPUS on validated functional outcomes (Short Form [SF]-36 PCS [Physical Component Summary] and HUI [Health Utilities Index]-III) and healing (RUST score). All patients over 18 years old with an acute closed or open fracture of the tibial diaphysis who were to be treated with intramedullary nailing were eligible. Fracture exclusion criteria included: soft-tissue damage precluding the use of the device, bilateral fractures, segmental fractures, and defects after open fracture of >75% of the circumference and longer than 1 cm. Patients were allocated to an active or sham LIPUS device through central randomization in a 1:1 ratio, stratified by fracture severity (ie, open vs closed). Patients used the device once daily after training. The device was set to an automated 20 minutes and recorded compliance. Outcomes were obtained at 6, 12, 18, 26, and 52 weeks. The study was powered for the minimum clinically significant difference in the SF-36 PCS using a repeated measures analysis at three levels (patient, center, and visit) at 500 patients assuming a 10% loss to follow-up. Time to adjudicated union was evaluated using a Cox proportional hazards regression model.

Results: 501 patients (156 F, 345 M, average age 38 years) with 114 open and 387 closed fractures were enrolled. The fracture patterns were: comminuted (132), transverse (114), spiral (177), and oblique (154). 125 were lost or withdrew consent, and 303 patients were followed for 1 year at which point the interim analysis met stopping rules and the study was concluded. The results are summarized in Table #1. There was no difference in time

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to union, with the hazard ratio = 1.06 (95% confidence interval [CI]: 0.85, 1.33), P = 0.594. The Kaplan-Meier curves for percentage not united for both groups in days from surgery are seen in Figure #1.

Conclusion: LIPUS does not result in improved functional outcomes or time to union in patients with tibial diaphyseal fractures treated with IM nails. Only the presence of an open fracture had a negative influence on outcomes.

**Low Intensity Pulsed Ultrasound in Acute Tibial Shaft Fractures Treated with IM Nails:
The Results of the TRUST Trial**

Table 1: 3-Level Repeated Measures Analysis. N=2294 observations from 477 patients (p values)

	SF-36 PCS	HUI-III
Randomized Treatment	0.346	0.345
Time from surgery	<0.001	<0.001
Open vs closed fracture	0.008	<0.001
Treatment by time interaction	0.230	0.904
Open/closed by time interaction	0.629	0.965
Pre-injury score	<0.001	<0.001

PAPER ABSTRACTS

Figure #1

