

Δ A Prospective Randomized Trial Investigating the Effect of the Reamer-Irrigator-Aspirator (RIA) on the Volume of Embolic Load and Respiratory Functions During Intramedullary Nailing of Femoral Shaft Fractures

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Background/Purpose: Reamed, statically locked intramedullary nailing of femoral shaft fractures is associated with a high rate of clinical success. However, reaming is associated with the generation of embolic debris from the intramedullary canal that can cause serious pulmonary, neurologic, and systemic sequelae, including death. The Reamer-Irrigator-Aspirator (RIA) device has been introduced to minimize the amount of marrow debris from the femoral canal during the reaming process. However, to our knowledge, there are no definitive clinical data to confirm this theoretical advantage of the RIA. Using a randomized clinical trial, we sought to determine if the use of the RIA resulted in a decreased amount of emboli compared to standard reaming.

Methods: We performed a prospective, multicenter, randomized clinical trial comparing standard intramedullary reaming versus reaming with the RIA device for isolated, closed femoral shaft fractures. A random number generator was used to randomize consecutive patients to one of two treatment groups: (1) statically locked reamed intramedullary nailing using standard reamers (SR), or (2) statically locked reamed intramedullary nailing using the RIA device (RIA). In addition to physiologic monitoring, all patients were monitored intraoperatively with a continuous transesophageal echocardiogram (TEE) in order to determine the quantity of embolic debris generated by the procedure. The TEE was divided into preoperative (PREOP), reduction (RED), guidewire passage (GW), reaming (REAM), nail insertion (NAIL), and postoperative (POSTOP) segments. The TEE recordings were analyzed for duration, size, and severity of emboli by 3 blinded independent observers.

Results: 28 patients were enrolled; 6 were excluded due to technical difficulties with the TEE/recording. 22 patients completed the study (SR 11, RIA 11). There were no demographic differences between the two groups (SR male/female 7/4, RIA 8/3, $P = 0.879$; mean age SR group 39.2 years, RIA group 39.2 years, $P = 0.998$). The ISS and mechanisms of injury were similar between the two groups. We used a standard, previously validated scoring system for the measurement of emboli from the TEE video recordings. There was a high degree of agreement for the measurements between the three reviewers (intraclass correlation coefficient 0.740, substantial agreement). There was no significant difference in emboli (which escalated beginning with the GW phase) between the two groups during the PREOP, RED, GW, or POSTOP segments. There was a modest reduction in total emboli score during the REAM (SR 5.36 vs RIA 4.06, $P < 0.05$) and NAIL segments (SR 5.15 vs RIA 4.18, $P < 0.05$) in favor of the RIA group. We were unable to correlate this reduction with any improvement in physiologic parameters (mean arterial pressure, end tidal CO_2 , O_2 saturation, pH, paO_2 , paCO_2).

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Conclusion: To our knowledge, this is the first clinical study that examines the effect of the RIA device on emboli; it resulted in a modest reduction of embolic debris during the reaming and nail insertion segments of the operative procedure. We were unable to correlate this with any change in physiologic parameters. Further research in this area is warranted to determine if this modest reduction in emboli with the RIA during the REAM and NAIL segments of femoral nailing results in any physiologic improvement and warrants its increased expense.

Morbid Obesity Increases the Risk of Systemic Complications in Patients With Femoral Shaft Fractures

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Purpose: Morbid obesity (body mass index [BMI] ≥ 40) is being encountered with increasing frequency in orthopaedic trauma patients. We sought to investigate the impact of obesity on morbidity and mortality in patients that underwent reamed intramedullary nailing of closed femoral shaft fractures.

Methods: All patients with a closed femoral shaft fracture that were treated with reamed intramedullary nailing over a 5-year period were queried. Clinical data collected included height, weight, BMI, ISS, GCS (Glasgow Coma Scale), Chest AIS (abbreviated injury scale), time to definitive fixation, hospital days, ICU days, ventilator days, and complications (acute respiratory distress syndrome [ARDS], sepsis, pneumonia, pulmonary embolism, and death). Normal weight patients (BMI < 25) were compared to morbidly obese patients (BMI ≥ 40). Odds ratios (ORs) were used to compare risk of complications. BMI was also analyzed as a continuous variable.

Results: 507 patients were treated; 184 (36%) were of normal weight (BMI < 25) and 39 (8%) were morbidly obese (BMI ≥ 40). Patients with morbid obesity were more likely to be older (39.6 vs 29.3 years, $P < 0.0001$) and female (49% vs 27%). Systemic complications occurred in 9 (23.1%) of morbidly obese and 16 (8.7%) of normal weight patients (OR 3.15, $P = 0.013$). When evaluating individual systemic complications between normal weight and morbidly obese patients, the presence of morbid obesity resulted in an increased risk of ARDS (OR 35.38, $P = 0.019$) and sepsis (OR 6.49, $P = 0.0015$). There was a trend for increased risk of pulmonary embolism in morbidly obese patients compared to normal weight patients (OR 5.028, $P = 0.0536$). Overall, morbidly obese patients with a femur fracture had a mortality rate of 10.2%. Morbidly obese polytraumatized patients (ISS > 17) with a femur fracture had a mortality rate of 20%. When comparing mortality between normal weight and morbidly obese patients, the presence of morbid obesity resulted in a significantly increased risk of mortality (OR 46.77, $P = 0.01$). BMI, analyzed as a continuous variable, was found to be an independent predictor of ARDS, sepsis, and death.

Conclusion: Morbid obesity conveys a significantly increased risk for systemic complications in patients with closed femoral shaft fractures. Patients and patient families need to need to be counseled regarding the high risk of morbidity and mortality. More research is required to determine which physiologic factors in morbidly obese patients make them more susceptible to complications following intramedullary nailing of femoral shaft fractures.

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Operative Versus Nonoperative Treatment of Femoral Fractures in Spinal Cord Injury Patients

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Purpose: The purpose of this study was to compare perioperative morbidity and mortality after operative and nonoperative treatment of femoral fractures in a large cohort of patients with and without spinal cord injury (SCI).

Methods: This was a retrospective cohort study in the Veterans Affairs (VA) hospital system comparing femur fracture patients with and without spinal cord injury over a 5-year period (2001-2006). Demographic information, fracture pattern, and morbidity and mortality data were extracted and analyzed.

Results: We identified 396 veterans with femur fractures and SCI during the study period as compared to 13,350 veterans with femur fractures but without SCI. The SCI group was younger (60 vs 74 years) and had more distal fractures compared to the non-SCI group (51% shaft or distal femur vs 7% shaft or distal femur). In the SCI group, 37% of patients had their fractures managed surgically compared to 78% in the non-SCI group. The only significant difference in morbidity between operatively and nonoperatively treated SCI patients was in the development of decubitus ulcers, with the nonoperative group being more frequently affected. There was no difference in mortality between SCI patients treated with and without surgery. In the non-SCI group, mortality was higher in patients managed nonoperatively as were rates of respiratory failure and thromboembolic events. Bleeding complications were more common in non-SCI patients managed surgically.

Conclusion: This study did not find increased rates of morbidity or mortality among SCI patients treated surgically for femur fractures. On the contrary, the only significant difference in adverse events between SCI groups was a higher rate of pressure ulcers in those who did not have surgery. Surgical treatment optimizes nursing care, physical therapy, and patient mobilization, minimizing the risks of prolonged bed-rest and immobilization. When modern surgical techniques are coupled with meticulous and individualized perioperative management, surgery can be safe and effective. Subsequent research should aim to identify patients and fracture patterns that would benefit the most from surgery.

Δ Locked Plating Versus Retrograde Nailing for Distal Femur Fractures: A Multicenter Randomized Trial

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Purpose: Distal femur fractures are challenging injuries. Both retrograde nails and locked plates are used for their treatment with good success. Plates are thought to be more stable, but may be more rigid and be more irritating to soft tissues. The purpose of this study was to evaluate the radiographic, functional and physical outcomes of locked plates versus retrograde nails in an IRB-approved randomized controlled trial (RCT).

Methods: All adult patients with A1-3 or C1 distal femur fractures were offered entry into an IRB-approved RCT. If consented, randomization scheme was with permuted blocks for open and closed fractures using a HIPAA-compliant computer-based system. Demographic data, fracture characteristics, surgical variables, and outcomes were assessed.

Results: 156 patients were randomized to locked plate (80) or intramedullary (IM) nail (76). 126 patients were followed (71 men and 55 women, aged 16 to 90 years [average 51]). The average ISS was 12.6 (range, 9-43) and 34 (27%) were open. 34% had simple intra-articular extension. There were no differences in demographic information or injury pattern. Surgical

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time was 125 ± 61 minutes for nails and 124 ± 51 minutes for plates ($P = 0.96$). Malalignment $>5^\circ$ in any plane was present in 22% of nails and 32% of plates ($P = 0.4$), but valgus of $>5^\circ$ accounted for 87% of plate deformities. Valgus $>5^\circ$ was present in 12% of nails and 20% of plates ($P = 0.05$). Walking ability, stair climbing, pain, and use of supports were graded using categorical values. There were no differences at 3, 6, or 12 months between the groups. The average patient could walk 10 blocks, go up and down stairs using a rail, and occasionally used a cane. At 1 year, 16% of plates and 12% of nails lacked at least 5° of extension. A summary of the 1-year results are seen in the table:

1-Year Results

Group	SMFA*	Bother	EQ-Health	EQ-Index	Flexion	Extension	Walking (1 – 6)	Stairs (1 – 5)
Nail	21.5	22.6	79.5	0.78	114 ± 29	6.2 ± 21	2.74	2.3
Plate	27.4	30.8	71	0.68	111 ± 28	3.7 ± 11	2.89	2.66
P value	0.21	0.16	0.08	0.07	0.63	0.57	0.71	0.33

*SMFA = Short Musculoskeletal Function Assessment.

There was significant improvement in all measures at each interval (see example SMFA below)

Complications included 5 pulmonary embolisms/deep vein thromboses and one death. Revision surgery was needed for nonunion or failure in 5% of nails and 8% of plates and hardware removal in 8 of 54 nails (7 screws and 1 nail) and 6 of 60 plates (plate removal) in which this information was available.

Conclusion: Distal femur fractures have significant disability at 1 year. The average patient had an SMFA of 25, bother index of 27, could walk approximately 10 blocks, and climb stairs with the railing. Additionally, 15% had a flexion contracture of $>5^\circ$. Malalignment was present in 22% of nails and 32% of plates, with plates having a higher rate of valgus malalignment and full implant removal. Overall functional results trended toward better outcomes in nails than plates for all measures, and although with the current numbers this did not reach statistical significance, the score difference was above the minimum clinical relevance for the SMFA (5.5).

Distal Locking in Femoral and Tibial Nailing of 265 Patients Without X-Ray Guidance: A Multicenter Study

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Purpose: This study was undertaken to determine the accuracy and safety of a new distal locking device in femoral and tibial nailing without x-ray guidance.

Methods: This new distal locking technique was used in 265 femoral and tibial patients in 69 institutions by 127 orthopaedic surgeons. Distal locking was performed using a disposable locking device inserted into the nail to create a pilot hole from inside-out of the distal femoral or tibial nail holes. The device drives a cable drill through the distal nail holes, drills from inside-out through the lateral cortex and out of the bone or skin at 90°. Using this pilot hole either from bone or skin as reference, a drilling-back technique using the cable drill wire was developed without x-ray guidance. A sounding test confirmed screw insertion and was double-checked with x-ray after surgery. Assessment of success rate and average time for locking, as well as monitoring for adverse events were conducted.

Results: 99% of patients (263 of 265) were successfully locked using the device without aid of x-ray. The 2 cases with technical problems were locked using other methods. Average time for complete distal locking was 14 minutes. No device-related adverse events were encountered.

Conclusion: Use of this innovative distal locking device was 99% effective on the first attempt. This device is easy to use, saves time, and eliminates radiation exposure to the surgical team and patient. This locking device (DISTALOCK) was approved by the US Food and Drug Administration in 2011.

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A Prospective Randomized Control Trial of Fixation of Intertrochanteric Fractures: Compression Hip Screw Versus Third Generation Long Cephalomedullary Nail

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Purpose: This study evaluates the clinical outcomes of patients with intertrochanteric fractures treated with dynamic hip compression devices versus third generation long cephalomedullary nails. The hypothesis was that there is no difference in failure rate between the two devices.

Methods: This is a prospective, randomized control trial of fixation of intertrochanteric fractures comparing the Intramedullary Hip Screw (IMHS) and Dynamic Hip Screw (DHS) (Smith & Nephew). Between 2007 and 2010, there were 232 patients (68 males, 164 females) randomized into two equal groups at the Princess Alexandra Hospital. Inclusion criteria were: (1) patient age greater than 60 years, (2) patient had sustained an intertrochanteric femoral fracture, and (3) consent was attained for their randomization and inclusion in the trial. Exclusion criteria for this trial were: (1) multitrauma patients, (2) patient age less than 60, (3) subcapital fractures, (4) subtrochanteric fractures, (5) concomitant femoral shaft fracture, and (6) preexisting distal metalware or malunion precluding the use of a long nail. Each patient was followed up at 3 months and 1 year postoperatively. The primary outcome measures were failure of fixation and the need for reoperation. Secondary outcome measures included intraoperative measures (procedure time, operator, tip-to-apex distance), perioperative measures (hemoglobin levels and transfusion requirements), and postoperative functional outcomes.

Results: The mean age of the total group was 79.5 years. Fractures were divided into stable ($n = 109$) versus unstable fractures ($n = 125$). Average operative times were 51 minutes for DHS and 72 minutes for IMHS ($P \leq 0.001$). Tip-to-apex distance was independent of type of fracture or level of surgical expertise (consultant versus registrar) ($P \leq 0.0001$). **Fixation failures** were observed in 7 of 116 patients in the DHS group and 3 of 116 in the IMHS group. Of the 7 fixation failures in the DHS group, 3 were in patients' unstable fractures. Of the 3 failures in the IMHS group, 2 were in patients with unstable fractures. **There were 7 revisions in total, 4 in the DHS fixation failure group versus 3 in the IMHS fixation failure group.** 49% of patients had a drop of hemoglobin postoperatively and required postoperative blood transfusion (43 DHS, 71 IMHS). Unstable fractures with IMHS had the highest rates of transfusion ($P \leq 0.002$). Mortality rate was 21% at 3 months and 26% at 12 months.

Conclusion: This study did not find a significant difference in fixation failures when comparing DHS and IMHS in patients with intertrochanteric fractures. It also found that DHS has a shorter operating time, independent of operator, and that unstable fractures fixed with IMHS have the highest rates of requiring blood transfusion postoperatively.

Femoral Neck Shortening Impairs Gait Pattern and Muscle Strength After Internal Fixation of a Femoral Neck Fracture

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Purpose: Knowledge of long-term physical limitations in patients after internal fixation of a femoral neck fracture is limited. The aim of this study was to assess femoral neck shortening and its consequences on gait pattern and muscle strength in femoral neck fracture patients treated with internal fixation.

Methods: Patients were selected from a multicenter randomized controlled trial, in which femoral neck fracture patients aged ≥ 50 years, who were ambulatory and not demented prefracture, and treated with internal fixation were studied. Patients were included at least 1 year after internal fixation. Exclusion criteria were (1) revision surgery, (2) unable to walk, (3) other limb abnormality expected to influence gait pattern, (4) previous surgery of the contralateral hip, and (5) radiographs inadequate for measurements. Patient characteristics, SF-12 (Short-Form 12), and WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) scores were collected. Femoral neck shortening was measured radiologically and gait parameters were measured using plantar pressure measurement. Maximum isometric forces of the hip muscles were assessed using handheld dynamometry. Differences between the fractured and the contralateral leg were calculated. Patients were divided into three subgroups of patients with increasing level of femoral neck shortening. Univariate and multivariable analyses were performed to determine risk factors for femoral neck shortening and effects of femoral neck shortening.

Results: 76 patients (median age 68 years) were included. The median femoral neck shortening was 1.1 cm. A heel lift to compensate for this shortening was used by 30% of the patients. Patient self-reported functioning was good (median WOMAC score 86.5). Overall, subtle changes in gait pattern as well as a reduced gait velocity (median 1.1 m/sec) and reduced abductor muscle strength (median -20 N) were observed. Age, weight, and Pauwels classification were risk factors for increased femoral neck shortening. Femoral neck shortening decreased gait velocity and seemed to impair gait symmetry and physical functioning.

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Conclusion: Internal fixation of femoral neck fractures resulted in permanent physical limitations, such as femoral neck shortening, subtle changes in gait pattern, reduced gait velocity, and reduced abductor muscle strength. The relatively young and healthy patients in our study seem capable of compensating. Therefore, attention should be paid to femoral neck shortening and proper correction with a heel lift, as inadequate correction may cause physical complaints and influence outcome.

Implication of Subgrouping in Valgus Femoral Neck Fractures: Comparison of 31-B1.1 With 31-B1.2 Fracture in OTA Classification

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Purpose: This study aimed to identify the clinical implications of valgus impacted femoral neck fractures and compare fractures with $>15^\circ$ of impaction (31-B1.1) against fractures with $<15^\circ$ of impaction (31-B1.2).

Methods: Between February 2005 and November 2010, 89 femoral neck fractures with valgus deformity (31-B1.1 and 31-B1.2) were treated by screw osteosynthesis. The valgus impaction was not disimpacted; however, posterior tilt of the capital fragment (apex anterior angulation) was reduced by internally rotating the leg and applying pressure from the front. A total of 78 patients were followed for >12 months. We evaluated the clinical and radiographic outcomes.

Results: 36 patients sustained 31-B1.1 fractures, and 42 patients sustained 31-B1.2 fractures. The average follow-up period was 15 months, and bony union occurred in all cases. The mean femur neck shortening was 8.88 mm for B1.1 and 3.70 mm for B1.2 fractures ($P < 0.001$). The mean sliding distance of the screw (SS) was 3.36 mm for B1.1 fractures and 1.38 mm for B1.2 fractures ($P < 0.001$). The mean Harris Hip Score was 82.0 for B1.1 and 88.8 for B1.2 fractures ($P = 0.029$). Osteonecrosis (ON) of the femoral head occurred in 4 patients with B1.1 fractures and none with B1.2 fractures ($P = 0.041$). 18 of the 78 patients required a second operation and 15 of them were included in 31-B1.1 fracture ($P = 0.003$). Three patients underwent arthroplasty due to ON, and 15 patients required hardware removal due to pain after bony union.

Conclusion: More femoral neck shortening and less functional recovery should be expected in the valgus impacted femoral neck fracture patient based on the severity of initial deformity. Even though we could obtain bony union in all of the cases, the risk of ON and second operation after bony union was higher with greater initial deformity.

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• **Fixation of Displaced Femoral Neck Fractures in Young Adults: Fixed-Angle Devices or Pauwel Screws?**

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Purpose: Traditional parallel screws have been shown to perform poorly compared to fixed-angle devices for displaced femoral neck fractures. However, many North American trauma surgeons use Pauwel screws that feature a lag screw directed from the greater trochanter inferiorly towards the calcar instead of parallel screws. Our hypothesis was that Pauwel screws would perform as well as fixed-angle devices for these fractures.

Methods: A retrospective analysis of consecutive femoral neck fractures was performed using our prospectively maintained database. From January 2001 to June 2012, 205 femoral neck fractures in young adults (16-60 years old) were treated with internal fixation at our Level I trauma center. After excluding patients with nondisplaced fractures (72), parallel screw configurations (20), locking plates (8), cephalomedullary nails (2), and <6 month follow-up (41), 2 cohorts were formed. The fixed-angle group consisted of 47 patients (48 hips) that were treated with a side plate and screw/blade device (DHS/DHHS, Synthes), while in the screw group 15 patients (15 hips) were treated with a lag screw placed from the greater trochanter into the inferior neck followed by multiple cancellous screws parallel to the femoral neck. The quality of reduction was judged using the Haidukewych criteria. There were no significant differences between the treatment groups with regard to age, sex, initial displacement, time to surgery, or reduction quality (all $P > 0.05$). An open reduction was performed in 95% of cases resulting in a good-excellent reduction in 83% of cases (Table 1). The average follow-up was 17.2 months.

Table 1: Reduction Quality

	Excellent	Good	Fair	Poor	Total
Fixed-angle group	27 (56%)	13 (27%)	5 (10%)	3 (6%)	48
Screw group	8 (53%)	4 (27%)	3 (20%)	0 (0%)	15

The primary outcome measure was a composite failure metric of a completed or scheduled operation to treat ON (osteonecrosis) or nonunion.

Results: There were significantly more failures in the screw group (60%) compared to the fixed-angle group (21%) ($P = 0.008$) (Table 2). ON was rare in the fixed-angle group, occurring in 2% of cases versus 33% in the screw group ($P = 0.002$). Consistent with prior work, good-excellent reductions had a failure rate of 31% compared to 64% with a fair-poor reduction ($P = 0.08$). The best-case scenario of a good-excellent reduction with a fixed-angle device yielded a success rate of 85%.

Table 2: Results

	Fixed-Angle Group	Screw Group	<i>P</i> Value
Composite failure	10 (20.8%)	9 (60.0%)	0.008
ON	1 (2.1%)	5 (33.3%)	0.002

Conclusion: Despite the theoretical mechanical advantage of Pauwel screws over parallel screws, this screw configuration still performed poorly compared to fixed-angle devices. In young patients with high-energy femoral neck fractures, lower complication rates are observed with anatomic reduction and fixed-angle devices.

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