Intramedullary Versus Extramedullary Fixation for Unstable Intertrochanteric Fractures

A Prospective Randomized Controlled Trial

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Background: The use of intramedullary devices for the management of intertrochanteric fractures has steadily increased without good evidence of their clinical efficacy. This prospective randomized multicenter study was designed to compare the clinical and radiographic outcomes of patients who had been treated with a traditional extramedullary hip screw for an unstable (AO/OTA 31-A2) intertrochanteric hip fracture with those of patients who had been treated with the newer intramedullary device for the same injury.

Methods: The Lower Extremity Measure (LEM) was used as the primary hip-specific outcome tool. The Functional Independence Measure (FIM), the timed “Up & Go” (TUG) test, as well as a timed two-minute walk test were used as secondary clinical outcome tools. Specific radiographic parameters were collected to assess for fracture movement, heterotopic ossification, and implant failure.

Results: No significant differences were noted between the intramedullary and extramedullary treatment arms with regard to either the primary or the secondary clinical outcome tools. The radiographic parameters favored the intramedullary treatment arm, which had less femoral neck shortening.

Conclusions: While the use of the intramedullary devices led to better radiographic outcomes in this study, this did not translate to improved functional outcomes.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

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Intertrochanteric fractures of the hip are common fractures in the elderly. While the incidence of these fractures has actually decreased slightly in the western world, the absolute increase in the elderly population has led to a doubling of the number of these fractures over the past three decades, and this trend is expected to continue. Hip fractures in elderly individuals will continue to place an ever increasing financial burden on health-care systems. The total annual cost of hip fractures in the U.S. will double to $16 billion by 2040. A substantial part of this cost is directly related to the cost of the implants. The clinical efficacy of more costly implants should be objectively evaluated before their general use is adopted. The purpose of this study was to compare the newer intramedullary devices with the more traditional plate-and-screw devices used in the repair of unstable intertrochanteric fractures (AO/OTA [Orthopaedic Trauma Association] 31-A2).

Surgical management of these fractures has evolved over the past few decades in a quest to improve mobility and functional outcomes in this patient population. The initial extramedullary sliding screw device introduced in the 1950s revolutionized the care of intertrochanteric fractures. It quickly became the standard of care for the acute management of intertrochanteric fractures. In the 1990s, cephalomedullary nails started gaining popularity despite any conclusive evidence of superior performance. Several biomechanical studies point to the advantages of intramedullary devices for the management of proximal femoral fractures.

Despite the increased use of intramedullary devices for the treatment of all intertrochanteric fractures, outcomes have not

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changed. In fact, the current clinical evidence seems to favor the more economical extramedullary device. While the mechanical benefits of the intramedullary devices may not lead to improved outcomes in patients with a simple intertrochanteric fracture, the more complex unstable patterns addressed in this study may be different. This prospective randomized multicenter study was designed to shed some light on the clinical and radiographic outcomes in patients treated with an extramedullary device for an unstable (AO/OTA 31-A2) intertrochanteric hip fracture as compared with the outcomes in those treated with an intramedullary device for the same injury.

**Materials and Methods**

**Participating Sites**

This prospective randomized trial involved nine sites across Canada. The study was directed by the Canadian Orthopaedic Trauma Society (COTS). The study was approved by the ethical review boards at all participating institutions and was registered at ClinicalTrials.gov (NCT00597779). Patients with an unstable intertrochanteric hip fracture were identified on admission to the emergency department. If they met the inclusion criteria, and proper consent was obtained, the patients were scheduled for surgery.

**Randomization and Allocation Procedure**

Permuted block randomization (blocks of four, five, or six) was used to assign the two treatment modalities. Sealed envelopes containing the randomly generated modality were mailed from the primary site to the participating sites. The envelopes were opened just prior to surgery, and the designated procedure was then performed. The clinical follow-up evaluations were performed by qualified research assistants who had access to all of the patient files and documents at the various participating sites. The radiographic evaluation was performed by a single independent orthopaedic surgeon.

**Patients**

Eligible patients were prospectively enrolled (Fig. 1) over a four-year period on the basis of the following inclusion criteria: (1) an age of fifty-five years or older,
(2) a Type-A2 intertrochanteric fracture (AO/OTA 31-A2), (3) an isolated fracture, (4) medical fitness for surgery, and (5) a fracture that had occurred less than two weeks before the time of enrollment. The exclusion criteria were (1) a fracture due to malignancy, (2) an inability to walk before the fracture, (3) severe dementia, (4) limited life expectancy due to substantial medical co-morbidities, (5) a medical contraindication, and (6) an inability to comply with rehabilitation or to complete the forms.

The patients were followed for a period of twelve months with serial clinical and radiographic evaluations. The radiographs were evaluated immediately postoperatively and at the scheduled follow-up intervals. The clinical evaluations were performed at six weeks, three months, six months, and twelve months. Baseline questionnaires were administered at the time of the injury.

**Surgical Procedure**

The surgical procedure for implantation of the extramedullary and intramedullary devices included the use of a fracture table with an attempt at closed reduction with use of fluoroscopic guidance. Following this, the procedures differ substantially for the various implants.

To insert the extramedullary device, a lateral incision is made over the proximal aspect of the femur. The fascia lata is split, and the underlying vastus lateralis is exposed. The fascia of this muscle is then opened, and the muscle is
retracted anteriorly to see the femur. Under fluoroscopic guidance, the femoral head screw is then placed in a center center position inside the femoral head. A side plate is then attached to the hip screw. This plate ranges in length from two to six holes at the surgeon’s discretion. The dynamic hip screw (DHS, Synthes) was used in all patients treated with extramedullary fixation.

The exact techniques employed for the different intramedullary nails used in this study vary slightly. However, in general terms, the incision is made in the gluteal area in line with the proximal part of the femur. A guidewire is placed into the greater trochanter and down the medullary canal. The trochanter is then drilled. The medullary canal may be reamed. The nail is then inserted and is fixed into the femoral head with a single screw, double screws, or a helical blade, depending on the implant used. The nail is then locked distally with use of a guide arm. The devices were not locked proximally to maintain the dynamic nature of all implants and to allow compression across the intertrochanteric fracture. In this study, all patients were treated with short nails specifically designed for intertrochanteric fractures. A Trochanteric Fixation Nail (TFN; Synthes), Gamma nail (Stryker), or Trigen INTERTAN nail (Smith & Nephew) was used (Fig. 2).

Clinical Parameters
The primary functional outcome tool used in this study was the Lower Extremity Measure (LEM). Additionally, the Functional Independence Measure (FIM), a timed “Up & Go” (TUG) test (measuring the time needed to rise from a sitting position and walk 20 m), as well as a timed two-minute walk test were performed.

Radiographic Parameters
Anteroposterior and lateral radiographs were evaluated for implant position with use of the tip-apex distance described by Baumgaertner et al. (Fig. 3). All radiographs were calibrated and the amount of femoral neck shortening was measured (Fig. 4). Additionally, the radiographs were evaluated for heterotopic ossification, and a Brooker stage was assigned to each case.

Data Management
The appropriate clinical data were collected at each site with the help of a research assistant. Those data were then transmitted at variable intervals to the primary site. All radiographs from all participating sites were sent to the primary site for evaluation by a single orthopaedic surgeon. The data were entered into a Microsoft Office Access database. All participants in the study were assigned a four-digit number. No personal information on the individual patients was transmitted. All data were stored securely in accordance with the Health Insurance Portability and Accountability Act (HIPAA) regulations.
also used if deviation from the normality assumption was very large. Mixed-effects models appropriate for longitudinal data were used to compare LEM scores over the whole study period between the two groups, accounting for correlation between measurements over time. A nonparametric approach (modeling the score ranks or log ranks) was also used in these models when data were skewed.

Source of Funding
Funding for this study was provided by an $80,000 (USD) grant from the Orthopaedic Trauma Association (OTA), 2007.

Results

Demographics

Two hundred and four patients who met the inclusion and exclusion criteria and were willing and able to participate in this study were enrolled (Fig. 1). The two groups had similar ages; there was an approximately equal number of male and female patients in the nail group, whereas the majority of the patients in the DHS group were female (Table I). Enrollment in the trial was terminated when the desired sample size was reached. Ninety-two patients received the DHS; forty-two, the TFN; forty-eight, the INTERTNail; and twenty-two, the Gamma nail (Fig. 2). One hundred and sixty-seven patients returned for the twelve-month follow-up visit (Fig. 1 and Table II). The reasons for loss to follow-up were variable. Two DHS implants and a TFN failed and were revised to hip arthroplasties. No other patients in this study cohort underwent implant removal during the study period. Nineteen patients died within twelve months after the hip fracture. Eight patients were not able to, or did not wish to, return for follow-up visits at variable time points. The fate of seven patients is unknown.

Radiographic Findings

The average tip-apex distance was 17 mm for the nail group and 18 mm for the DHS group. At the twelve-month follow-up visit, the nail group had a significantly higher prevalence of Brooker Stage-1 heterotopic ossification, but there was no difference between the two groups with regard to Stage 2 or 3. There were no cases of Stage-4 ossification (Table III).

The average loss of neck length was 1.0 cm with the DHS implants and 0.2 cm with the nails. This difference was significant (Table IV). All of the collapse, or fracture settling, occurred within the first six weeks after the index procedure (Fig. 2).

Clinical Findings (Table IV)

The baseline preinjury LEM scores were 74.5 and 71.0 points for the DHS and nail groups, respectively. This difference was not significant. While there was steady improvement in the LEM scores over the twelve-month period, the scores did not return to their preinjury level in either the nail or the DHS group (p < 0.05). There was no difference in the LEM scores between the two groups at any of the study time points. Similarly, there was no difference between the two groups with regard to the FIM scores.

The results of the two-minute timed walk test also significantly improved as time went on after the surgery, but there was no difference in the distances walked between the two groups at any of the follow-up time points. The results of the TUG test also did not differ significantly between the two groups.

Statistical Analysis

Sample Size Calculation

The clinically relevant difference in the LEM scores (the primary dependent outcome variable) was assumed to be 5 (5%) of 100 points. According to Jagal et al., at six weeks, the mean LEM score for community-dwelling patients with a hip fracture is approximately 70 points (standard deviation [SD], 12 points). Alpha was set at 0.05 (two-sided) and power, at 0.80. Using nQuery Advisor software (version 7; Statistical Solutions), we estimated that sixty-four patients would be required in each group for a t test to achieve an 80% power to detect a difference of 5 points in the LEM score between the two treatment groups at a significance level of 5% (two-sided). Considering an anticipated attrition rate of 30% to 40%, we concluded that approximately 100 patients needed to be randomized into each group.

Data Analysis

Descriptive statistics are presented as means and SDs, and proportions as appropriate, to summarize the data at baseline, six weeks, three months, six months, and twelve months. An intention-to-treat approach was used in the main analyses, whereby missing data were imputed with use of a multiple imputation technique based on the Markov chain Monte Carlo method. We also conducted per-protocol analyses in which only patients who had completed the assessments were included. Two-sided t tests were used to compare the main outcome (LEM score) and secondary outcomes between the two groups at each time point. We performed t tests in this study as they are thought to be appropriate for large samples (usually more than thirty). Nonparametric tests (Wilcoxon rank-sum tests) were used if deviation from the normality assumption was very large. Mixed-effects models appropriate for longitudinal data were used to compare LEM scores over the whole study period between the two groups, accounting for correlation between measurements over time. A nonparametric approach (modeling the score ranks or log ranks) was also used in these models when data were skewed.

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The results of the two-minute timed walk test also significantly improved as time went on after the surgery, but there was no difference in the distances walked between the two groups at any of the follow-up time points. The results of the TUG test also did not differ significantly between the two groups.

TABLE I Demographics

<table>
<thead>
<tr>
<th></th>
<th>DHS</th>
<th>Nails</th>
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<tbody>
<tr>
<td>Female (no.)</td>
<td>61</td>
<td>55</td>
</tr>
<tr>
<td>Male (no.)</td>
<td>31</td>
<td>57</td>
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<tr>
<td>Mean age (SD) (yr)</td>
<td>80 (9.9)</td>
<td>82 (8.6)</td>
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TABLE II Enrollment

<table>
<thead>
<tr>
<th>Time Point</th>
<th>No. of Patients Who Completed Follow-up</th>
<th>DHS</th>
<th>Nails</th>
<th>Total</th>
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<tbody>
<tr>
<td>Baseline</td>
<td>92</td>
<td>112</td>
<td>204</td>
<td></td>
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<tr>
<td>6 wk</td>
<td>89</td>
<td>105</td>
<td>194</td>
<td></td>
</tr>
<tr>
<td>3 mo</td>
<td>85</td>
<td>96</td>
<td>181</td>
<td></td>
</tr>
<tr>
<td>6 mo</td>
<td>85</td>
<td>93</td>
<td>178</td>
<td></td>
</tr>
<tr>
<td>12 mo</td>
<td>80</td>
<td>87</td>
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TABLE III Brooker Stage of Heterotopic Ossification at Twelve Months

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<thead>
<tr>
<th>Heterotopic Ossification</th>
<th>No. of Patients</th>
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<td>None</td>
<td>57</td>
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<tr>
<td>Stage 1</td>
<td>12</td>
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<tr>
<td>Stage 2</td>
<td>7</td>
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<tr>
<td>Stage 3</td>
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Revised: October 14, 2015

Intramedullary Versus Extradmedullary Fixation for Unstable Intertrochanteric Fractures
<table>
<thead>
<tr>
<th>Variable/Time Point</th>
<th>DHS</th>
<th>Nails</th>
<th>Mean Difference</th>
<th>95% Confidence Interval</th>
<th>P Value</th>
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<tbody>
<tr>
<td>Femoral neck shortening (cm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 wk</td>
<td>1.0 (0.95)</td>
<td>0.2 (0.44)</td>
<td>0.86</td>
<td>0.62, 1.11</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>3 mo</td>
<td>1.2 (0.97)</td>
<td>0.2 (0.50)</td>
<td>0.94</td>
<td>0.67, 1.22</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>6 mo</td>
<td>1.1 (0.98)</td>
<td>0.3 (0.52)</td>
<td>0.88</td>
<td>0.61, 1.16</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>12 mo</td>
<td>1.0 (0.85)</td>
<td>0.2 (0.48)</td>
<td>0.82</td>
<td>0.54, 1.09</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>LEM (points)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>74.5 (20.02)</td>
<td>71 (20.46)</td>
<td>3.43</td>
<td></td>
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</tr>
<tr>
<td>6 wk</td>
<td>42.1 (20.45)</td>
<td>44 (20.13)</td>
<td>−2.30</td>
<td>−9.00, 4.41</td>
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<tr>
<td>3 mo</td>
<td>55.4 (24.02)</td>
<td>56 (22.41)</td>
<td>−0.60</td>
<td>−8.22, 7.03</td>
<td>0.88</td>
</tr>
<tr>
<td>6 mo</td>
<td>63.9 (22.28)</td>
<td>61 (23.20)</td>
<td>2.88</td>
<td>−4.58, 10.35</td>
<td>0.45</td>
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<tr>
<td>12 mo</td>
<td>64.4 (25.00)</td>
<td>66 (21.10)</td>
<td>−1.57</td>
<td>−9.46, 6.32</td>
<td>0.69</td>
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<tr>
<td>Timed 2-min walk test (m)</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 wk</td>
<td>47 (22.89)</td>
<td>46 (24.76)</td>
<td>0.74</td>
<td>−8.63, 10.10</td>
<td>0.88</td>
</tr>
<tr>
<td>3 mo</td>
<td>71 (30.81)</td>
<td>62 (28.70)</td>
<td>9.06</td>
<td>−2.22, 20.34</td>
<td>0.11</td>
</tr>
<tr>
<td>6 mo</td>
<td>75 (32.86)</td>
<td>70 (30.82)</td>
<td>5.49</td>
<td>−6.21, 17.19</td>
<td>0.35</td>
</tr>
<tr>
<td>12 mo</td>
<td>81 (36.00)</td>
<td>80 (35.55)</td>
<td>1.29</td>
<td>−13.06, 15.64</td>
<td>0.86</td>
</tr>
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<td>TUG (sec)</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 wk</td>
<td>34 (23.19)</td>
<td>48 (64.20)</td>
<td>−14.76</td>
<td>−32.37, 2.85</td>
<td>0.10</td>
</tr>
<tr>
<td>3 mo</td>
<td>26 (20.07)</td>
<td>26 (18.95)</td>
<td>0.32</td>
<td>−6.67, 7.32</td>
<td>0.93</td>
</tr>
<tr>
<td>6 mo</td>
<td>21 (12.76)</td>
<td>24 (22.76)</td>
<td>−2.71</td>
<td>−8.96, 3.55</td>
<td>0.39</td>
</tr>
<tr>
<td>12 mo</td>
<td>20 (15.87)</td>
<td>19 (22.74)</td>
<td>0.91</td>
<td>−6.84, 8.67</td>
<td>0.82</td>
</tr>
<tr>
<td>FIM total (points)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>113 (13.69)</td>
<td>109 (18.46)</td>
<td>3.80</td>
<td>−1.03, 8.63</td>
<td>0.12</td>
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<tr>
<td>6 wk</td>
<td>98 (21.46)</td>
<td>93 (23.39)</td>
<td>4.33</td>
<td>−2.85, 11.50</td>
<td>0.24</td>
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<tr>
<td>3 mo</td>
<td>103 (22.64)</td>
<td>99 (23.79)</td>
<td>3.16</td>
<td>−4.36, 10.69</td>
<td>0.41</td>
</tr>
<tr>
<td>6 mo</td>
<td>106 (24.68)</td>
<td>104 (22.75)</td>
<td>2.18</td>
<td>−5.66, 10.01</td>
<td>0.58</td>
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<tr>
<td>12 mo</td>
<td>111 (17.83)</td>
<td>106 (23.00)</td>
<td>4.77</td>
<td>−2.20, 11.74</td>
<td>0.18</td>
</tr>
</tbody>
</table>

**Fig. 5**

*From left to right* Displaced intertrochanteric fracture stabilized with a TFN. The anteroposterior and lateral intraoperative views demonstrate an excessive tip-apex distance. At three months, the screw is seen penetrating the femoral head. The TFN was revised to an arthroplasty at four months.
Complications
The failure of the two DHS implants occurred by the usual “cut out” mechanism despite adequate initial reduction and implant position. The TFN failure was likely due to poor fracture reduction and implant position (Fig. 5). No infections or wound complications were documented in this study. Nineteen patients died during the study follow-up period, but none of the deaths were directly related to the implants used in this study.

Discussion
Currently, failure rates for the treatment of intertrochanteric hip fractures are 9% to 16%.[14] Successful union frequently comes at the expense of substantial femoral neck shortening. In the past, implants designed to restore and maintain the anatomy of the hip have resulted in high failure rates[10–18]. The intramedullary device may have distinct advantages from a biomechanical standpoint as it is a load-sharing device more closely located to the axis of weight-bearing than the plate-hip screw device[2]. Furthermore, the amount of femoral neck collapse is reduced as the distal cortex of the proximal fragment abuts the more medially located nail. Advances in intramedullary designs have been promising, but the clinical results have varied[10,19]. Adoption of the intramedullary devices was initially slow because of reports of femoral fractures at the distal locking bolt. This issue seems to have been successfully addressed with the newer implant designs, so that modifications of the surgical technique, such as foregoing distal locking or using long implants, are no longer required[20–22]. The large diameter of the proximal aspect of the implant requires extensive reaming of the greater trochanter and partial detachment of the gluteus medius[23]. This may lead to abductor weakness and a Trendelenburg gait. Some studies have revealed increased reoperation rates after use of these early hip-nail devices compared with those following use of the plate-hip screw implant[13]. Other studies have shown decreased blood loss and operative time with the nails[14,24]. A meta-analysis of the literature favors the sliding hip screw design[25]. More recent randomized prospective studies of all intertrochanteric fractures seem to suggest equivalent results regardless of the implant used[26]. Despite a paucity of supportive clinical evidence, the use of the intramedullary implants has been steadily increasing in North America. Between 1999 and 2006, their use has increased from 3% to 67% with great regional variation[27]. This great variability in the use of these implants suggests that other factors besides their clinical efficacy determine their usage.

Most studies have focused on radiographic evidence of failure and reoperation rates without considering patient function, and most have involved the first generation of intramedullary devices[28]. The design modifications of the newest generation of nails have to some degree corrected the shortcomings of earlier designs. Implant and perioperative fractures are now relatively rare complications. There are several manufacturers of these implants, with variable designs, but the overall outcomes seem to be similar[28–30].

From an economic perspective, the threefold to fivefold increase in implant cost of the intramedullary nails should be considered when managing patients with an intertrochanteric fracture[12].

Our study did not show any significant difference in clinical function, as assessed with the hip-specific LEM score at the different time points, regardless of which implant had been used. The LEM scores at the twelve-month time point were significantly lower than the initial prefracture values, indicating overall loss of function after the fracture regardless of the treatment modality employed. Similarly, the more general FIM scores did not differ between the groups at the different time points.

This study did show that the nails lead to significantly less femoral neck shortening, with almost 1 cm more shortening in the DHS group. As this finding did not correlate with any functional impairment in the cohort, it is not consistent with the conclusions of other studies that showed a clear correlation between femoral neck shortening and worse clinical function[31–34]. It is possible that the violation in the abductor musculature negates any biomechanical advantage of a longer neck length in this patient population.

The major limitation of this study is the inherent attrition of study participants for various reasons. The advanced age and medical comorbidities led to a mortality rate of almost 10% within the first year after the fracture occurred. Furthermore, eight patients were unwilling or unable to continue in the study and the fate of seven patients is unknown. Theoretically, those patients could have had adverse effects and additional surgical procedures without our knowledge.

In conclusion, the current literature regarding intertrochanteric fracture treatment does not clearly favor one implant over another[25]. In an attempt to define fracture types for which the intramedullary implants might be superior, we restricted our study to patients with an unstable AO/OTA 31-A2 fracture type. The intramedullary devices led to significantly less shortening across the fracture site. This did not translate to a significant difference in extremity or general function as measured with the LEM and FIM, respectively.
References


