The Extended-Short Nail System, a Novel Concept in the Management of Proximal Femur Fractures

Russell C. Wright, BS, Stephan V. Yacoubian, MD, Garrett A. Salzman, Raymond B. Raven III, MD, Yuri Falkinstein, MD, and Shahan V. Yacoubian, MD

Abstract

In light of recent health care reform and the aging US Medicare population, it is becoming increasingly important for orthopedic surgeons to use effective and efficient strategies for hip fracture surgery.

The Extended-Short Nail System (ES nail) is a US Food and Drug Administration–approved titanium nail which is locked at the same location as the locking hole of a short intramedullary (IM) nail. The ES nail takes advantage of an "extended-short" hybrid design combining the mechanical characteristics of a long IM nail with the surgical ease of use offered with a short IM nail.

We retrospectively studied the 2-year outcomes of the first 150 patients who underwent intertrochanteric fracture fixation with ES nails. Fifty-four of the 93 patients (58.1%) available at 2 years had returned to prefracture level of activity (based on UCLA Activity Scale scores). There were 2 postoperative periprosthetic fractures, 2 wound infections, and 3 postoperative hematomas, but no nonunions, implant failures, cutouts, or fixation failures.

Our experience with the ES nail system—its ease of use, low complication rate, high union rate, and favorable rate of patients' return to prefracture activity level—suggests it is a viable option in the management of hip fractures.

Mr. Wright is Research Fellow, Department of Orthopaedic Surgery Research, Orthopaedic Surgery Specialists, Burbank, California.
Dr. Stephan V. Yacoubian is Orthopaedic Surgeon, Department of Orthopaedic Surgery, Providence Saint Joseph Medical Center, Burbank, California.
Mr. Salzman is Research Assistant, Department of Orthopaedic Surgery Research, Orthopaedic Surgery Specialists.
Dr. Raven is Orthopaedic Surgeon, Dr. Falkinstein is Orthopaedic Surgeon, and Dr. Shahan V. Yacoubian is Orthopaedic Surgeon, Department of Orthopaedic Surgery, Providence Saint Joseph Medical Center.

Address correspondence to: Russell C. Wright, BS, Orthopaedic Surgery Specialists, 2625 W Alameda Ave, Suite 116, Burbank, CA 91505 (tel, 818-841-3936; fax, 818-841-5974; e-mail, russellc.wright@gmail.com).

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Proximal femur fractures represent a major public health problem that affects more than 266,000 US Medicare beneficiaries annually and costs an estimated $2.9 billion per year.[1,2] The anticipated increase in the world's elderly population is expected to result in an estimated 6.3 million hip fractures occurring annually by 2050.[3] Almost 47% of all proximal femur fractures occur in the intertrochanteric (IT) region, and, though several implants are available, there is no gold standard for IT fracture fixation. Given the impending boom in the geriatric population, it is becoming increasingly important for orthopedic surgeons to use effective and efficient strategies for hip fracture surgery.

Management of proximal femur fractures continues to evolve as new devices are developed and more studies describe novel methods of fixation. Short intramedullary (IM) nailing has been compared extensively with plate fixation. However, review of the orthopedic literature has demonstrated varying results and often insignificant differences in functional and clinical outcomes.[4-8] Therefore, it is difficult to establish the superiority of one implant type over another for the management of all hip fractures.[9]

Among young orthopedic surgeons, use of short IM nail fixation has surpassed that of plate fixation in recent years. On the American Board of Orthopaedic Surgery part II examination between 1999 and 2006, there was a 20-fold increase in the number of surgeons who reported managing IT fractures with short IM nails versus plate fixation.[10] These findings suggest that the short IM nail has become an accepted fixation technique for IT fractures. Considering the lack of scientific evidence, it is presumed that the increasing popularity of the short IM nail likely can be attributed to surgeons' personal preference.[10,11]

Long IM nail technology was adapted in the 1990s for IT fracture fixation with the addition of a sliding compression hip screw component. Long IM nail technology had been used routinely since the late 1940s for management of femoral shaft fractures,[12,13] and, more recently, several authors have reported on the effectiveness of long IM nails for proximal femur fractures.[14-16] Although the canal-spanning length of long IM nails offers potential mechanical benefits, the operative technique is often technically challenging.

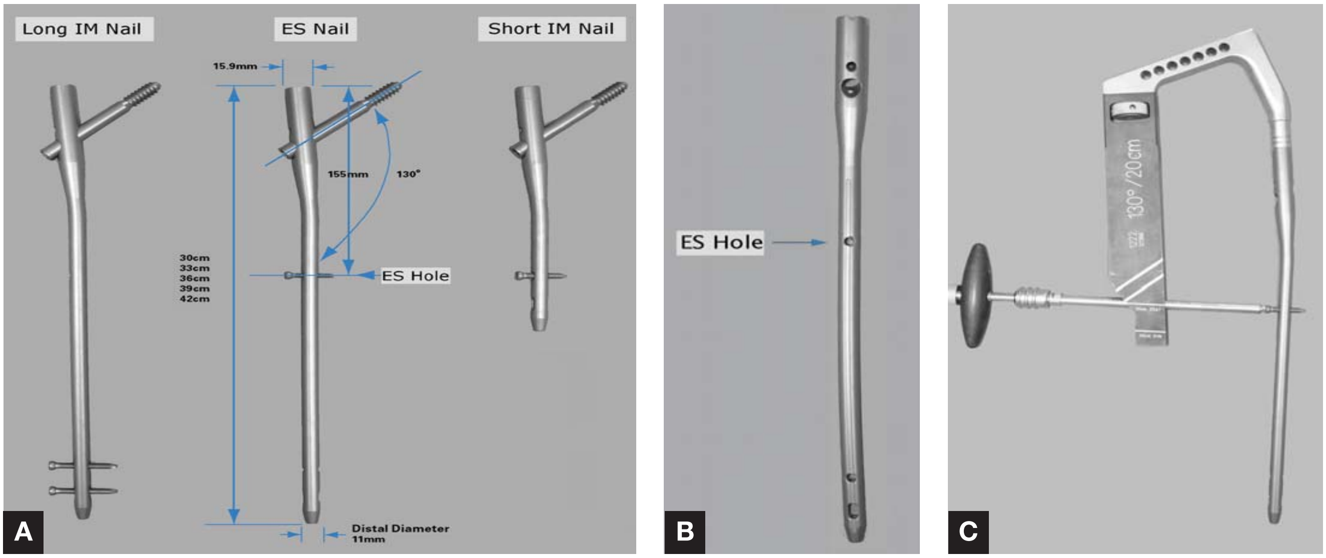

Figure 1. (A) The length of the Extended-Short Nail System (ES nail; Advanced Orthopaedic Solutions, Torrance, California) is the same length as the corresponding standard long intramedullary nail, and the "ES hole" is at the same distance (155 mm) from the proximal tip of the nail as a standard short intramedullary nail. (B) Lateral radiograph of ES nail demonstrating various screw holes and slight anterior bow. (C) ES targeting module locking at ES hole.

Targeting distal locking screws can be difficult and burdensome, increasing both operative time and radiation exposure. Many new targeting devices for distal interlocks have been developed; however, many are cumbersome and unreliable.[17-21] Consequently, the "freehand technique" continues to be the most popular method for locking distally.[19-22] These issues have led to some surgeons' preferring short IM nails or long distally unlocked IM nails, which can be easier and faster to use.

The Extended-Short Nail System (ES nail; Advanced Orthopaedic Solutions, Torrance, California) was developed in 2005 to address these concerns and provide an alternative solution. The ES nail takes advantage of an "extended-short" hybrid design that combines the mechanical characteristics of a long IM nail with the surgical ease of use offered with a short IM nail.

We retrospectively studied the 2-year outcomes of the first 150 patients who underwent IT fracture fixation with ES nails.

Extended-Short Nail System

The ES nail is a US Food and Drug Administration–approved titanium nail indicated for the treatment of stable and unstable proximal fractures of the femur, including pertrochanteric, intertrochanteric, and high subtrochanteric fractures (Figure 1) (Advanced Orthopaedic Solutions, Torrance, California). These nails are available in lengths of 30, 33, 36, 39, and 42 cm. They have diameters of 10, 11, and 14 mm, with a slotted design and a slight anterior bow to conform to the shape of most femurs. The radius of curvature is 1.0 m for the 30- and 33-cm nails, 1.3 m for the 36-cm nail, and 1.5 m for the 39- and 42-cm nails. The nails accept a 10.5-mm titanium lag screw and an optional 5.0-mm titanium antirotation screw, both at angles of 130° or 125°, depending on the nail used.

Proximal screw locking at the "ES hole" using the ES targeting module provides fracture stabilization analogous to that of short IM nails and eliminates the need to distally lock the nail (Figure 1). The ES hole is located at the same distance as the distal locking hole of a standard short IM nail, 155 mm below the top rim of the ES nail, and accepts a 5.0-mm titanium locking screw (Figure 1A). If indicated, however, the ES nail maintains the option of distal locking with 5.0-mm locking screws applied to the distal end of the nail at the static round and dynamic oval-shaped holes.

Patients and Methods

One hundred fifty consecutive patients with IT fractures were treated with the ES nail system by 4 orthopedic surgeons between May 2006 and April 2008. Included in the study were all patients who presented with IT fractures to the emergency department at a single community hospital, who were medically cleared for surgery, and who consented. Excluded were patients who had pathologic fractures and patients who were not medically cleared for surgery. No other devices or treatments were compared in this study. Approval was obtained from the institutional review board at our institution and data were collected on age, sex, comorbidities, prefracture living conditions, fracture classification, intraoperative and postoperative complications, blood transfusions, discharge location, and date of fracture union. Data are presented as means (SDs).

We analyzed preoperative radiographs and classified fracture patterns using the AO (Arbeitsgemeinschaft für Osteosynthesefragen) Müller classification system.[23] Simple 2-fragment fractures with good support at the medial cortex are classified as stable type A1 fractures; unstable

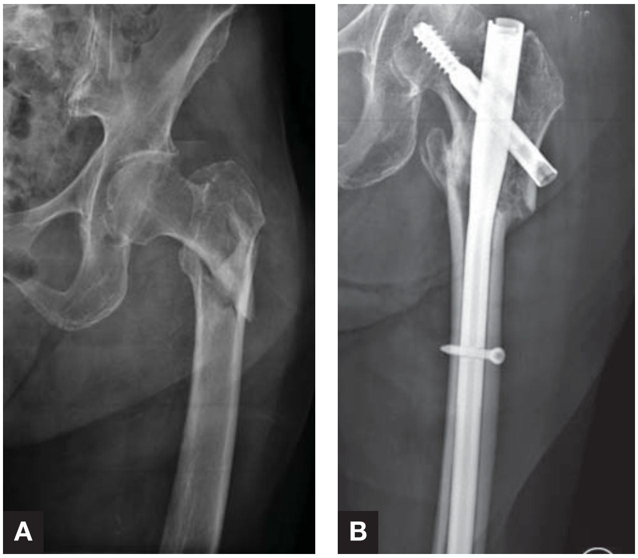

Figure 2. (A) Preoperative reverse obliquity fracture, AO (Arbeitsgemeinschaft für Osteosynthesefragen) Müller classification A3. (B) Healed fracture with ES nail at 12 months.

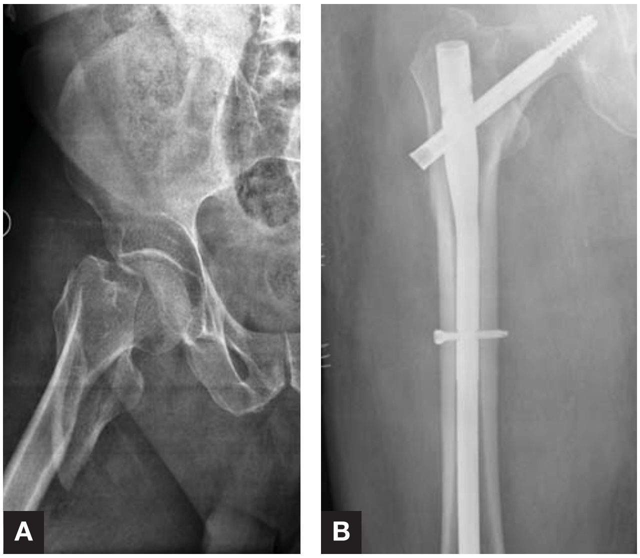

Figure 3. (A) Preoperative intertrochanteric fracture with subtrochanteric extension, AO Müller classification A3. (B) Postoperative radiograph of fracture with ES nail.

multifragment fractures with the medial and dorsal cortices broken at several levels, but with an intact lateral cortex, are defined as type A2 fractures; reverse obliquity and multifragment unstable fractures involving the lateral cortex are defined as type A3 fractures.

The operative technique for the ES nail system follows standard trochanteric-entry nailing methods. The patient is placed in a supine position on a fracture table, and an operative closed reduction is performed and verified under fluoroscopic control. A 4-cm to 8-cm skin incision is made proximal to the greater trochanter. A cannulated curved awl is then used to make entry to the greater trochanter and a 3.0-mm ball-nose guide wire is inserted. This is followed by 17-mm proximal reaming and subsequent flexible canal reaming to the desired diameter. Reaming to 1.5 mm to 2.0 mm larger than the selected nail diameter is recommended. The selected nail is attached to the targeting module and passed over the guide wire. The lag screw and the ES locking screw are inserted through the targeting module. The only divergence from standard practices occurs with targeting and inserting the ES locking screw using the ES targeting module at the ES hole (Figure 1C). All surgical procedures involved antibiotic prophylaxis and deep vein thrombosis prophylaxis pursuant to Surgical Care Improvement Project protocol.[24]

Postoperative weight-bearing status was determined by the operating surgeon on the basis of fracture pattern and fixation. Depending on individual needs, patients were typically admitted to the acute rehabilitation ward for 2 weeks to 3 weeks, transferred to a skilled nursing facility, or discharged home. Patients were followed up in intervals of 2 weeks to 4 weeks until the fracture was deemed healed, based on physical examination, ambulatory status, presence of pain with weight-bearing, and radiographic union. Radiographic union was defined as bridging callus formation on 3 or more cortices. At follow-up 1 year and 2 years after surgery, patients were examined and radiographed to analyze fracture healing and implant position.

Patient and family interviews were conducted retrospectively, at the 1-year and 2-year follow-up examinations, to determine patients' prefracture activity levels. As there is no universally accepted activity scale for patients who have undergone hip fracture fixation, we used the UCLA Activity Scale.[25] This scale was originally developed to assess patient activity after joint replacement, but we felt its versatility and ease of use would make it a good outcome measurement tool for this study. Patients' self-reported activities of daily living are used to subjectively rate patients on a scale ranging from 1 (totally inactive) to 10 (vigorously active).

Results

Of the 150 IT fractures managed with ES nails between May 2006 and April 2008, 67 (44.7%) were stable and 83 (55.3%) were unstable. Sixty-seven (44.7%) were classified A1, 60 (40%) were A2, and 23 (15.3%) were A3. There were 78 left and 72 right hip fractures. Mean (SD) age at time of fracture was 84.0 (10.8) years (range, 44-101 years). There were 36 men and 114 women. Figures 2 through 4 represent typical preoperative and postoperative radiographs from the patient cohort. Before fracture, 38 patients lived at a skilled nursing facility and 112 lived independently or in a family setting at home. Mean (SD) prefracture UCLA Activity Scale score for the 150 patients was 3.9 (1.2).

The concomitant medical disorders documented in the patient cohort were cardiovascular disorder (n = 75), endocrine/metabolic disor-

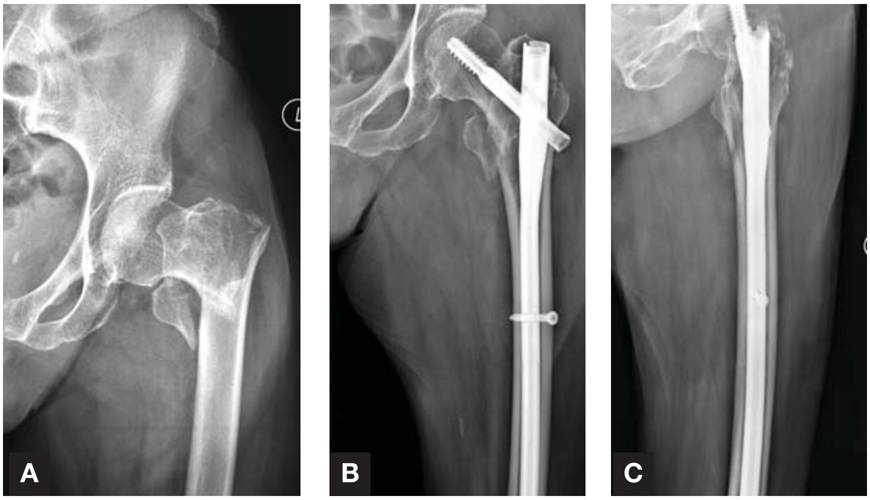

Figure 4. (A) Preoperative intertrochanteric fracture, AO Müller classification A2. Postoperative anteroposterior (B) and lateral (C) radiographs illustrating canal spanning length and slight anterior bow of the ES nail.

der (n = 54), neurologic disorder (n = 49), gastrointestinal disorder (n = 18), respiratory disorder (n = 14), and genitourinary disorder (n = 4). Previously documented osteoporosis was noted in 41 patients. Mean number of comorbidities was 2.4. Mean (range) time from hospital admission to surgery was 1.6 (0-21) days. Mean (range) operative time, measured from skin incision to end of wound closure, was 27.4 (18-41) minutes. In all 150 patients, closed reduction was achieved and use of the ES hole provided sufficient fracture stabilization. Locking at the distal static round or dynamic oval holes was not necessary in any of the operations. Mean (SD) operative blood loss was 196 (43) mL per patient. Blood transfusions were required for 5 patients (3.3%) before surgery and for 92 patients (61.3%) after surgery. Hemoglobin and hematocrit levels were used in conjunction with clinical evaluation to determine need for transfusion. Seventy-one patients (47.3%) were admitted to the acute rehabilitation ward, 62 (41.3%) were transferred to a skilled nursing facility, 16 (10.7%) were discharged home, and 1 (0.7%) died in hospital as a result of comorbidities.

Nineteen patients (12.7%) were lost to follow-up within the first year after discharge from hospital. In addition to the 1 patient (0.7%) who died in the hospital, 26 patients (17.3%) died within the year of the index procedure. This resulted in a cumulative 1-year mortality rate of 18%.

One hundred twenty-three patients were alive 1 year after surgery and 104 of these patients (84.6%) were available for the 1-year follow-up. Two superficial wound infections and 3 hematomas occurred among these 104 patients, and all 5 of these postoperative complications resolved with conservative management. There were no nonunions, implant failures, cutouts, or fixation failures. Two (1.9%) of the 104 patients fell after surgery—one at 5 weeks and the other at 11 weeks—and sustained femoral shaft fractures distal to the ES hole and proximal to the tip of the nail (Figure 5A). In both cases, closed reduction under fluoroscopic control was successful and the fracture was stabilized with insertion of 2 distal locking screws (Figure 5B). The ES nail was not compromised and did not need to be removed in either case.

For these 104 patients, mean (SD) time to union was 11.3 (2.2) weeks (range, 8-16 weeks). Mean (SD) UCLA Activity Scale score was 3.9 (1.2) before fracture and 3.5 (1.4) at 1-year follow-up. Sixty-five of the 104 patients (62.5%) had returned to their prefracture level of activity.

During postoperative year 2, no patients were lost to follow-up. Eleven patients died that year, resulting in a cumulative 2-year mortality rate of 25.3% (38/150). Of the 112 patients alive 2 years after surgery, 93 (83%) were available for the 2-year follow-up. For these 93 patients, mean (SD) UCLA Activity Scale score was 3.9 (1.2) before fracture, 3.6 (1.4) at 1-year follow-up, and 3.5 (1.4) at 2-year follow-up. Fifty-four of the 93 available patients (58.1%) had returned to their prefracture level of activity.

Discussion

An immense amount of data are available on numerous viable and effective implant options; however, establishing the superiority of one implant type over another for the management of all hip fractures remains difficult. Extramedullary devices were successfully used in the past, and, to some degree, are still used by many surgeons. Nonetheless, the use of intramedullary devices has overtaken extramedullary devices in recent years.[10] Although controversial, the reported advantages of using IM devices include less blood loss, smaller incision, less soft-tissue dissection, shorter surgical time, and quicker return to weight-bearing.[26,27] IM devices also have the potential to allow for load sharing between bone and implant,[28-30] which can be relevant for promoting healing at the fracture site.[27,31,32]

Results from a number of randomized controlled trials indicate extramedullary devices such as the dynamic hip screw (DHS) should not be used for some unstable IT fractures including transverse and reverse obliquity fractures.[33-36] The ability to manage these fracture types, as well as many subtrochanteric fractures, with the ES nail exceeds the scope of indications of DHS-type devices. The versatility of the ES nail is a significant advantage for both surgeon and hospital, as a single implant can be used consistently to manage a variety of hip fractures, and hospitals can minimize inventory and streamline staff training.

Periprosthetic fracture secondary to cortical impingement at the distal tip of a short IM nail or DHS-type device is well-documented in the orthopedic literature as a common

Figure 5. (A) Preoperative radiograph of traumatic periprosthetic fracture with ES nail. (B) Postoperative radiograph demonstrating management with distal locking screws; hardware extraction was not necessary.

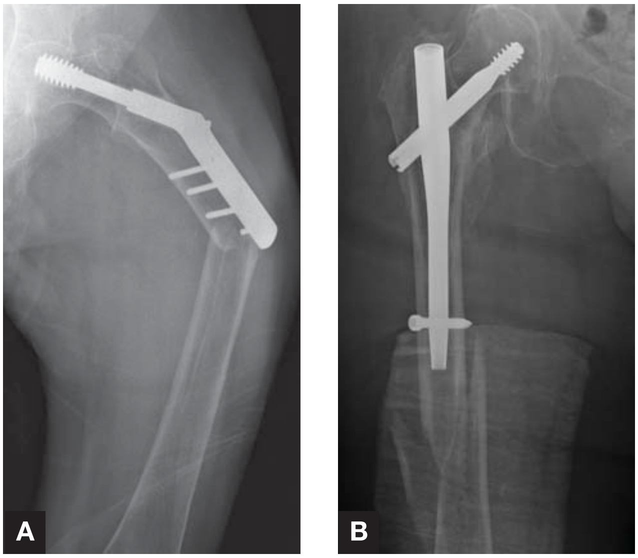

Figure 6. (A) Periprosthetic fracture at distal tip of dynamic hip screw. (B) Periprosthetic fracture at distal tip of short intramedullary nail. These 2 example radiographs are not from our patient cohort.

complication.[26,33,37-39] Figure 6 shows 2 radiographic examples (not from our patient cohort) of this complication. In a patient of short stature, the distal tip of a short IM nail can terminate in the isthmus and potentiate a stress riser effect,[36] which can increase the risk for femur fracture at the tip of the device with subsequent trauma. The canal-spanning length of the ES nail (Figure 4C) theoretically reduces the risk for periprosthetic fracture secondary to postoperative trauma. The risk for catastrophic fracture at the tip of a short IM nail or a DHS-type device can therefore potentially be reduced.

Regardless of surgeons' implant choices and best efforts, postoperative falls and periprosthetic fractures will continue, with disastrous consequences. The ES nail system can make such complications much more manageable. Both periprosthetic fractures observed in this study were stabilized with 2 screws placed through the distal-most locking holes, and hardware extraction was not necessary (Figure 5B). Use of the ES nail system—versus a short IM nail or DHS-type device—potentially avoids the major surgical dissection necessary to extract hardware and apply a plate, strut graft, and cables to manage a periprosthetic fracture.

Use of long IM nails has gained popularity with a number of orthopedic surgeons worldwide. Several authors have reported on the usefulness and effectiveness of long IM nails in managing proximal hip fractures.[14-16] Reported union rates range from 95% to 100%, which is consistent with our results.[14,40-44] The ES nail system shares many characteristics with long IM nail technology but has several unique practical options, including the ES targeting system (Figure 1).

The freehand method for targeting distal locking screws is widely known to be a time-consuming technique that involves significant radiation exposure.[45-48] In a study of surgeons who used the freehand technique to distally lock IM nails, Levin and colleagues[45] found that the radiation dose during an operation was 90 times higher than the maximum recommended daily dose. Use of the ES nailing system eliminates freehand distal locking and provides a significant long-term benefit to surgeons, operating room staff, and patients.

Although there have been no studies characterizing and supporting use of the technique, a number of orthopedic surgeons manage IT fractures by using long IM nails without locking screws. Presumably, this is done to prevent periprosthetic fractures (with the canal-spanning length of the long IM nail) while avoiding the technically challenging task of distal locking. Biomechanical and clinical studies must be performed so surgeons can understand the implications of using unlocked long IM nails before the widespread acceptance of this technique. Possible complications are decreased torque rigidity and distal implant lever arm micromotion, which may cause thigh pain, nonunion, malunion, or implant failure. Our concerns with this technique are suboptimal fracture healing and implant failure, particularly in unstable fractures. The ES nail offers a viable alternative for surgeons who wish to eliminate the cumbersome task of distal locking and potentially protect against periprosthetic fractures.

The present study had its limitations. There were problems with the retrospective design, particularly regarding follow-up. Making statements about complications and function with 12.7% of patients unavailable for the 1-year follow-up was difficult. That challenge, however, is inherent to all studies involving fracture management, and our follow-up rate is comparable to that of other IT fracture reports.[9] Studies with larger patient cohorts and longer follow-ups would be well suited to addressing these shortcomings. Other study limitations were lack of biomechanical testing and use of a single implant without comparison. Subsequent studies should use a randomized controlled trial design to further assess the efficacy of the ES nail system.

Conclusion

Our experience with the ES nail system's ease of use, low complication rate, high union rate, and favorable rate of patients' return to prefracture activity level suggests the ES nail system is a viable option in the management of hip fractures.

Authors' Disclosure Statement

Dr. Stephan V. Yacoubian reports that he was involved in the product development of the Extended-Short Nail and receives royalties from Advanced Orthopaedic Solutions. The other authors report no actual or potential conflict of interest in relation to this article.

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