Early Results of the Less Invasive Stabilization System for Mechanically Unstable Fractures of the Distal Femur (AO/OTA Types A2, A3, C2, and C3)

Mark Weight, MD and Cory Collinge, MD

Objectives: Historically, mechanically unstable fractures of the distal femur have been difficult to treat. Problems such as varus collapse, malunion, and nonunion frequently resulted before fixed-angle plates and indirect reduction techniques were popularized. More recently, the Less Invasive Stabilization System®, or LISS (Synthes, Paoli, PA), has been designed to combine these 2 approaches with the intended goals of achieving adequate stable fixation and early healing. Early clinical results for the femoral Less Invasive Stabilization System® have been promising. The purpose of this study is to evaluate the clinical results of patients with high energy, mechanically unstable fractures of the distal femur treated with the Less Invasive Stabilization System®.

Design: Retrospective analysis of a treatment protocol, consecutive patient series.

Setting: Busy level II trauma center.

Patients/Participants: Twenty-six patients with 27 high-energy AO/OTA types A2, A3, C2, and C3 fractures of the distal femur.

Intervention: Treatment with indirect fracture reduction and internal distal femoral fixation using the Less Invasive Stabilization System®.

Main Outcome Measurements: Clinical and radiographic assessment.

Results: Twenty-one patients with 22 fractures were available for evaluation at an average 19 months postinjury (range 12–35 months). The mechanism of injury included 12 motor vehicle collisions, 4 high falls, 5 motorcycle crashes, and 1 bicyclist struck by a car. Twenty patients had associated injuries. Six fractures were open. All fractures were comminuted; according to the AO/OTA fracture classification there were 4 A2, 3 A3, 12 C2, and 3 C3 fractures. All fractures healed without secondary surgeries at a mean of 13 weeks (range 7–16 weeks). There were no cases of failed fixation, implant breakage, or infection. Average joint line orientation relative to the femoral shaft axis (valgus) measured 99° on postoperative radiographs and 99° on final radiographs. A comparison of postoperative to healed final radiographs for each femur demonstrated no case with greater than a 3° difference in either varus or valgus. Complications included 1 malunion where the fracture was fixed in 8° of valgus and 2 cases of external rotation between 10° and 15°. Painful hardware occurred in 4 patients, of which 3 underwent implant removal. The average knee range of motion was 5° to 114°.

Conclusions: The Less Invasive Stabilization System® allows for stable fixation and facilitates early healing in mechanically unstable high-energy fractures of the distal femur. There were no patients with fixation failure, varus collapse, or nonunion in this “at-risk” population. This treatment safely allows for immediate postoperative initiation of joint mobility and the progression of weight bearing with early radiographic signs of healing.

Key Words: minimally invasive plating, biologic plating, fracture fixation, femur, supracondylar femur

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ods for comminuted or unstable fractures of the distal femur were proposed, including double plating, use of plates for endosteal substitution, and anatomically contoured plates.

In the 1980s, advances in fracture care were applied to these difficult injuries and clinical results improved. First, indirect reduction and improved maintenance of the fracture biology was popularized by Mast et al and others. Second, improvements in implant design occurred, leading to fixed-angle plates such as the 95° angle blade plate and dynamic condylar screw. These fixed-angle implants impart a measure of stability to plate fixation in this area not previously available: in particular, they resist relative shortening of the medial side that may result in varus deformity. When these 2 treatments were employed together, dramatically improved rates of bone healing and fewer complications of treatment were found compared with historical controls.

Recently, “locked plating” systems have been developed, where screws are inserted that attach to the plate forming a multiple fixed-angle construct. Some of these systems are designed to apply the implants in a minimally invasive fashion that may diminish problems with fracture healing and infection. Additionally, the Less Invasive Stabilization System® (LISS, Synthes USA, Paoli, PA), functions as an “internal fixator,” as the implant is designed not to compress the periosteum, thus potentially allowing maintenance of the vascularity to the injured bone (Fig. 1). Early clinical results for the distal femoral LISS have been promising.

METHODS

Twenty-six patients identified from our trauma registry with 27 mechanically unstable distal femur fractures (AO/OTA 33-A2, A3, C2, and C3) that were treated with LISS between August 1999 and October 2002. All fractures were treated by a single fellowship-trained orthopaedic trauma surgeon at a busy level II trauma facility. Treatment of patients with these injuries included a protocol of early fracture fixation using either LISS definitively or spanning of the fracture and knee joint with a temporizing external fixator. Open fractures, fractures with articular comminution, and polytraumatized patients were treated in a staged fashion. Definitive treatment included open reduction of any intra-articular fractures, indirect reduction of metaphyseal and metadiaphyseal fractures, and minimally invasive plate application and fixation.

Operative treatment of the patients included in this report is as follows. Patients were positioned supine on a radiolucent operating table. A wide surgical prep of the entire lower extremity was performed, and prophylactic antibiotics were administered. If an external fixator was in place, it was carefully cleansed with iodine soap and paint and handled as little as possible throughout the case. Alcohol moistened sponges were placed around the pin sites and held in place with elastic gauze. A 5 to 10 cm skin incision was made along the lateral aspect of the distal femur and the iliotibial band fibers were incised in line with the skin. Displaced articular injuries were addressed first with reduction and application of 1 or 2 small fragment lag screws placed anterior to the expected site of plate placement. The surgical tactic was altered for comminuted articular fractures to include a lateral parapatellar approach to the joint to allow for improved access for articular reconstruction.

Indirect reduction of the metaphyseal or metadiaphyseal fractures was achieved by a combination of methods. The external fixator (Stryker-Howmedica-Osteonics, Mahwah, NJ),
if present, or a femoral distractor (Synthes USA) was used to gain length and was universally helpful in reduction. A well-placed knee roll was used in all cases to aid in obtaining and maintaining reduction in flexion–extension. Additional tools used for indirect reduction included the “whirlybird” device from the LISS set, Kirschner wire joysticks, or gentle manipulation of the condylar fragment using a large periarticular clamp (DePuy-Ace, Warsaw, IN).

Using the radiolucent arm as a handle, the plate was inserted above the peristomeum of the lateral femur in a submuscular tunnel beneath the vastus lateralis. The plate is designed to fit the anatomy of the distal femur and was applied such that the plate was nestled up next to the metaphyseal flare and lateral condyle of the distal femur by sliding it proximally and distally. The plate was centered on bone both proximally and distally and oriented flush with the lateral femoral condyle. A large periarticular clamp was used distally to gently hold the bone to the plate, which typically aided in the sagittal plane fracture reduction. All of these fractures had some level of comminution, and, in many cases, approximation of the “normal” anatomy was necessary. The opposite uninjured femur was useful as a template in many of these cases, as bony landmarks on the injured side were obscured by fracture. Great effort was then expended toward critically assessing the fracture alignment in varus-valgus, flexion–extension, as well as rotation, prior to application of definitive fixation, a basic principle when using indirect reduction methods. Quality imaging was used, including an anterior-posterior (AP) view to assess varus-valgus, and a true lateral view to assess plate placement and flexion–extension. Restoration of limb alignment in rotation was assessed clinically as compared to the contralateral side on preoperative examination.

The successful use of the LISS system for the treatment of complicated fractures is technique dependent, and a learning curve exists. Once the LISS plate was inserted, a mini-open approach was performed at the proximal end of the plate to ensure that the plate was centered on the lateral side of the femur bone. A locking bolt in the most proximal screw hole was then inserted into the most proximal screw hole; this added stability to the aiming arm by “rectangularizing” the construct. A ny gross adjustment of fracture reduction was done before provisional fixation was applied, using K-wires through the cannulated stabilization bolts. The “whirlybird” push-pull device was applied to bring the shaft of the femur toward the plate, fine tune the varus-valgus alignment, and augment stability of the provisional construct. At this time, great effort was again made to carefully scrutinize the fracture reduction in all planes before application of definitive fixation.

Self-drilling locking screws (5 mm) were first placed for fixation into the condylar segment, and then into the shaft portion after drilling and measuring with K-wires. Considerable effort was made to apply K-wires and screws parallel to the joint surface as assessed on the AP imaging as a guide for restoring alignment. All screws were inserted in a unicortical fashion. They were placed using irrigation to cool the self-drilling screws in an effort to prevent potential problems with bone necrosis and loss of fixation. Once adequate fixation was achieved, the guide system was removed and the wounds irrigated, dried, and closed. External fixators were only removed after all plating wounds were closed and steriley dressed.

Postoperatively, knee motion was initiated in patients on day 1 or 2 using physical therapy while they were awake. For those patients remaining intubated or in the intensive care unit, a continuous passive motion machine (CPM) in patients was used. Progressive weight bearing was encouraged once there was radiographic evidence of callus formation. Clinical and radiographic examinations were performed until the fracture was healed, and patients more than 12 months postinjury were called back in and examined. Records and radiographs were reviewed for demographics, fracture type, postoperative alignment, time to fracture healing (3 cortices bridged), and complications. Final clinical and radiographic evaluation was performed for knee range of motion, limb rotation, fracture healing, and final radiographic alignment. Final radiographic alignment was assessed using standing bilateral AP and lateral views of the distal femurs on long cassettes. A ligament in varus-valgus was assessed on long AP views with the patient standing, using the intramedullary line of the femur relative to that of the distal femoral articular surface. Flexion–extension was evaluated on the lateral view by comparing the lines of the posterior (or anterior) cortical bone. Limb rotation was assessed with the patient prone and the knee flexed; this was compared to the contralateral side.

RESULTS

Of 26 patients, 2 died and 3 were lost to follow-up, leaving 21 patients with 22 fractures available for study. Of these 21 patients, the average age was 44 years (17–71 years) and follow-up averaged 18 months (range 12–35 months). Fourteen men and 7 women were available for inclusion. There was a high-energy mechanism of injury in all cases, including 12 motor vehicle collisions, 5 motorcycle crashes, 2 falls from a height greater than 10 feet, a parachuting accident (bilateral), and 1 bicyclist struck by a car. According to the AO/OTA fracture classification, there were 4 A2, 3 A3, 12 C2, and 3 C3 fractures (Fig. 2).31 Only 1 patient had significant bone loss. Fifteen of 22 fractures extended proximally into the femoral diaphysis. Six fractures were open and were classified as 1 grade I, 1 grade II, and 4 grade III open fractures according to the system of Gustilo and Anderson.32 There were 2 peri prosthetic fractures, one in an active 71-year-old man with a total hip arthroplasty and the other in an active 71-year-old woman above a knee arthroplasty. Neither had profound signs of osteopenia radiographically nor were they being treated for os-
teoporosis. Fourteen of 22 fractures were initially treated with a knee spanning external fixator, and definitive surgery was delayed until the patient and/or soft tissues had recovered enough to "safely" undergo surgery (mean 5 days, range 2–18 days).

All fractures healed without secondary surgery. The mean time to healing was 13 weeks (range 7–16 weeks). There were no cases of failed fixation, nonunion, or infection, and no bone grafts were required. The mean time to full weight bearing was 11.5 weeks (range 8–15 weeks).

Averager joint line orientation relative to the femoral shaft axis measured 99° (valgus) on postoperative radiographs and 99° on final radiographs.9 No patient measured a difference of more than 3° from postoperation to final radiographs. The average anatomic axis of the contralateral side measured 97°. Only 1 of 22 fractures had greater than a 5° alteration of alignment in varus-valgus or flexion–extension, a case found to be fixed in 8° of valgus relative to the other side. Two patients were found to have external rotation deformity of 10° to 15° relative to the contralateral side, but one of these had trauma to the contralateral femur. None had greater than a 15° difference in limb rotation from side to side.

Four patients had symptomatic instrumentation at the lateral distal femur. Three had complete relief after implant removal, and 1 has surgery scheduled. Two patients underwent late knee ligament reconstruction, one for a symptomatic anterior cruciate deficiency and the other for unstable posterolateral corner injury. No other secondary surgeries were performed. The average range of motion was 5° to 114° (extension range −2°–22°, flexion range 55°–145°). One patient with a C3 fracture pattern and associated severe ligamentous knee injury developed Brooker grade IV heterotopic ossification and marked knee stiffness. Excluding this patient, the average range of motion was 3° to 119°. Extra-articular fractures or AO/OTA type A fractures had a mean arc of motion from 2° to 130°, whereas intra-articular injuries or AO/OTA type C had an arc of motion of 7° to 102° (P < 0.01). The average knee range of motion for patients with open fractures was 3° to 117°.

**DISCUSSION**

Minimally invasive plating techniques have been developed as a method of fracture fixation where additional soft tissue trauma is minimized and the fracture biology is left intact. The goals of these techniques are to restore the important anatomy, provide stable fixation, and to promote early fracture healing. This method of treatment has been applied to fractures of the distal femur,19,21,22,29,30 as well as other complex lower extremity injuries from the hip to the pilon.1,21,22,25,26,28 The use of fixed-angle implants has also shown benefits in the treatment of complex lower extremity injuries, including the distal femur.10,20,21,24 Recently, LISS was developed with the rationale of combining the biologic advantages of a minimally invasive insertion technique with the mechanical advantages of a multiple fixed-angle device. Previous studies have demonstrated successful early results and relatively low complication rates using this treatment method for fractures of the distal femur.19,29,30 The goal of this report was to specifically evaluate the results of LISS in mechanically unstable high-energy fractures of the distal femur where the stability of the fixation construct and preservation of fracture biology may be critical.

All 22 high-energy, mechanically unstable fractures of the distal femur treated in this study group healed after the index procedure at an average of 13 weeks. There were no cases of fixation failure or implant breakage, and no fracture required bone grafting. Little information is available as to the results of treatments for high-energy injuries of the distal femur or those with mechanically unstable fractures that may be especially prone to healing or alignment problems and diminished clinical results. Two distinct patterns of distal femur injury have been recognized,2,12,15,19,20,24,29 those in young patients resulting from high-energy trauma and those in elderly osteoporotic patients suffering low-energy injuries. To date, previous reports have made no clinical distinction between these 2 distinct types of injury, and results have been grouped together for analysis.

Historically, treatment failures have been relatively common, and complication rates have been high for these injuries.2–7 Early attempts at open anatomic reduction and rigid internal fixation with traditional plates had significant problems, with delayed or nonunion occurring in 29% to 38% of fractures5,33 and infection rates of 7% to 20%.3,27,34 These
problems likely reflect the effects of further trauma on the surrounding soft tissues during the wide dissection required for the technique. Dramatically improved results have been reported in similar injuries using more biologic approaches and improved implants.\textsuperscript{20,23,24} Reports by Bolhofner et al\textsuperscript{20} and Ostrum and Geel\textsuperscript{24} in treating distal femur fractures with techniques of indirect fracture reduction and internal fixation using 95° fixed-angle devices revealed markedly improved results compared with previous methods. They found early union in 93% to 100% of fractures and infections in only 0% to 2% of cases. The authors do, however, acknowledge certain limitations of their surgical technique, including the demanding nature of correct implant insertion and that it may not be suitable for all injuries. Early reports on distal femur fractures treated with similar principles using LISS have shown promising results as well. Schutz et al described their early results from multiple European centers\textsuperscript{30}; they found early healing in 37 of 40 patients (93%) treated for fractures with the distal femoral LISS. Kregor et al reported early union in 58 of 61 patients (95%) with distal femur fractures treated similarly with LISS.\textsuperscript{29} The authors attribute successful early healing to vigilant maintenance of the fracture biology and strict adherence to the fixation principles of LISS.

We have found that using indirect fracture reduction and fixation with LISS provides ample fixation to maintain fracture alignment in these high-energy and mechanically unstable fractures. In this series, the authors found no problems with fixation failure, varus collapse, or other changes in alignment postoperatively for injuries “at risk,” and radiographic alignment remained unchanged from operative fixation to final healed radiographs. Although earlier series demonstrated excellent fixation in the relatively osteopenic distal or “condylar” segment,\textsuperscript{19,29,30} Schandelmaier et al found 4 patients whose fixation failed due to proximal screw pullout in their series of patients with a combination of low-energy and high-energy injuries.\textsuperscript{19} Our results demonstrated no problems with either proximal or distal fixation. This may be attributed to the dissemination of information regarding the “learning curve” for this system and technique. Proximal failure due to eccentric placement of the plate on the lateral femur may result in inadequate purchase of the unicortical screws; this problem has been well recognized and may be avoided relatively easily.\textsuperscript{19,29,30}

Three of 22 fractures treated resulted in malunion found in this series. One patient experienced an 8° valgus deformity, and 2 others were found with mild deformities in external rotation. All were operatively fixed in these positions early in this series. Persistent deformity has been noted as the most common risk in minimally invasive fracture surgery, with rates as high as 32% or 44%.\textsuperscript{19,21,22,28} The question no longer appears to be will the fracture heal or will it heal straight, but will we fix it straight? Most of the preliminary reports where malunion rates were extremely high described techniques that were still evolving at the time.\textsuperscript{21,22,25,26} Although the risk for malunion is real, improved results should be expected if careful vigilance toward achieving alignment intraoperatively is observed.

Limitations of this study include all of the shortcomings inherent to its retrospective nature. Also, there is no alternative treatment or control group included in this study with which to compare these results. There are 2 main strengths of this study. First, it is a consecutive series by a single surgeon who had the opportunity to consider and benefit from the “learning curve” of others. Strict adherence to the mechanical, biologic, and technical principles of LISS were upheld. Thus, these mostly positive clinical results should be reproducible by other orthopaedic surgeons. Second, the data analyzed only pertain to a limited type of patient, which are those who have experienced high-energy trauma resulting in comminuted or mechanically unstable fractures. These are patients that may reap the most benefit from these treatment methods, that is, a minimally invasive approach and use of fixed-angle implants.

**CONCLUSIONS**

A multiple fixed-angle and minimally invasive plating system such as LISS provides adequate stable fixation and facilitates early healing in mechanically unstable, high-energy fractures of the distal femur. There were no nonunions or patients who required bone grafting in this series of 22 similar fractures. There were no problems with fixation failure, varus collapse, or other postoperative changes in alignment in this “at risk” population. Radiographic alignment remained unchanged from operative fixation to final healed radiographs. It appears that LISS achieves the goals of stable fixation and early healing in these mechanically unstable injuries. It must be remembered that careful intraoperative attention should be given to restoring alignment in all planes.

**REFERENCES**

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