The Fixion intramedullary nail technology is safe and effective in the treatment of pathologic bone fractures.

Metastasis to the skeleton can cause substantial morbidity, including pain, pathologic fractures, neurologic deficits, anemia, and hypercalcemia secondary to bone lysis and forced immobilization. Patients with metastasis to the skeleton often suffer from loss of ambulation, self hygienic maintenance, activities of daily living, and overall poor conditioning. The focus of treatment should initially be on prevention of pathologic fractures, and this may be accomplished either medically, with chemotherapy and bisphosphonates, surgically with internal fixation devices or with external beam radiation, either alone or in combination with other modalities.

Early detection of skeletal involvement is important because of the impact it has on both the patient's prognosis, as well as, management decisions to minimize disability. The goals of surgical intervention for skeletal metastasis are pain relief and restoration of maximal function. Stabilization with an intramedullary nail remains the mainstay of treatment for the prevention of impending long bone fractures and treatment of pathologic fractures.

Frequently, patients with skeletal metastasis are poor surgical candidates, and an implant system that would reduce operative time, allow for placement with small incisions and obviate the need for intramedullary reaming would be of significant benefit. The Fixion expandable intramedullary nail (Fixion; Disc-O-Tech, Tel Aviv, Israel) may be such a device.

The stainless steel nail is composed of a solid core shaft, surrounded by an outer-metallic sheath and 4 perpendicular reinforcement bars (Figure 1). Ease of insertion is related to its inherent malleability when uninflated. The distal tip is conical in shape, aiding direct intramedullary advancement without the use of a guide wire. After it is positioned in the medullary canal, the system is inflated with normal saline through a unidirectional valve, expanding the nail’s original diameter by up to 50%. Pressurized saline is used for expansion purposes only and theoretical loss of saline into the intramedullary canal does not weaken the construct or pose any threat to the patient.
The small, collapsed form of the nail facilitates passage though the canal often without reaming and allows the surgeon to minimize skin incisions. A small manual pump is used to generate the required pressure up to 70 bar. In cross section, the nail has 4 external longitudinal bars that are forced against the cancellous and cortical bone to contour to the medullary cavity (Figure 1). The large frictional contact area prevents localized pressure peaks, and the ridges of the bar control rotation. Pressure is distributed over the entire length of the nail, avoiding the highly localized forces that are typically seen with the screws that secure standard interlocking nails. Inflation of the nail makes the diaphysis of the bone stable over most of the length of the nail (Figure 2).\(^6\) In addition, the lack of locking screws offers the potential advantage of reducing fluoroscopy exposure and shortening the operative time.\(^6\)\(^-\)\(^8\)

An intramedullary nail system that would minimize operative time, blood loss, and possibly the risk of pulmonary embolization, due to the lack of reaming, would be beneficial to patients requiring surgical stabilization due to pathologic bone. The purpose of this study is to evaluate the safety and effectiveness of the Fixion nail in patients with pathologic or impending long bone fractures.

Materials and Methods

Thirty patients were treated for pathologic or impending long bone fractures with the Fixion inflatable intramedullary nail by a single orthopedic surgeon (H.J.S.). The study group consisted of 18 proximal femur fractures, 3 distal femurs fractures, 6 humerus fractures, and 3 tibia fractures.

Seven patients had impending fractures and all involved the proximal femur. All fractures and impending fractures were secondary to metastatic disease (12 lung, 6 renal, 6 breast, 3 prostate, 1 thyroid, and 1 gastrointestinal). No fractures were open, segmental or associated with a neurologic injury.

The mechanism of injury in all cases involved low-impact trauma. In those with impending fractures the most common complaint was pain associated with ambulation. Pain at night while resting was reported in 24 of 30 (80%).

In the 2 patients without a known primary, a complete serologic and imaging work-up was obtained prior to surgery. This work-up included: a complete blood cell count, calcium, blood urea nitrogen, creatine, prostate-specific antigen (males), thyroid function test, computed tomography scan of chest and abdomen, whole body Tc-99m bone scan, and a mammogram (females). Additionally, an open biopsy with a frozen section to confirm the diagnosis was performed prior to internal fixation. External beam radiation was used in the postoperative period (average 2 weeks postoperatively) in all patients.

Data was prospectively collected regarding operative time, blood loss, fluoroscopy time, and perioperative complications. Operative time was recorded from the initial incision until the final suture was placed. The perioperative complications collected prospectively included propagation of the fracture due to nail expansion, wound infections, fat and/or pulmonary embolism, and neurovascular injury. Follow-up ranged from 6 to 18 months with an average of 9.3 months.
All intramedullary nails, except for the 3 distal femurs, were placed anterograde. Patients with involvement of the humerus were placed in a beach chair position and an anterior approach through a small rotator cuff incision was used. All patients with proximal femur lesions were positioned supine on a fracture table and approached through a trochanteric entry point. The 3 patients with distal femur lesions were positioned supine on a radiolucent table and a retrograde nail was placed along with distal locking screws. No reaming was performed for any of the retrograde nails. The entry hole was established in the humerus with an awl and in the femur with a 3.2-mm guide wire followed by a 10-mm cannulated drill. Reaming was performed on 4 femurs and 3 humeri, because of concern regarding the diameter of the canal. The smallest nail (8.0 mm) was selected in these cases, which has the capacity to expand to 12.7 mm. In all but 4 femurs, a proximal inflatable locking bolt was used and in 3 of 6 of the humeri proximal locking screws placed.

All patients were weight bearing as tolerated in the immediate postoperative period. Those with upper extremity involvement began shoulder and elbow range of motion exercises on postoperative day 1. Follow-up data collection consisted of a review of the patients’ medical records and radiographs to determine incidence of complications (wound dehiscence, implant failure, pulmonary embolism, reoperation), and fracture outcome.

Results

Of the 30 treated patients, 28 were alive at last follow-up, and two had died of their disease within the first year after surgery. No intraoperative complications were seen. Upon pressurizing the nail, no propagation of the fracture was noted and in those with impending fractures, intervention did not result in intraoperative fracture. The incision length averaged 3.5 cm at the hip and 2.8 cm at the shoulder (Figure 3). Blood loss ranged from 25 to 100 cc (average, 65 cc) in humeral nails and 50 to 150 cc (average, 110 cc) at the hip.

Two patients returned to the operating room for revision due to loss of reduction; they did not have their Fixion nails removed. The patients who returned to the operating room both had renal cell involvement. One patient had subsidence of his humerus fracture 6 weeks postoperative and the proximal end of the nail became prominent. By releasing the saline from the nail and backing it out approximately 20%, the nail will collapse enough to be advanced back into the canal and re-expanded, by pressurizing to 70 barr. Following this repositioning of the Fixion nail, bone cement was placed in the canal entry hole to prevent future occurrences. The operative time for this revision procedure was 35 minutes. The patient is 2 years out from surgery and has returned to his previous occupation. No further surgical interventions have been required. This nail was placed prior to the introduction of a proximal locking screw option. The other patient lost fixation approximately 3 months after surgery. However the nail was retained and a LISS plate (Synthes, Paoli, Pennsylvania) was used to supplement the fixation. The revision surgery required an open approach with cable application to improve stability of the plate, and thus, preoperative embolization was performed. The operative time was 3 hours and she was hospitalized for 5 days after surgery. This patient has Parkinson’s disease and is a household ambulator with a walker. She is 18 months out from her revision and has had no further interventions.
demonstrating the Fixion proximal femoral nail. An expandable locking bolt was used to provide additional protection to the trochanteric region and femoral neck.

No pulmonary or fat emboli were noted. Twenty of 24 (83%) with lower extremity involvement returned to ambulatory status postoperatively. No implants required removal. Operative time ranged from 16 to 41 minutes (average, 22.3 minutes). The operative time for impending fractures ranged from 16 to 24 minutes (average, 18.1 minutes). Twenty-seven of 30 patients reached union at an average of 4.4 months (range, 2.3-8 months). Radiographic union was defined as bridging callus noted on both anteroposterior and lateral views, with the inability to see a lucent fracture line on at least 1 view.

Three of 30 patients had evidence of progression of their disease (2 renal cell and 1 gastrointestinal). Progression was noted radiographically (8, 10, and 17 months after stabilization), however clinically the patient’s symptoms are unchanged and there is no evidence of loss of fixation. These patients presented with impending fractures involving the femur. They each use an assistive device for ambulation, however their pain is well controlled with non-narcotic medication. None of these patients have required further surgical intervention.

Discussion

Skeletal metastasis remains a difficult problem with little improvements in recent history in medical management. The palliative treatment includes chemotherapy, radiation, and surgical stabilization. Early detection and intervention may avoid significant disability and hospitalization as a result of pathologic fracture. The surgical technique for intramedullary nailing has remained for the most part unchanged for many decades, however a movement toward minimal incisions, decreasing operative time, and blood loss with total bone stabilization achieved by intramedullary expansion may be of significant benefit for the oncology patient.

Several studies have been published regarding the experience of the Fixion nail for long bone stabilization in trauma patients. Lepore et al treated 43 patients with the Fixion nail and compared them to a matched cohort treated with statically locked nails. They concluded that the inflatable nail allows effective management of diaphyseal fractures of the femur and that interlocking is not necessary, operative times are reduced, and fluoroscopy exposure is minimized.

Lorich et al reported on their experience in the treatment of humeral shaft fractures in 11 patients. They found that indirect reduction was facilitated by the conical tip and small diameter of the Fixion nail. Furthermore, the longitudinally aligned bars were thought to provide rotational stabilization with equal distribution along the entire length of the diaphyseal canal, which may prove to be desirable in pathological or severely osteoporotic bone.

Franck et al reported the experience of 2 centers treating 23 pathologic humerus fractures with the Fixion nail system. The average operative time was 32 minutes with an average fluoroscopy time of 1.4 minutes. They reported no complications and found the fixation to be stable enough to allow immediate physical therapy with unrestricted range of motion.
Biomechanical studies have been performed to test the proximal femur Fixion nail system, which consists of a nail, a peg, and an anti-rotational pin (Figure 1). Steinberg et al.\textsuperscript{16} investigated the nail bending strength and stiffness, fatigue properties, and hip peg strength. A cadaveric study that determined the effect of the expandable peg on the femoral head included subsidence testing, pull and torsion testing, and intraosseous pressure measurements before and after expansion. The cadaver study yielded equivalent results for the pullout test between the peg and the hip screw, but found the peg superior in the torsion strength test. The intraosseous pressure testing found substantially lower than threshold pressure needed to cause avascular necrosis. In the same study, the stainless steel Fixion nail passed fatigue testing and its biomechanical properties met ASTM F384 guideline requirements.\textsuperscript{16} To our knowledge, no fatigue fractures of the nail have been reported.

The trochanteric entry for the anterograde nails facilitates placement of the nail and has also allowed for small incisions. Minimizing reaming of the canal reduces the likelihood of injury to surrounding soft tissues (Figure 4). Although the impact of intramedullary reaming on fat emboli is not well understood, reaming has been implicated in increasing the risk of embolic events. Attempts have been made to limit this risk with interventions such as: venting of the canal, reamer modifications, and delaying surgery in patients with long bone fractures that also have a pulmonary injury.

Roth et al.\textsuperscript{17} showed that venting reduces pressurization during prophylactic reamed intramedullary nailing of femoral metastases, but may increase the spread of tumor to extraskeletal tissue if vented tissue is not contained. Others have shown that placement of unreamed femoral nails have fewer deleterious pulmonary effects than nailing with reaming.\textsuperscript{18} The effects of reaming remain controversial and in a recent study, Schemitsch et al.\textsuperscript{19} studied the impact of plate fixation compared to intramedullary nailing on the incidence of fat emboli in a canine model. They found that the different methods of fixation had similar effects on pulmonary function.

The Fixion nail is ideal for diaphyseal involvement, however with the option for proximal locking it may be used in metaphyseal locations as well. The Fixion nail contours to the diameter of the bone, whereby more involved areas with cortical thinning have additional nail expansion (Figure 5). There are some situations where the Fixion nail may not be optimal. The anatomic regions where the use of the Fixion nail should be avoided are extensive lesions involving the distal 25% of the tibia and humerus, as well as the femoral and humeral head/neck. These areas are not optimally protected by intramedullary nails in general and require alternative methods of treatment. These other methods include: endoprosthetic joint reconstruction, intercalary implants, and curettage/cementation with or without plate fixation.

Loss of fixation was noted in 2 patients in the present study, however, these patients were treated early in the study, prior to the introduction of proximal locking options (Figure 6). Although no Fixion nails were removed in the study group, removal can be accomplished by releasing a univalve at the tip of the nail allowing the fluid to be released. A tool is provided in the standard set to allow this to be done without difficulty. Once the pressure inside the nail is relieved, the nail’s outer shell will recoil to such an extent that the nail will slide out under traction.

Fixion expandable intramedullary nail technology appears to be safe and effective in the treatment of pathologic long bone fractures. Without using locking screws and reaming operative time was minimized. Extensive implant-bone contact may improve stability, however, fixation was lost in 2 of 30 (7%) patients, thus patient selection is crucial. Proximal locking screws or a proximal expandable locking bolt are recommended and are currently routinely used at our institution on all pathologic fractures and impending fractures treated with the Fixion nail. This recommendation is based on the potential for the humeral nail to become prominent and irritate the rotator cuff.

Additionally, in patients with metastatic disease, it is important to protect the trochanteric/femoral neck region and an expandable locking bolt inserted through a user-friendly locking guide adds only a small increase in operative time. No distal locking screw options are available and we have not found them necessary in our experience. The difference in cost of the Fixion nail compared to a standard locking nail is negligible, if the expense for distal locking screws and guide wires are included.

References


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