A BIOMECHANICAL EVALUATION OF AN INTRAMEDULLARY FIXATION DEVICE FOR INTERTROCHANTERIC FRACTURES

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The strength and stability of an intramedullary device when used to fix intertrochanteric fractures were determined and compared with the dynamic hip screw (DHS). A standard four-part osteotomy was created in eight paired fresh frozen human cadaver femurs. The intramedullary fixation device and a DHS were implanted in each pair member, and mechanical testing was performed. Micromotion was measured during cyclic loading to determine implant stability, and then the specimens were loaded to failure. The intramedullary fixation device had significantly greater stability in cyclic loading than the DHS and required more than twice the force for failure. For patients with osteoporosis, this device may be a useful alternative to standard sliding nail systems.

IN ORDER FOR A PATIENT with an intertrochanteric fracture to return to activity as soon as possible, and to avoid the complications associated with nonambulatory treatment, open reduction and internal fixation of the fracture have become the standard procedure. Since a patient may not have the strength, coordination, or mental acuity for following instructions to protect the fracture from excessive stresses while using a walker or crutches, femoral fixation systems have been developed that attempt to provide fixation stable enough to bear the full weight of the patient. The dynamic hip screw (DHS) has been used successfully for intertrochanteric fractures.1 Although excellent results can be achieved for the great majority of the patients, there are some whose cases pose technical and physiologic problems for orthopedic surgeons. One such group of patients are those who are markedly osteoporotic, older, and anemic. Fixation often fails in patients with marked osteoporosis because the device cuts through the osteoporotic bone and reduction is lost. The screw may then penetrate the hip joint or the fracture may collapse, causing pain and the inability to walk.2

Acrylic bone cement has been used in conjunction with screw-plate systems in older patients with osteoporosis.3-5 The cement effectively prevents screw migration and collapse of the fracture, allowing mobility and weight bearing in these patients, who are otherwise often confined to bed or chair until the fracture heals.6

In 1989, a 90-year-old osteoporotic Jehovah’s Witness fell and sustained an intertrochanteric fracture of her right hip. In reviewing the problem with trauma sur-

geons, it was felt that, with a hematocrit of 28, open reduction and internal fixation with the traditional dynamic hip screw would result in a blood loss beyond her estimated safe hematocrit level. Furthermore, it was questionable whether the dynamic hip screw would be able to achieve enough fixation to stabilize the fracture because of her severe degree of osteoporosis. Therefore it was decided to open the fracture and internally stabilize it by using cement and an intramedullary device extending from the shaft of the femur into the femoral neck (Fig. 1). The patient was taken to the operating room, the fracture was opened, and fixation was achieved by reaming the femoral canal, head, and neck, and then cement was placed in the femoral head and neck and then into the femoral canal. A total hip replacement stem was then inserted into the femur, and the femoral head and neck were reduced over the femoral stem and held until the cement hardened. The operative time was approximately 1 hour, and the blood loss was 150 mL. The patient awoke on the following day and bore full weight on her fractured hip. She left the hospital within 10 days of surgery without complication. She did well at home and walked without difficulty; 6 months later she died of what appeared to be a myocardial infarction.

Because of the success with this internal fixation, another device was produced. To improve fixation, a sleeve with a porous coated surface was added to the end of the implant for insertion into the femoral head (Fig. 2). However, there were no data to determine the strength and stability this type of device might achieve. Furthermore, it was suggested that this device would likely be less stable than the traditional DHS system. The purpose of this study was to determine the stability and strength of this intramedullary device when used to fix intertrochanteric fractures and to compare it with the dynamic hip screw.

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MATERIALS AND METHODS

Eight paired fresh frozen human cadaver femurs were used. A standard four-part osteotomy, resembling many naturally occurring unstable intertrochanteric fractures, was created in each femur (Fig. 3). Three cuts were made using a Stryker oscillating saw. First, a straight cut was made through the femoral attachment of the hip-joint capsule. Anteriorly, the cut crossed the tip of the greater trochanter at the proximal end and the medial femoral cortex at the distal end. Posteriorly, the cut passed midway between the linea aspera and the base of the lesser trochanter. A second cut was made perpendicular to the anterior capsular line and passed through the tuberculum adductoriium of the greater trochanter, thus creating a large fragment of the greater trochanter. A final cut was made perpendicular to the anterior cut, crossing the base of the lesser trochanter at its junction with the femoral neck and terminating at the posterior cut. This fragment produced a portion of the posterior and medial cortex and the entire lesser trochanter.

After producing the fracture, a dynamic hip screw and the intramedullary fixation device were implanted into paired members of the four pairs and were evenly divided between right and left femurs. Four stainless steel dynamic hip screws with an angle of 135 degrees or 150 degrees were implanted following standard technique. The dynamic hip screw was inserted into the femoral head, and the plate was placed on the lateral side of the femur and held with four cortical screws.

The femoral component of the intramedullary device consisted of a titanium femoral component (Biomet, Warsaw, Ind) of a total hip system. The porous coated sleeve was implanted in the head of the femur. For implantation, the femoral canal and the femoral head were reamed using a Stryker reamer, and then the canal was rasped using a Stryker rasp. The canal and femoral head were then packed with bone cement (Zimmer, Warsaw, Ind). The femoral component was inserted into the canal and the sleeve was inserted into the head while the cement was still doughy. The femoral head was then pressed onto the shaft along with the other fragments. Pressure was applied until the cement had hardened. Roentgenograms were then taken of the implanted devices (Fig. 4).

For mechanical testing, the femurs were positioned in a jig...
and held with a low melting point metal. The jig was mounted on a materials testing system (MTS, Bionix, Minneapolis, Minn) such that the femur was loaded at 25 degrees to the shaft, simulating a weight-bearing stance. An extensiometer was attached during cyclic loading to measure any motion of the femoral head with respect to the shaft (Fig. 5). The femurs were cyclically loaded to 450 N (100 lb) at a rate of 40 N/sec for five cycles to determine implant stability. After cyclic loading, the extensiometer was removed and the system was loaded to failure to determine the strength of the system. Data were recorded using a Apple Macintosh computer with a 16-bit resolution analog board (National Instruments, Houston, Tex). Roentgenograms were taken again after mechanical testing. Statistics were performed using analysis of variance.

RESULTS

Mechanical testing showed that the intramedullary fixation device was more stable during cyclic loading and required a higher force for failure than the DHS devices. The DHS with a 135-degree angle had significantly less micromotion than the DHS with a 150-degree angle, and the intramedullary fixation device had significantly less micromotion than each of the DHS devices ($p = 0.0001$). The amount of micromotion during cyclic loading was $1.37 \pm 0.1$ and $1.68 \pm 0.1$ mm for the DHS devices with 135-degree and 150-degree angles, respectively. For the intramedullary fixation device, the amount of micromotion was $0.33 \pm 0.01$ mm (Fig. 6). The intramedullary fixation device was significantly stronger than the DHS devices ($p = 0.02$). There was no significant difference in the ultimate strength between the 135-degree and 150-degree DHS devices. Failure with the intramedullary fixation system occurred in the bone, whereas the DHS devices yielded. The ultimate strength of the bone/intramedullary fixation system was more than twice that of the DHS system. The ultimate strength was $2562 \pm 260$ N for the DHS and $5490 \pm 909$ N for the bone/intramedullary fixation system (Fig. 7).

Since clinical failure of the devices would occur with significant deformation, failure was defined as 10 mm of deformation. The force at 10 mm of displacement (or at failure if at less than 10 mm) was determined. The force required for failure was significantly greater ($p = 0.0097$)
in the intramedullary fixation device system, 5475 ± 918 N compared to 2014 ± 124 N for the DHS (Fig. 8).

The levels of displacement under cyclic loading were approximately three times higher in the DHS group, indicating the intramedullary fixation device was approximately three times as stiff as the DHS as seen in the load displacement curves (Fig. 9). There was no clear yield point for the DHS, and the intramedullary device did not yield before failure of the bone.

**DISCUSSION**

The intramedullary fixation devices had significantly less micromotion during cyclic loading than did the DHS devices, indicating greater stability in a weight-bearing stance. The 135-degree angle DHS was more stable than the 150-degree angle DHS. Since the 135-degree angle is at a greater angle to the load, the screw is less likely to slide than in a DHS with a higher angle.7,8

The DHS devices had significantly lower ultimate strength than did the bone/intramedullary fixation system. In three of the DHS devices, with both 135-degree and 150-degree angles, telescoping of the screw failed to occur. Instead, the screw bent at the barrel. Bending also occurred at the plate-barrel angle in one DHS. In the other DHS, telescoping occurred at 1640 N. The device was loaded further, and the screw penetrated the femoral head at approximately 2700 N. Because bending of the lag screws occurred in three DHS devices, there was no clear yield point. Previously, the yield points for stainless steel sliding screw-plate implants have been about 1740 N for 135-degree angles and 1680 N for 150-degree angles.9

Since the DHS devices yielded before failure, there was a large amount of displacement without telescoping, ranging from 10.0 to 35.4 mm. In contrast, displacement in the bone/intramedullary fixation system ranged from 3.7 to 11.2 mm. The force at 10 mm of displacement (excluding telescoping) was arbitrarily chosen as “failure,” since a displacement of 10 mm would be considered detrimental to union. The force required for failure was significantly greater in the intramedullary fixation device system than in the DHS system.

The DHS devices were approximately one third as stiff as the intramedullary fixation devices. The intramedullary devices were much stronger than bone and did not yield before failure, thus providing intimate contact and rigid fixation. In the bone/intramedullary device system, failure occurred in the bone at the femoral head/neck junction.

Since the intramedullary fixation device was more stable than the DHS and required a greater force for failure, it should provide sufficient fixation for intertrochanteric fractures. This system is advantageous in that it provides stable and rigid fixation. The exposure for implantation of this device can be done with minimal blood loss, and furthermore the addition of bone cement to osteoporotic cancellous bone impedes further bleeding. For patients who are osteoporotic, older, or anemic, it may be a useful alternative to standard sliding nail fixation systems.

In conclusion, the intramedullary fixation device was more stable in axial cyclic loading compared with the DHS. In addition, more than twice the force was required for failure of the intramedullary fixation device than for the DHS. The intramedullary fixation device appears to have sufficient stability and strength for fixation of intertrochanteric fractures. This device may be a useful alternative for patients who are not well suited for the standard sliding nail fixation systems.

**REFERENCES**

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