The fixion proximal femur nailing system: biomechanical properties of the nail and a cadaveric study

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Abstract

The treatment of choice for early mobilization of hip fracture is surgery, which traditionally employs side plates and screws or intramedullary nails. We examined the biomechanical properties of a new proximal femoral nail system. The new expandable Fixion proximal femur nailing (PFN) system, made of stainless-steel alloy, consists of a nail, a peg and an anti-rotation pin. Upon positioning, the nail and peg are expanded to their maximal diameter. The current biomechanical study investigated: 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 intra-osseous pressure (IOP) measurements before and after expansion. Biomechanical properties of the new nail met ASTM F384 guideline requirements. 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. IOP during peg insertion and expansion was substantially lower than the threshold pressure that causes avascular necrosis. The biomechanical tests found the new system to be safe and able to provide good abutment of the nail to the bone. We conclude that the Fixion PFN system proved to be an effective proximal femur fracture fixation device.

Keywords: Hip fracture; Expandable proximal femoral nail; Expandable peg; Biomechanical tests; Intraosseous pressure

1. Introduction

Hip fracture is a main concern of the elderly, most of whom suffer from osteoporosis in addition to various medical and mental diseases that result in their being a high-risk population. It is currently estimated that 250,000 hip fractures occur annually in the United States alone and that this number may double within 40 years (Cummings et al., 1990). Rogers et al. (1995), White et al. (1987) and Evans (1951) found that surgery is the treatment of choice for early mobilization and prompt return to pre-fracture functionality level, as well as for reducing mortality and morbidity.

Historically, extra-capsular fractures of the femoral neck were treated by side plates, intramedullary devices, rods (Aprin and Kilfoyle, 1980), screw bolts, static plates, Jewett nails (Jensen, 1980; Wilson et al., 1980), Wiessman and Salama nails (Wiessman and Salama, 1969) and compression sliding hip screws (Chang et al., 1987; Clawson, 1964; Jacobs et al., 1980; Medoff and Maes, 1991; Rao et al., 1983). Factors that may affect the functional outcome are the strength of the inserted device, bone quality and fracture reduction. Sheer body weight and muscle contraction can result in nail failure, as well as bone penetration due to improper positioning or bone quality. However, in spite of these limitations as well as those of medial displacement and shortening, sliding hip nails have gained considerable popularity (Rao et al., 1983).

The intramedullary hip nail may have some advantages over the dynamic side hip plate and the sliding screw. It combines intramedullary shaft stabilization with the sliding feature of a hip screw. Such a device may offer a decreased bending strain because the shaft fixation is moved medially in the intramedullary canal, and this decreases the lever arm on the implant.
Moreover, its mass may act as an internal block against neck translation and prevent medial displacement of the shaft. Such a hip nail may also offer a biological advantage of combining a closed technique with limited periosteal disruption. Only a slight valgus configuration would be necessary to permit the introduction of the intramedullary nail portion through the tip of the greater trochanter, while the distal interlocking screws of these longer nails require a freehand technique or a targeting device. Mahomed et al. (1994), Halder (1992) and Rosenblum et al. (1992) biomechanically evaluated these devices that have been in use since 1990, among them the Gamma nail (Howmedica), IMHS (Smith and Nephew, Richards), and others, but no study has shown a definite superiority of one over another in improving patient clinical or functional outcome (Bridle et al., 1991; Leung et al., 1992; Radford et al., 1993).

Hip nails are implanted with significantly shorter fluoroscopy time, smaller incisions, and less intra- and post-operative bleeding (Leung et al., 1992), but they are unfortunately associated with an increased complication rate (Sailer et al., 2000), especially in femoral shaft fractures (Bridle et al., 1991; Radford et al., 1993). Kukla et al. (2001) explained this by the nail’s design that may impinge on the anterior cortex of the bowed shaft. In this study, we examined a new proximal femoral nail (PFN) system that employs expandable nail technology (Lepore et al., 2000; Shasha et al., 2002; Steinberg et al., 2001), intended to reduce the mentioned complications.

In this study, we present the biomechanical properties of this nail and peg as well as the influence of the peg’s expansion upon cadaveric femoral heads.

2. Methods

2.1. Nail description

The new expandable Fixion (PFN) system is comprised of a nail, a peg and an anti-rotation pin (Fig. 1). The system is constructed of stainless-steel 316L alloy. The nail’s proximal end consists of a one-way valve and two holes—the proximal for the pin and the distal for the peg—and a nail shaft. The nail shaft is composed of four longitudinal rectangular bars connected by a thin (0.2 mm) membrane. Following insertion and positioning in the medullary canal the initial folded configuration of the nail (10 or 12 mm) is expanded (to 16 or 19 mm) with saline solution by use of a disposable pump. The innovative hip peg has an oval-shaped body and an expandable cone-shaped distal end that replaces the standard lag screw. After peg insertion the cone is expended (to 12 mm) with saline solution in the same manner as the nail shaft. The nail is inserted into the femoral medullary canal through the tip of the greater trochanter in its reduced diameter. After the nail is properly positioned, the hip peg is inserted into the inferior third of the femoral neck–head through an 8 mm hole located at the nail’s proximal end. Both the nail and the peg are then expanded to achieve their maximal diameter. An integral peg-locking mechanism, located at the nail’s proximal end, permits limited (18 mm) hip peg movement. This limitation eliminates hip peg migration (Florin et al., 1999) and prevents severe femoral neck shortening. Alignment of the hip peg and locking mechanism is easily achieved due to the oval shape of both the hip peg and the respective nail furrow.

The first series of tests were designed to evaluate the biomechanical properties of the nail and hip peg and the second series examined the influence of peg expansion on cadaveric femoral heads.

2.2. Biomechanical characteristics

The nail and hip-peg were tested both separately and in their combined configuration.

1. Nail-bending strength and stiffness: The procedure that was chosen to evaluate the nail-bending strength
was based on the ASTM F384 method, which had originally been developed for DHS testing (Annual book of ASTM, 2000). This method is designed to evaluate the bending strength properties of the nail and either the hip peg or lag screw assembly in a single test. The test device (Fig. 2) consists of a trolley placed on a single axis tension/compression apparatus and a custom-made platform with adapters for each nail type. The adapters fix the nail to the platform through the test sequence. The nail’s peg/screw assembly is subjected to axial load, and the load versus deflection values are recorded and analyzed. In order to eliminate the effect of the expanded part or that of the threaded lag screw end, the tip of the hip peg and the lag screw were inserted into an acetal bar. This configuration distributes the axial load applied upon the hip peg or lag screw in order to simulate the actual load distribution in a bone in a method similar to that described by Haynes et al. (1997). The nail and hip peg assembly is subjected to axial load, and the nail yield strength is then calculated and compared with the 4-point bending method.

2. Nails fatigue properties: evaluated according to ASTM F384, which is a standard method for DHS evaluation (Annual book of ASTM, 2000). The basic test configuration is similar to that used in a static bending test but, in this case, the Fixion PFN system is firmly attached to the platform. The nail and hip/peg assembly are fixed in an epoxy reservoir (Chemieast, Chemibond, Israel). The hip peg is subjected to a cyclic sinusoidal load ranging from 98 to 980 N (R-ratio = 0.1, when R is maximal and minimal load ratio) for 1,000,000 cycles. Testing is performed and recorded using a highly accurate single axis fatigue machine (Instron LTD, Buckinghamshire, UK).

The unique hip peg was tested to evaluate the effectiveness and safety of the new concept. Since the hip peg design incorporates volume expansion instead of threading, some new features needed to be tested such as the hip peg’s strength, the effect of the expansion on the femoral head’s internal pressure and the peg’s gripping characteristics.

3. Hip peg strength: resistance of the hip peg’s distal section to axial load was evaluated using a method similar to that of ASTM F384. The hip peg’s cone-shaped distal end (the “cone”) consists of a thin membrane (0.2 mm) and three longitudinal bars arranged symmetrically at an angle of 120° (Fig. 1). During the test, the peg is fixed to a Fixion PFN, laterally branched out 40 mm. The test platform is placed on a single axis compression machine (Testometric, Rochdale UK) at a constant speed rate of 5 mm/min. In order to simulate an extreme loading case, a concentrated load is directed at the tip of one of the hip peg’s longitudinal bars. Load versus deflection is recorded until the bar fails. Bar failure is defined as the point where the bar returns to parallel orientation relative to the hip peg’s shaft.

2.3. Cadaver studies

The following studies were conducted in order to determine the effect of the expandable peg on the femoral head:

1. Hip peg subsidence test: For testing the resistance of an osteoporotic femoral head to subsidence due to the hip peg’s reversed conical-shape distal end, a fresh cadaveric femur head is submerged in epoxy. The peg is implanted in the femoral head using a standard implantation procedure which involves drilling an 8 mm hole, insertion of the hip peg and then expansion of the hip peg’s cone under an internal pressure of 90 bar. This assembly is placed into a single axis compression machine (Testometric, Rochdale UK) under a
constant speed rate of 5 mm/min. The hip peg is connected to the machine’s load cell, and the load versus hip peg displacement values are recorded and analyzed.

2. **Hip peg pull-out and torsion test**: The hip peg’s performance relative to standard hip lag screw (Smith & Nephew, Memphis) was tested and compared under two different load configurations: pull-out load and torsional stability. The hip peg and lag screws are implanted inside submerged fresh osteoporotic cadaveric femoral heads with a similar bone mineral density in both tests:

- **Pull-out load**: is defined as the amount of load required to remove the implant from the femoral head. This test configuration is similar to the cut-out test except that the implanted devices are subjected to tension instead of compression loading. Load versus displacement values were recorded and analyzed.

- **Torsion stability resistance**: is defined as the minimal torsional load needed to cause fulcrum. This test utilizes a custom-made torsion adapter (Fig. 3) mounted on the single axis tension apparatus, which allows transformation of axial load into torsion by the pulling of a cable wrapped on a wheel. The tension and cable displacement versus the load, as measured by the testing machine load cell, are recorded. The pull test machine speed is set to a constant speed rate of 5 mm/min, and the maximal torque is the product of the tension load multiplied by the wheel’s radius.

The following research aimed to evaluate the intraosseous pressure of the femoral head after hip peg expansion.

3. **Intraosseous pressure (IOP)**: This parameter was evaluated on 13 femoral heads retrieved from patients (8 males and 5 females) with intracapsular femoral fractures and who had been treated by hemiarthroplasty. Mean patient age was 79.2 years (range 70–95). The femoral heads were stored at a temperature of −70°C and thawed in saline solution at room temperature (22 ± 2°C) 24 h before testing. They were covered with a transparent epoxy resin (Chemcast, Chemibond, Israel) so that full solidification was obtained. A 1.4 mm drill bit was used to penetrate the cartilage and subchondral bone of the femoral head for insertion of a pressure gauge. An 8 mm channel was drilled from the distal femoral neck along the femoral head axis, while avoiding penetration of subchondral bone and cartilage. IOP measurements were taken using a compartment pressure monitor (Stryker Pressure Monitor 295/1). This monitor consists of an 18-gauge side-ported needle, a transducer, and a digital display monitor. Three pressure values were recorded: at rest, during drilling and following peg expansion.

2.4. **Statistic analysis**

All data was subjected to Student’s t-tests and Wilcoxon paired test, with significance set at P < 0.05. Correlations between variables was evaluated using the Pearson correlation (2-tailed), and were considered of importance if the value exceeded ±0.05.

3. **Results**

3.1. **Biomechanical properties**

1. **Nail bending strength and stiffness**—using the ASTM F384 method, the Fixion hip nail (10–16 mm) yield strength [My] measured 45 Nm. The Synthes PFN measured 25 Nm.

2. **Nails fatigue tests**—Three nails were subjected to sinusoidal cyclic compression loads under load ranges of 98–980 N for 1,000,000 cycles. The nail hip peg withstood the load with no indications of failure. There was no evidence of damage to the proximal end or to the shaft of the hip peg during the second fatigue sequence as well.

3. **Hip peg distal end compression test**—four hip pegs were placed on a fixture complying with the requirements of the ASTM F384 guidelines. The tip of the hip peg was subjected to compression load and yielded a bending force of 642.4 ± 35.2 N.

3.2. **Cadaver studies**

1. **Hip peg subsidence test**—The peg’s deflection within the femoral head during the test measured 3.2, 3.6 and 5.0 mm following axial loads of 400, 460 and 550 N, respectively.

2. **Hip peg pull-out and torsion stability tests**

   2.1. The pull-out test results for three hip pegs were 268 ± 23.6 [N] and 298.8 [N] for one hip screw (Smith & Nephew, Memphis).
2.2. The torsion test results for hip pegs were $128.9 \pm 8.1$ [N cm] and $25.6$ [N cm] for one hip screw (Smith & Nephew).

3. The mean baseline intraosseous pressure for 13 femoral heads was measured at $3.84(\pm 3.5)$ mmHg and it increased insignificantly to $4.84(\pm 1.9)$ mmHg after expansion ($P = 0.44$ for paired Students’ $t$-test and $P = 0.29$ for Wilcoxon paired test).

4. Discussion

This study was performed to evaluate the mechanical and biomechanical properties of a new device for proximal femur fracture fixation. The design of the nail is based on the expandable technology of implants (Shasha et al., 2002; Steinberg et al., 2001; Lepore et al., 2000) and was intended to overcome the possible complication of shaft perforation by the currently employed stiff proximal nails and the cutout effect of the hip screw. We performed a biomechanical assessment and cadaveric studies, and the results were compared to biomechanical results of other available devices.

The first step of this study was to conduct nail strength and stiffness test according to ASTM study guidelines and to compare the findings to those of a commercially available nail. Although the ASTM F384 guideline was designed for a hip plate, method resemblance enabled the application of these guidelines in this study. Moreover, the same methodology was applied for the same purpose by other researchers (Haynes et al., 1997; Teubner and Ulrich, 1988).

The substantial increase in hip peg torsional resistance was compared to a standard lag screw and was found to be fivefold greater. The combination of enhanced bone torsional stability with the oval-shaped hip peg may reduce the need for an additional hip pin in an unstable fracture. Ramamurti et al. (1997) showed that a press fit implant under different elastic moduli of bone sharply increased the stability of the bone implant interface, especially for torsion.

Hip peg and lag screw pull-out testing described in this study revealed similar characteristics for both implants. One reason for the reduced pull-out strength of the hip peg may be the reverse cone shape or its insufficient expansion in the single case in which it had been tested.

The Fixion PFN successfully passed fatigue tests based on the ASTM F384 guidelines, thereby demonstrating its safety for long-term activity and loading. Unlike other devices, the Fixion PFN was tested without the support of a bone structure that might have borne a substantial part of the load that had been placed on the nail/plate structure (Teubner and Ulrich, 1988).

The cadaver study was performed to evaluate the possibility of an implant failure and the effect of peg expansion on the surrounding bone. As noted above, the biomechanical cadaver study found equivalent pull-out test results for the peg and the hip screw, but found that the peg was superior in the torsion strength test. Fixation of femoral head fractures depends mostly on the quality of the bone in the femoral head (Clark et al., 1990). The unique hip peg expansion feature may contribute in achieving improved bone-implant stability, especially under torsional forces, and we believe that this will reduce the risk of a hip-peg cut-out. Based on the findings of Ramamurti et al. (1997), the extent of press fit in cancellous bone contributes in achieving improved implant fixation. The hip peg expansion of up to $4$ mm (from $8$ to $12$ mm) improves torsional stability with pullout strength similar to that of a lag screw.

Intraosseous pressure in the femoral head was measured in order to determine the effect of peg expansion on the surrounding bone during implant expansion. A pressure of more than $30$ mmHg could cause avascular necrosis of the femoral head (Kier, 1997; Lausten and Arnoldi, 1993). The recorded pressures during peg insertion and expansion were substantially lower than $30$ mmHg. Based on those results, we may assume that peg expansion is a safe procedure, which does not damage the femoral head.

Hip nails are implanted with significantly shorter fluoroscopy time, smaller incisions, and less intra- and post-operative bleeding than side plates and screws (Leung et al., 1992), but they have an increased complication rate, especially in association with femoral shaft fractures (Radford et al., 1993; Bridle et al., 1991). This is explained by the nail’s design that may allow it to impinge on the anterior cortex of the bowed shaft (Kukla et al., 2001). The Fixion PFN radially expands in the medullary canal along the inner surface of the cortical bone. The loads applied on the nail are distributed uniformly along its bars without a single stress concentration point and without locking screws, thus minimizing the possibility of bone failure at any given point.

Based upon the results of this biomechanical study, we conclude that the Fixion PFN system proved to be an effective proximal femoral fracture fixation device.

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References


