CHAPTER 6

Retrograde Bridging nail in periprosthetic femoral fracture treatment allows direct weight bearing.

A biomechanical study

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Abstract

The Bridging nail is a retrograde intramedullary femoral nail designed to stabilize periprosthetic femoral fractures. It offers a minimal invasive surgical approach in combination with early mobilization. The goal of this study was to evaluate the osteosynthesis under full weight bearing conditions. Three groups of five composite fibreglass femora, were prepared with a cemented hip stem. Group 1 underwent cyclic axial loading with 1500 N during 150,000 cycles. After completion, linear loading to failure was conducted. Group 2 and 3 were submitted to linear increased torsional loading with and without an axial load, respectively. Failure was defined as rotational movement of the connection (slippage). In the axial cyclic loading configuration one specimen failed after 122,000. Four specimens passed 150,000 cycles and failed after linear increasing axial loading of 1,940-2,600 N (mean 2,408 N ± 313 SD). Slippage was first detected at a torque varying between 2.5 and 8.2 Nm (mean 5.1 Nm ± 2.1 SD) in Group 2 and between 10.0 and 15.4 Nm (mean 13.0 Nm ± 2.3 SD) in Group 3. In conclusion the Bridging nail offers a stable connection with the stem of a hip arthroplasty which can resist high repetitive loads, representative for direct full axial weight bearing. The biomechanical results support the clinical experience of a stable osteosynthesis enabling early postoperative mobilisation.
Introduction

Periprosthetic fractures (PPF) of the hip are a complex problem for patient and surgeon. The young and active patient with displaced PPF is best served by revision arthroplasty. However, PPF often occur in geriatric patients with a compromised physical condition limiting the possibilities of extensive surgery. High morbidity and mortality up to 20% is reported in this population. Hence, for these older patients a more conservative treatment is required. If the implant is still adequately fixed, internal fixation of the PPF can be an appropriate option. Several methods of internal fixation have been described for the treatment of fractures. Classic plate osteosynthesis, LISS® plates, cerclages with or without cortical allograft struts and various systems of cable-plate fixation are available. Closed retrograde nailing is a common solution for isolated femoral fractures in trauma patients for its minimally invasive aspects. However, retrograde nailing for fractures below a hip stem leaves a possible stress-rising zone between the ends of the implants. Custom made lengthened implants have previously been described although these are antegrade solutions that require stem revision.

By combining these reports and other articles the concept of the nailing system to treat retrograde periprosthetic fractures of the femur was initiated. Indications for this treatment were severely compromised patients in which revision surgery was considered a great risk. The first patients were treated with an adapted intramedullary femoral nail that was driven over the tip of the prosthesis and thus providing stable fixation. This evolved to a new fabricated device, the Bridging nail. There is confined clinical experience using this implant. The surgical technique and clinical experience of the first 18 patients treated with the retrograde Bridging nail were recently published.

In that study patients were not restricted in postoperative weight bearing, favouring nursing conditions. The X-rays showed that fracture healing occurred in all patients and no device failures were seen. The good outcome was achieved in combination with an early mobilisation which is of utmost importance for these patients in order to reduce morbidity from inactivity.

Currently the desired overlap of the prosthesis junction, its endurance and its effect on the stability of the fracture are unknown, which hampers the application of this technique in a reliable way.

Several reports have been published concerning rigidity of osteosynthesis in treatment of PPF. These studies describe plate osteosynthesis or plate-cable constructions with or without allograft struts. The specimens in these studies were exposed to loads well below full weight bearing conditions according to postoperative regimens associated with these treatment modalities.

The goal of this study was to evaluate the biomechanical performance of the Bridging nail in the treatment of periprosthetic femoral fractures under these loading conditions. This lead to the following research questions: Can the Bridging nail osteosynthesis resist full weight bearing without early...
failure and does the implant show fatigue failure after a larger number of loading cycles, representative for the time needed to heal the periprosthetic fracture?

**Materials and Methods**

Fifteen composite fibreglass femora, (Large Left Fourth Generation Composite Femora No. 3404, Sawbones, Pacific Research Laboratories, WA, USA), suitable for biomechanical testing were prepared with a cemented hip stem. Stanmore™ MK9 total hip stems (Biomet, Warsaw, IN, USA) were cemented using acrylic bone cement (Palacos R; Smith and Nephew, Richards Inc., Memphis, TN, USA) in the proximal femur. Distally of the stem, an oblique osteotomy of 45 deg. was created. To simulate a multifragmented periprosthetic fracture a 5 mm gap was realised using a handsaw. The location simulates a Vancouver type C fracture and was chosen based on Dennis et al. A gap of 5 mm will prevent bone-to-bone contact at the osteotomy site and is therefore a worst case scenario relying on maximal support of the nail. The notch of the distal femur was opened and a retrograde drill was used to remove the cement plug. A hollow drill reamed around the hip stem to provide space for the retrograde nail. The nail has a partially slotted design and is made of stainless steel 316 LVM. The slot facilitates the application over the prosthetic tip of the stem to obtain a rather rigid connection. The nail was inserted in accordance with its standard surgical procedures for insertion. Two locking screws (6 mm Ø x 56 mm) were fixed in the distal femur with the aid of an outrigger. The distal femur was totally embedded in PMMA cement to place the construction on a ball socket, since the evaluation of distal locking was not the aim of this study. Radiographs were obtained of the specimens (Figure 1) to evaluate contact area of the nail-stem junction.

Testing was performed using a servo hydraulic testing machine (MTS, Berlin, Germany) in three loading modalities: Specimens in Group 1 were loaded with a sinusoidal axial load to 1,500 N; specimens in Group 2 were subjected to torsional loading with an increasing load (from 0 to a maximum of 30 Nm); specimens in Group 3 received the same torsional loading as specimens from Group 2 with the addition of an axial compressive force.

![Figure 1. Pre test composite femur with osteotomy and retrograde nail osteosynthesis.](image)
Group 1

Five specimens were loaded in an axial direction. The centre of the femoral head was aligned with the centre of the knee under the hydraulic testing machine along the mechanical axis of the femur. The femoral head was loaded with a concave pusher, mounted on a platform that enabled horizontal translation. The distal femur was embedded in acrylic cement that was level with the centre of the knee (Figure 2). For Group 1 the sinusoidal load ranged from 15 to 1500 N with a frequency of 1 Hz. Every 30 s the displacement and force were recorded with a sample frequency of 30 Hz for 1.2 seconds to ensure that a complete loading cycle was captured.

The axial load of the Group 1 specimens was increased from zero to failure under displacement control at a rate of 50 mm/min. Hence, a relatively high loading rate was assumed to include the simulation of a sudden event (quickly sitting down in a chair or tripping over an obstacle). The applied force was recorded as well as the displacement of the femoral head. Failure in the axial loading configuration was defined as an abrupt change in the force-displacement curve indicating that the system clearly deformed plastically upon increasing displacement.

Group 2

Five specimens were submitted to torsional loading. A force around the centre of the axis of the stem was applied using a cable system. The experimental set-up was such that the rotational torque was increased dynamically while monitoring the relative rotation between the stem and the nail with an in-house developed inclination meter. In this way the moment that slippage between the stem and the nail and the torque associated with it could be detected and quantified. Failure was defined as rotational movement (slippage) at the stem-nail junction.

For Group(s) 2 (and 3) the rotational torque was applied under displacement (rotational) control. Every loading cycle the rotation started from zero to a maximal value at a constant rate of 2.18 deg/s. Every cycle the rotation angle was increased by 0.872 deg, and the frequency of the load applied was 0.5 Hz to ensure that a quasi-static level was reached every cycle. In this way the maximal torque before stem-nail slippage occurred could be measured in an accurate way. An internal torque was applied similarly to the direction of the in-vivo anterior-posterior force direction on the femoral head.
In the final 5 specimens the same torsional load as in Group 2 was applied with an additional static axial compressive load of 750 N to simulate weight-bearing conditions (Figure 3). The additional longitudinal load was applied by a pulley system parallel to the femur and directed from proximal to distal. This 750 N load was kept constant.

After completion of the dynamic loading tests the samples of Group 1 were loaded to failure. The failed samples were visually inspected to determine the failure mode. Pre- and post testing radiographs were examined to determine the achieved length of the junction between stem and nail. Mean stem-nail overlapping was determined by measuring on radiographs taken before testing. The mean overlapping distance of the stem was 3.3 cm (2.9-3.5), which was similar to what was observed in clinical practice.

The Mann-Whitney U test was used to compare the results of the study groups. P<0.05 was considered significant.

Results

Of the 5 specimens of Group 1 which were subjected to a dynamic axial force, four specimens completed the dynamic loading tests whereas one failed after 121,988 cycles. The hip stem had deformed the nail over the slotted area resulting in a disintegration of the connection. After completion the remaining four specimens were statically loaded and failed in the range of 1,943-2,600 N (mean 2,401 ± 313 N). (Table 1).

Although, one specimen failed already during the dynamic loading test, the failure pattern in Group 1 was identical for all 5 specimens. The nails deformed in the area of the osteotomy in a varus direction, opening the slot as shown in figure 4. Visual inspection of the failed nails showed a similar angle and location of bending although these were not measured (Figure 4).
The specimens in Group 2 failed due to slippage between the stem and the nail. Slippage was first detected at a torque varying between 2.5 and 8.2 Nm (mean 5.1 ± 2.1 Nm) (Table 1). At slippage, the containment of the hip stems in the nail was not lost. Other than rotation of the femoral segments, the nails showed no physical signs of damage during visual inspection. For group 3 the values ranged from 10.0 – 15.4 Nm (mean 13.0 ± 2.3 Nm) (Table 1).

The combined loading configuration resulted in much higher failure loads than those found in Group 2 (Table 1). The resistance against the torque before slippage occurred was about 4 times higher than without an additional axial load. The Mann-Whitney U test delivers a two-tailed significance of 0.009 for the difference between Group 2 and Group 3. Again, no deformation of the nail or hip stem was seen at visual inspection. The containment of the hip stem and the nail remained intact indicating that the reconstruction would not dramatically fail if rotational slippage between the nail and the stem tip would occur.

<table>
<thead>
<tr>
<th>Axial cyclic loading at 1500 N Group 1</th>
<th>Torsional loading Group 2</th>
<th>Torsional load combined with axial load Group 3</th>
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<tr>
<td>Femur Cycles Failure load (N)</td>
<td>Femur Nm</td>
<td>Femur Nm</td>
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<tr>
<td>A 121,988 n/a F 2.5 K 15.4</td>
<td>B 150,000 1943 G 8.3 L 12.6</td>
<td>C 150,000 2600 H 5.5 M 15.2</td>
</tr>
<tr>
<td>D 150,000 2507 I 3.8 N 11.6</td>
<td>E 150,000 2582 J 5.3 O 10</td>
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<td>Mean ± SD</td>
<td></td>
<td>2401 ± 313 5.1 ± 2.1 13.0 ± 2.3</td>
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**Discussion**

Especially in geriatric patients, who often have a compromised physical and mental condition, a minimal invasive surgical approach in combination with the possibility for direct post-operative weight bearing is desirable. In this study we found failure loads under axial loading in the order of 1900-2400 N, which is about 3 times body weight. From this perspective, the Bridging nail in periprosthetic fracture treatment can sustain the direct post-operative axial loading magnitudes because the measured values are higher than the in-vivo load reported by Bergmann et al. (240% body weight(BW)). Bergmann et al. mentions measured mean peak loads on the hip. In axial direction during
normal walking the peak load is 240% BW. This equals 1,500 N for a normal person of 62.5 kg. The torsional peak load is for the same person is around 1.72 to 1.91% BW*m. (10.7 to 11.9 Nm). Torsional loading of the femoral reconstruction seems to have a smaller range of safety as we found lower failure loads than those that occur in-vivo during normal walking. A co-existing axial load on the proximal femur is more realistic in vivo. This study shows that when an axial load of 750 N is applied simultaneously, the torsional load capacity increases significantly. Hence, this technique seems capable of allowing weight bearing conditions at the direct post-operative stage. The authors are not aware of any other reported reconstruction methods for PPF that are able to sustain immediate load bearing conditions. Conventional implants used for PPF treatment are not eligible for full weight bearing and were only tested to measure fracture movement with sub-maximal loads.

Revision with a long stem prosthesis or revision with allograft struts are considered the gold standard in healthy patients with a loosened stem. Dennis et al. compared the stability of plate cable to allograft cable osteosynthesis. At 500 N, during 10,000 cycles, and during linear torsional loads until failure, they found failure rates of 1,295 and 950 N, at 5.5 cm from the axis respectively. In clinical practice, the risk of plate failure is generally too high to allow full weight bearing. In compliant patients partial weight bearing can be properly instructed. However, in geriatric patients this compliance might be a significant problem leading to possible failure.

During surgery the overlap between the stem tip and the nail is estimated by the force needed to slide the nail over the stem. For the biomechanical testing we chose to prepare them as is commonly performed during surgery, representing a more realistic representation of the actual osteosynthesis. Logically the strength of the stem-nail connection should depend on the overlap. This parameter was not varied in this study. In a pilot study a nail-hip connection was tested. We measured that an overlapping distance of 1.5 cm was too small to generate a reliable and stable connection. An overlap of at least 2 cm was needed to achieve a stable connection for the used Stanmore™ hip stem. Though this evidence is anecdotal, it may indicate that there is a minimum amount of overlap required for an adequate stem-nail junction.

In this study an axial sinusoidal load of 1,500 N was chosen to simulate full weight bearing. Obviously the loading configuration was simplified and did not include the muscle forces and other soft tissue stabilisation. The magnitude of these stabilizing factors and their subsequent effect on the stability of the reconstruction are, however, unknown. Therefore we chose for least favourable loading conditions and tested torque and axial loading separately hereby simulating worst-case scenarios. It was believed that 150,000 cycles was sufficient to evaluate the post-operative period in PPF treatment. The number of steps for an active patient with a THA is around 6,000 steps a day. The impaired patient is expected to be less active. Therefore, the 150,000 cycles may equal a period of about 6 weeks. Hence, considering the age and mobility of the patients the number of steps roughly correlated with the post-operative period required for fracture healing.
The hip stem chosen for the tests was a cemented stem with a tapered distal contour. We considered this type of stem representative for a large arsenal of hip stems on the market today, especially in the older patient. The implants showed similar failure patterns at visual inspection. All implants bend at the osteotomy site under an axial force. Without the osteotomy gap, cortical contact could have prevented the bending and by this gaining stability. However, a simulated comminuted zone was considered a more critical representation of reality.

Although the femur of the geriatric patient is expected to be more fragile than the sawbones, the latter offer more reproducible results. Our tests were performed using sawbones suitable for biomechanical testing because they have superior inter-specimen biomechanical characteristics over cadaver bones. The mechanical properties for axial rigidity, torsional rigidity, and cortical bone screw purchase are similar to cadaveric femora. Finally, practical issues played a role in specimen selection regarding the limited access to cadaveric bones. Cadaveric bones are relatively scarce and therefore expensive. Furthermore in this study the bone quality was expected to be of only minor influence on the test results as the tests focussed directly on the nail-stem connection, rather than its interaction with the surrounding bone. The implant supports the entire femur and the loads are transferred along the metal construction. Higher bone quality, though, might be expected to provide additional stabilisation of the stem-nail junction, thereby delaying slippage. Kaufer showed higher resistance of at least 20-30\% in testing intramedullary nails with and without bone. However, these assumptions would need to be verified experimentally by mechanically comparing slippage of the stem-nail junction with and without surrounding femoral tissue in this specific test session of the Bridging nail.

In conclusion the Bridging nail offers a stable connection with the stem of a hip arthroplasty. The implant can resist high repetitive loads, representative for direct full weight bearing. The construction can be used as an alternative treatment option for compromised geriatric periprosthetic fractures. Rotational movements with foot contact in non-weight bearing conditions should be limited. The major advantages of this technique are its less invasiveness and the ability of allowing early post-operative mobilisation.

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Reference List


