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What is the underlying mechanism for the failure mode observed in the proximal femoral locking compression plate? A biomechanical study

Kerstin Schneider [a,b], Jong-Keon Oh [c,*], Ivan Zderic [a], Karl Stoffel [d,e], R. Geoff Richards [a], Stefan Wolf [f], Boyko Gueorguiev [a], Sean E. Nork [g]

[a] AO Research Institute Davos, Davos, Switzerland
[b] Schulthess Clinic Zurich, Zurich, Switzerland
[c] Guro Hospital, Korea University College of Medicine, Department of Orthopaedic Surgery, Seoul, Republic of Korea
[d] Cantonal Hospital Baselland, Liestal, Switzerland
[e] University of Basel, Basel, Switzerland
[f] Synthes GmbH, Zuchwil, Switzerland
[g] Harborview Medical Center, Department of Orthopaedic Surgery, Seattle, WA, USA

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ABSTRACT

Purpose: Recently, several cases of clinical failure have been reported for the Proximal Femoral Locking Compression Plate (PF-LCP). The current study was designed to explore biomechanically the underlying mechanism and to determine whether the observed failure was due to technical error on insertion or to implant design.

Methods: A foam block model simulating an unstable intertrochanteric fracture was created for 3 study groups with 6 specimens each. Group C was correctly instrumented according to the manufacturer's guidelines. In Group P and Group A, the first or second proximal screw was placed with a posterior or anterior off-axis orientation by 2° measured in the transversal plane, respectively. Each construct was cyclically tested until failure using a test setup and protocol simulating complex axial and torsional loading. Radiographs were taken prior to and after the tests. Force, number of cycles to failure and failure mode were compared.

Results: A screw deviation of 2° from the nominal axis led to significantly earlier construct failure in Group P and Group A in comparison to Group C. The failure mode was characterised by loosening of the off-axis screw due to disengagement with the plate, resulting in loss of construct stiffness and varus collapse of the fracture.

Conclusions: In our biomechanical test setup, the clinical failure modes observed with the PF-LCP were reproducible. A screw deviation of 2° from the nominal axis consistently led to the failure. This highlights how crucial is the accurate placement of locking screws in the proximal femur.

Introduction

Unstable fractures of the trochanteric region (AO/OTA 31 A2.2, A2.3 and A3) are challenging injuries due to the particular anatomy of the proximal femur and the high loads transmitted via the hip joint [1,2]. AO/OTA 31 A2.2 and A2.3 fractures are considered to be unstable mainly due to the loss of posteromedial support. In AO/OTA A3 fractures, where the lateral femoral wall is broken, instability mainly comes from the loss of lateral wall support when the proximal fragment slides down.

The advantages and disadvantages of various intra- and extramedullary implants, available for the treatment of such fractures, are widely discussed in literature [3–13]. Whereas for simple pertrochanteric fractures (AO/OTA 31 A1 and A2.1) implants like the dynamic hip screw [3] and for intertrochanteric fractures (AO/OTA 31 A3) intramedullary devices are generally recommended and proven to be superior [5,6], cases with a highly comminuted fracture zone including the nail insertion sites and/or poor bone quality still seem to be an unsolved problem. Fixation of AO/OTA 31 A3.3 fractures, where both the posteromedial support

* Corresponding author. Tel.: +82 2 2626 3088.
E-mail address: jkoh@korea.ac.kr (J.-K. Oh).

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and the integrity of the lateral femoral wall are lost, is still controversial especially when the fracture line is extending to the greater trochanter. This specific fracture type is challenging for nailing because the entry point is along the main fracture line and the free lateral femoral wall fragment cannot be stabilised effectively with the nail itself. For this reason, plating is a reasonable alternative to nailing of such fractures.

In 2007, the Proximal Femoral Locking Compression Plate (PF-LCP 4.5/5.0; Synthes GmbH, Zuchwil, Switzerland) was introduced as a precontoured stainless-steel plate, available for left and right femurs, with a fix angled locking interface for the 3 proximal screws (95°, 120° and 135°) and combi-holes in the distal part [14]. The first two proximal 7.3 mm cannulated screws are designed to cross each other with the second screw positioned anteriorly to the first one. The third proximal 5.0 mm cannulated screw is lying in the same plane with the first screw, converging in a way that it contacts the first screw at a distance of 85 mm (kickstand screw).

To date, only 4 case series reporting on the clinical use of PF-LCP have been published [15–18]. According to their findings, PF-LCP osteosynthesis was applied to fix 37% to 52% complex fractures in the trochanteric region [17,18]. In addition, those authors also reported high failure rates which they observed, ranging from 28% to 70%.

Based on this background, our study was designed to investigate different failure modes and explore the underlying mechanism. Specifically, the study sought to determine whether the observed failures were due to implant design or to technical error on insertion.

Materials and methods

Specimen preparation, fracture model and study groups

A total of 18 foam block models (General Plastics 6718, Tacoma, WA, USA, density 288 g/l) divided in 3 study groups ($n = 6$) and 18 left PF-LCP plates (Synthes GmbH, Zuchwil, Switzerland) with 3 proximal screws each were used to achieve consistent biomechanical and anatomic conditions during testing. The foam block model was used to simulate the most unstable fracture pattern in the trochanteric region AO/OTA 31 A3.3(1) in poor bone quality with the following three components [19] (Fig. 1): (1) loss of posteromedial support by broken lesser trochanter and adjacent medial cortex; (2) broken lateral femoral wall; (3) extension of the fracture line to the greater trochanter. For consistency we used a custom made jig, produced with 3D printer, to hold the foam block and plate in place during the instrumentation (Fig. 2a). Each proximal screw was inserted as follows: (1) guide wire insertion; (2) drilling with a drill bit according to the manufacturer's surgical technique guide; (3) screw insertion over the guide wire and locking with 6 N m using a torque limiter tool.

The instrumented specimens in the 3 study groups only differed in the orientation of the first or second proximal screw with regard to the plate as follows. In Group C the instrumentation was performed correctly (C) according to the manufacturer's guidelines [14]. In Group P and Group A the first or the second proximal screw was placed in posterior (P) or anterior (A) 2° off-axis orientation measured in the transverse plane, respectively. The amount of 2° for off-axis orientation was arbitrarily chosen considering the clinical situations with possible multiple positioning and repositioning of the same guide wire which could lead to a small amount of unrecognizable screw malposition.

The distal part of all plates was cut up to the third proximal shaft screw hole after instrumentation and embedded in PMMA (Polymethylmethacrylate, Beracryl, Suter Kunststoff AG, Jegenstorf, Switzerland) using an additional plastic aid (Fig. 2b). Subsequently, the foam block was embedded in PMMA in a special fixture (Fig. 2c).

Biomechanical testing

Biomechanical testing was performed on a servo hydraulic testing machine (Bionix 858.20, MTS Systems, Eden Prairie, MN, USA). The specimens were mounted in a 20° valgus and 20° flexion inclination to ensure physiological loading simulation during normal gait [20,21] and focus on proximal screw loosening as a potentially possible clinically relevant failure mode [15–18] (Fig. 3). For this purpose, the proximal embedding of each specimen was fixed between two custom made aluminum plates connected via threaded steel rods. Loading was applied to the specimen through a proximal cardan joint mounted to the machine actuator. The distal embedding was fixed in a holder, inclined 20° in the frontal and 20° in the sagittal plane with respect to the plate mid-line and attached to the machine frame via a second cardan joint.

The loading protocol consisted of an initial non-destructive quasi-static axial compression ramp from 50 N to 200 N at a rate of 20 N/sec, followed by complex cyclic axial loading in compression-tension with a Bergmann profile of each cycle [1], applied at a rate of 2 Hz in combination with phased synchronal sinusoidal torsional loading in internal–external rotation up to 90,000 cycles

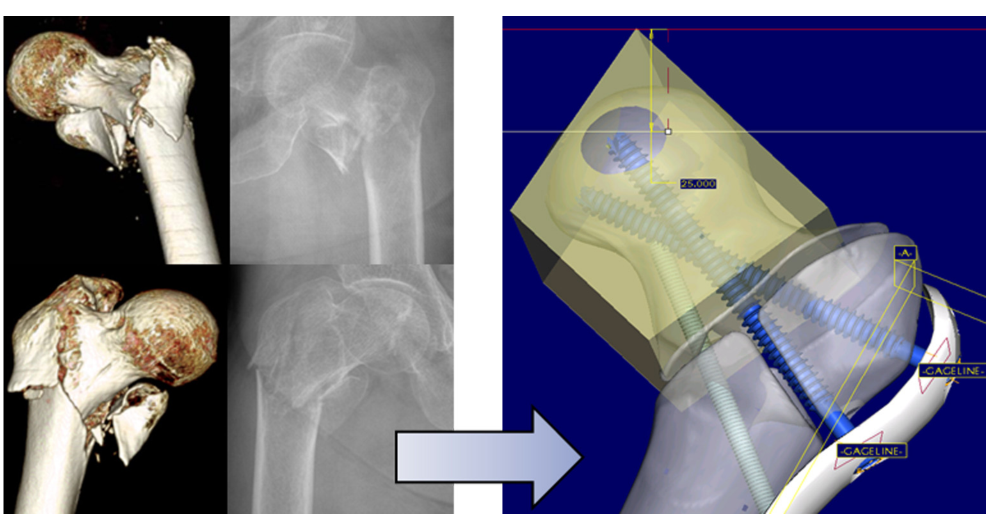

Fig. 1. Unstable comminuted fractures of the trochanteric region AO/OTA A3.3(1) (left) and foam block model used for their simulation (right).