Fatigue Testing of a New Locking Plate for Hip Fractures

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Abstract

Femoral neck shortening and varus deformity can have a significant effect on functional outcomes in patients with femoral neck fractures, particularly in young trauma patients. This study proposes a locking plate construct to address femoral neck fractures. The biomechanical properties of the locking plate are investigated with a specific focus on fatigue performance. The challenges associated with the development of a standardized pre-clinical testing model are also discussed. The development of a testing strategy and three mechanical tests are described. Each of the testing phases compare the proposed plate construct against the currently accepted gold standard of three cancellous screws. The first phase of biomechanical testing involves cadaveric specimens, which are statically loaded until ultimate failure of the construct. The second phase cyclically loads instrumented synthetic bone substitute samples with hardware installed without compression at the fracture site. The third phase cyclically loads samples with hardware installed with compression at the fracture site. Static testing results indicate that the proposed locking plate construct can withstand significantly higher static loads before failure than can the three cancellous screw technique. Fatigue testing results show that without compression across the fracture site, the samples instrumented with the locking plate construct had a shorter fatigue life than samples instrumented with 3 cancellous screws. With compression across the fracture site, the fatigue performance of the proposed locking plate is equivalent to that of 3 cancellous screws. The results indicate that the proposed locking plate construct for hip fractures has superior static strength and equivalent fatigue life compared to those of 3 cancellous screws. Biomechanical testing results show that compression across the fracture site is critical to the fatigue performance of both constructs. The development of a preclinical testing strategy for trauma products requires an understanding of the intended application of the product, expected modes of failure, and a thorough understanding of the product's service requirements.

Keywords: Hip fracture, Fatigue, Femoral neck, Trauma, Biomechanical, Locking plate

1. Introduction

Optimal fixation of femoral neck fractures remains an unsolved problem despite extensive biomechanical and clinical research. Femoral neck fractures are a very common orthopedic injury yet failure rates of operative fixation have been reported to be in the range of 10-30% [1-5]. Major challenges in treating femoral neck fractures can be divided into two broad categories: biological and biomechanical. The major biological challenges involve working with very-poor-quality osteoporotic bone and bone with reduced healing potential. The major biomechanical challenges relate to a large bending moment at the fracture site and poor fixation of hardware within bone. Fracture patterns vary with the patient population and injury mechanism. Typically, elderly patients demonstrate fractures with a low Pauwels' angle in osteoporotic bone whereas younger patients demonstrate more vertical fractures with a higher Pauwels angle in stronger, non-osteoporotic bone [6] (Fig. 1). Recent research into functional outcome measures in hip fracture patients has found that despite the high reported healing rates, many patients demonstrate unacceptable functional impairments after healing [7]. The purpose of this study is to develop a biomechanical test model to test a proposed orthopedic implant, which was designed to improve healing rates and decrease functional impairments in hip fracture patients. The main focus of the investigation is the biomechanical performance of the proposed implant under static loading, cyclic loading without compression at the fracture site, and cyclic loading with compression at the fracture site for an unstable fracture created in synthetic bone.

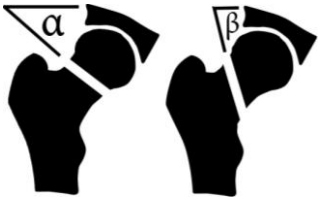

Figure 1. Diagrams of femoral neck fractures in elderly patients (low Pauwels angle (α)) and young trauma patients (high Pauwels angle (β)).

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2. Method

2.1 Testing protocol development

There is no standardized testing protocol for orthopedic trauma products. Although government regulatory approval is required before products can be brought to market for commercial use, the approval of products for use in clinical trials largely relies upon the discretion of the attending surgeon and their local health institution [8,9]. To develop a comprehensive testing protocol for orthopedic implants, a 9-point checklist was prepared to serve as a reference throughout the development process (Table 1).

Table 1. Product development checklist.

New Trauma Product Development Checklist
1.Establish need for new product
A.Identify surgical indications
B.Specify fracture type
i.Specify patient population
ii.Specify patient factors
C.Needs assessment
i.Currently available implants
ii.Obsolete implants
iii.Identify key attributes of new implant
2.Literature search
3.Conceptual design
A.Establish design criteria
i.Surgical - clinical and intraoperative criteria
ii.Engineering – mechanical criteria
4.Prototype design
A.Engineering consultation
B.Prototype manufacture
5.Model design
A.Model design
i. Static vs cyclic loading
ii. Load direction, magnitude, modeling
Clinically relevant testing parameters (Cycle count, magnitude, physiologic loading)
iii. Synthetic vs cadaveric substrate
iv. Existing standardized protocols
v. Failure criteria – stiffness, displacement, strength, fatigue life
B.Pilot testing
i. Observe mode of failure (type, load, cycles, location)
Evaluate modeling relevance (Output parameters (displacement, stiffness, load failure criteria)
ii. Iterative model development
6.Pre clinical biomechanical testing
A.Validate modeling criteria
B.Larger sample sizes
C.Statistical analysis
D.Cadaveric vs synthetic substrate
E.Reporting of results
7.Peer review
A.Surgical indications
B.Pre-clinical testing results
C.Critical surgical review
i. Potential failure
ii. Remediation
iii.Technical considerations
D.Cost
E.Sample size
i. Inclusion / exclusion criteria
ii.Power analysis
8.Pilot clinical testing.

The type of orthopedic implant used in a femoral neck fracture is decided by the surgeon at the time of surgery. Commonly, several surgical screws are used to secure the femoral head to the femoral neck and shaft. 316L stainless steel screws are typically 7.0 mm in diameter, partially threaded (16-mm thread length), and installed parallel to their longitudinal axis. The intention of this treatment is to compress the femoral head against the femoral neck to minimize motion between the two bone fragments, allowing the bones to heal. Too much motion at the fracture site leads to non-union, which is often painful and generally leads to catastrophic failure of the attempted repair within months [10].

Multiple-hole plates are often used in conjunction with surgical screws as part of an orthopedic construct. Locking plates are a subset of orthopedic plates that are designed to allow specially designed screws to rigidly anchor themselves into the plate [11]. Locking plates are manufactured by many orthopedic implant companies, each having a proprietary interface. The screws are designed to lock into the plate to provide angular stability for the construct. This is typically accomplished with a conical thread on the plate, and a corresponding thread on the head of the screw. There is a small amount of plastic deformation at the threads of the screw and plate that provide an interference fit and prevent the screw from loosening. Locking plate technology is a recent development in orthopedics. Due to their unique mechanical properties, locking plates are being used to treat fractures that previously could not be treated with plate and screw constructs l. Mechanical failures at the plate, screw, or plate-screw interface are not commonly observed during acute fracture healing. A patient's biological response generally requires 8-12 weeks to heal a fracture. Mechanical hardware failure rarely occurs in this time period due to the limited number of load cycles and the reduced loading by the patient [12] . Although locking plates have been developed for use in most bones in the body, few studies have investigated their use in femoral neck fractures.

An extensive checklist was prepared to guide the development of a new solution for hip fractures (Table 1). The prepared checklist was followed and a prototype implant was developed. The implant was manufactured by Synthes using a process very similar to that used to produce their commercially available LCP system (Synthes, West Chester, PA, USA). No extensive mechanical analysis was performed on the plate and screw because it is expected that failure of the orthopedic construct would be observed at the bone fracture site rather than in the implants themselves. The screw trajectory of the current gold standard treatment for femoral neck fractures, namely 3 cancellous screws, is incorporated into the design of the locking plate. The proposed design resists varus collapse at the femoral neck via a lateral locking plate [13] (Fig. 2). The primary objective of this study is to measure the biomechanical performance of the proposed orthopedic construct at the fracture site. The specific failure mechanics of the implants themselves were not considered as it is expected that the synthetic bone would fail before the metal implants, as is seen *in vivo*.

2.2 Static testing

2.2.1 Test A – Static mechanical testing

Pilot testing began with the static testing of the proposed construct and the currently accepted gold standard of 3

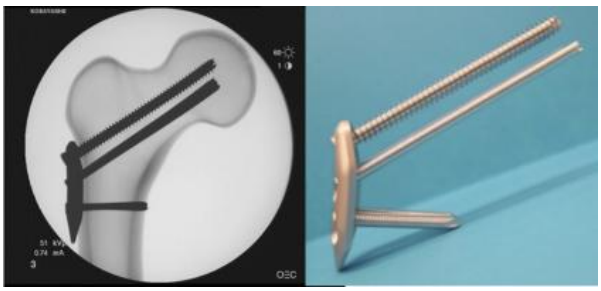

Figure 2. Prototype of lateral femoral locking plate.

cancellous screws. This testing was undertaken to evaluate how the proposed construct performs under catastrophic loading of the femoral neck. Nine paired cadaveric femurs (18 femurs) were instrumented with either 3 cancellous screws or the proposed locking plate and loaded until failure. Samples were tagged and identified so that sample pairs could be tracked though testing. Each cadaver was instrumented with one locking plate and one 3-cancellous screw construct. The side which received the locking plate was randomized. Specimens were positioned with 10° of adduction, potted in bismuth alloy, and axially loaded in an biaxial servo-hydraulic material testing system (Instron 8874, Instron, High Wycombe, UK) at 5 mm/s until failure (Fig. 3). The force, displacement, and time were recorded. Failure was defined as displacement equal to or greater than 5 mm measured at the point of load application (femoral head).

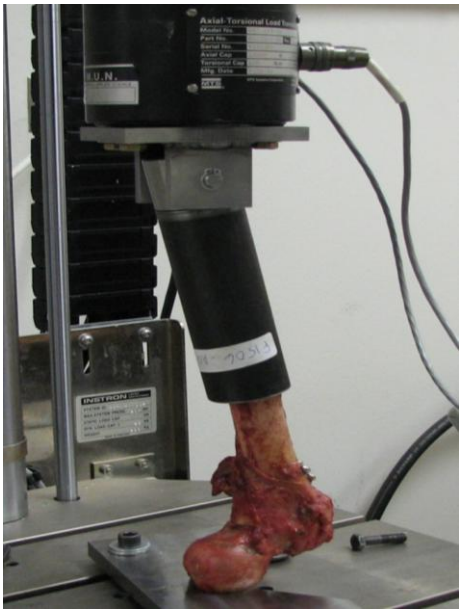

Figure 3. Photograph of static mechanical testing setup (Test A).

2.3 Fatigue testing

A fatigue testing protocol was developed to evaluate the performance of constructs under cyclical loading. All fatigue testing samples were prepared using the same technique with a type-II osteotomy (Pauwels angle = 50°) and a 10° wedge removed to a depth of 10 mm to represent anatomically relevant comminution (Fig. 4) [14,15]. Since there is no defined protocol for testing trauma implants for use in femoral neck fractures, a test protocol was created by modifying ISO 7206 [16], which was developed for testing hip arthroplasty prostheses. Slight modification of the loading parameters to reflect the anatomic loading and cycle counts seen in trauma products was considered reasonable for developing a trauma testing protocol. Synthetic femurs (4th generation Sawbones, Sawbones, Vashon, Washington USA) were instrumented with either 3 cancellous screws (Synthes, West Chester, Pennsylvania USA) or the proposed locking plate construct. Samples were potted in bismuth alloy and positioned in a 2-axis vice prior to being loaded into biaxial servo-hydraulic material testing systemm test frame with a load cell and a linear bearing plate (Fig. 5). Using the linear bearing plate, samples were loaded axially with the femurs positioned with 10° of adduction and 9° of flexion to represent a single leg stance. Failure was defined as displacement greater than 5 mm.

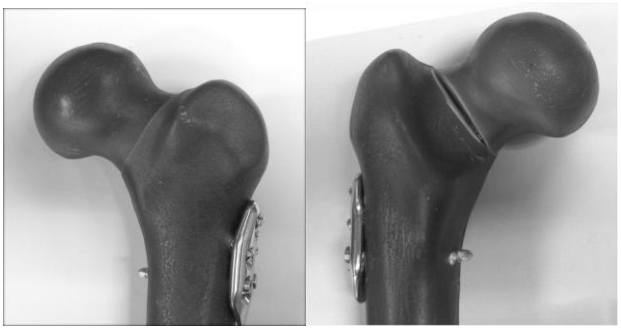

Figure 4. Photograph of femur instrumented with a locking plate (Test B). Left: anterior view; right: posterior view.

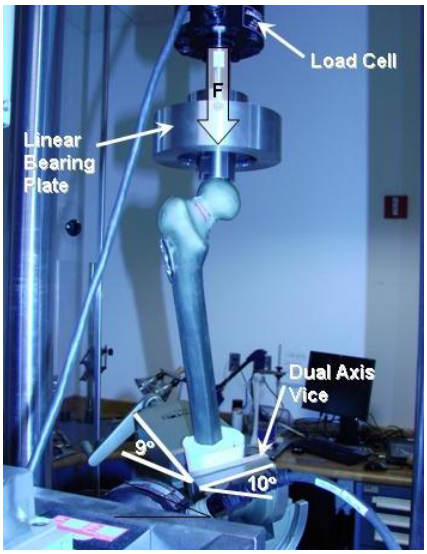

Figure 5. Photograph of fatigue model testing setup (Test B).

2.3.1 Test B – Fatigue testing without compression at fracture site

In the first set of fatigue tests (Test B), one femur was instrumented using the standard technique of using 3 cancellous screws. Cancellous screws are only threaded along their terminal 32 mm. Because they are partially threaded, they can be used to generate compression at the fracture site. Once the screw head has engaged the near cortex, the threaded portion of the screw produces compression with subsequent tightening. Screws were tightened to 4 Nm.

A locking plate was installed on a second femur with fully threaded hardware, in situ, without compression across the fracture site. Fully threaded hardware has threads on both sides of the fracture and thus does not have the ability to generate compression through tightening. Samples were cycled at 1 Hz. The fatigue life was set at 500, 000 cycles, which represents 12 weeks of recovery for a hip fracture patient at a typical reduced activity level. Samples were positioned in a 2-axis vice with 10° of adduction and 9° of flexion. The load was set at 700 N to approximate partial weight bearing of a 70-kg patient [17]. A preload of 50 N was chosen to ensure that the linear bearing plate always remained in contact with the femoral head. The load was cycled sinusoidally between 50 N and the desired load. The force, displacement, and time were recorded. If samples survived 500,000 cycles, the load was incrementally increased, as shown in Table 3, until failure was observed. For these cases, the force, displacement, and cycle count were recorded.

2.3.2 Test C – Fatigue testing with compression at fracture site

The second set of fatigue tests (Test C) were performed on samples instrumented with the fracture site under compression. 3 cancellous screws were installed in four femurs, respectively, using the standard technique. Locking plates were installed in an additional four femurs. For the latter installation, a single, partially threaded, non-locking 7.0-mm screw (Synthes, West Chester USA) was installed into the superior hole in the locking plate to produce compression across the fracture site. The remaining fully threaded, locking hardware was then installed in the remaining holes in the plate. The fully threaded hardware installed across the fracture site after compression had been generated with a partially threaded screw maintained the position of the two bone segments, and hence the compression. As the final step, the partially threaded, non-locking screw in the superior hole was exchanged for a locking screw. The cycling frequency was increased set to 3 Hz to reduce the time required for testing [18]. The amount of heat generated was not measured. Samples were positioned with 10° of adduction and 9° of flexion, and loaded with a sinusoidal waveform with a magnitude of 50 to 1500 N for 500,000 cycles or until failure was observed. The force, displacement, and cycle count were recorded.

3. Results

The results of the static mechanical testing are listed in Table 2. The Student paired t-test was used and statistical significance was set at $p < 0.05$. A significant increase in the maximum force required for failure was found when using the proposed locking plate compared with that for the cancellous screws ($p = 0.027$).

The results of the first fatigue test are listed in Table 3. The modes of failure for the cancellous screw and locking plate groups were similar despite the locking plate samples failing after fewer cycles. Considerable fretting was observed at the fracture site and loosening around the screws in both constructs. The locking hardware was plastically deformed. No deformity of the hardware was identified in the cancellous screw samples.

Table 2. – Static mechanical testing (Test A) results.

Sample	Force Required for Failure (N)	
	Cancellous screws	Locking plate
1	1488.850	2110.340
2	1926.400	1931.870
3	654.596	780.410
4	302.694	701.892
5	327.719	1984.850
6	156.355	868.532
7	259.524	136.364
8	319.782	905.898
9	607.029	888.933
Mean	671 +/- 618	1145 +/- 689

Table 3. Fatigue testing (Test B) results.

Load (N)	Number of cycles until failure	
	Locking plate	3 cancellous screws
700	500,000	-
1000	500,000	-
1500	500,000	500,000
1700	90,000	250,000

The results of the second fatigue test, with both constructs installed to achieve compression at the fracture site, are listed in Table 4. All constructs, with the exception of one 3 cancellous screw construct (which failed at 207,665 cycles), survived 500,000 cycles of loading at 1500 N. No significant deformation of hardware was observed. Subjectively, the samples remained cool to the touch throughout testing at 3 Hz.

Table 4. Fatigue testing (Test C) results.

Sample	Construct	Number of cycles @ 3 Hz, Load 1500 N
1	Locking plate	500,000
2	3 cancellous screws	500,000
3	Locking plate	500,000
4	3 cancellous screws	500,000
5	Locking plate	500,000
6	3 cancellous screws	500,000
7	Locking plate	500,000
8	3 cancellous screws	207,665

4. Discussion

The locking plate construct yielded at significantly higher static loads than did the 3 cancellous screw construct. Failure of fracture fixation *in vivo* is more commonly attributed to cyclic loading rather than single-event catastrophic loading (static test). The results for the proposed locking construct without compression across the fracture site indicate the important role of compression in resisting fretting at the fracture site. The mechanical substrate (4th Generation Sawbones) has a very hard (effectively wear-resistant) outer cortex which permits considerable motion at the fracture site without shortening or varus collapse. It is believed that the early failure of the locking plate group can be directly attributed to the lack of compression and subsequent decreased resistance to motion at the fracture site. A comparison of the two constructs reveals considerably more fretting in the locking plate sample immediately upon loading. The fracture model used in this study is commonly observed in osteoporotic patients with poor-quality bone.

The mechanical properties of durable synthetic bones do not match those of bones of the target population. Unfortunately, commercially available models of osteoporotic

bones with suitable mechanical properties were not available for this test. However, the synthetic bones are a good surrogate for those of young non-osteoporotic patients. Cadaveric testing is thus preferred for ongoing investigations of osteoporotic fractures in hips. Unfortunately, cadaveric testing introduces potentially confounding variables such as bone density, degradation of samples, and anatomic variability, which reduce the ability to measure subtle mechanical differences between constructs. Clinically, osteoporotic fractures demonstrate resorption and poor resistance to failure, which is different from the observed behavior in our testing. Although fretting behavior at the femoral neck has considerable clinical relevance, it is not well modeled in most biomechanical tests.

The second round of cyclic testing (Test C), with compression at the fracture site, revealed that the locking plate construct performs as well as the 3 cancellous screw construct. The single failure in the cancellous screw group did not represent a statistically significant difference between the two groups.

It is hypothesized that the larger cross-sectional diameter of the locking hardware combined with the mechanical attributes of a fixed-angle device will resist the shortening and varus collapse of femoral neck fractures. The sample size in this study was insufficient to derive any statistically significant conclusions about the biomechanical advantages of one construct over another. The testing to date has been part of an iterative test model designed to create a protocol to be used in a larger trial that can be used to establish statistical significance, if one exists, between the two constructs.

Hardware failures are rarely observed within the acute healing period of 8-12 weeks. Fractures that do not heal within 8-12 weeks and do not show any radiographic evidence of healing are termed delayed unions or non-unions. Patients with such fractures typically load their orthopedic constructs for much longer time periods, which frequently leads to hardware failure. This study did not examine the fatigue limit of the locking plate. Patients that have delayed unions or non-unions will most likely undergo further surgical intervention to address the underlying cause of their protracted healing. Generally, this additional surgical intervention occurs before catastrophic implant failure is observed.

The loads used in this study were assigned based on clinically relevant values. Joint reaction forces and mechanics are very complicated and considerable debate exists around the best manner to conduct biomechanical modeling of the hip. Uni-axial loading is a common approach used for bio-mechanical modeling. The magnitude of the loads selected in this study were an approximation of physiological loading, which varies significantly with patient due to body habitus, joint reaction forces, altered gait because of pain, use of mobility aids (walkers, canes, crutches), and a surgeon's preference for the amount of weight that may be placed on the affected leg. This study adopted a loading model that is consistent with other biomechanical tests on the hip.

The stiffness of the installed orthopedic constructs was not analyzed. In order for bone healing to occur, there is a range of micro-motion that is allowed at the fracture site. Measuring micro-motion at the fracture site will provide an additional comparison of the two constructs and a reference for acceptable motion limits for bone healing.

5. Conclusion

Numerous orthopedic implants are available for treating femoral neck fractures. This study investigated a newly designed locking plate which offers an alternative for treating challenging femoral neck fractures, however further testing will be required to define it's suitability for clinical trials. The authors believe that in order to introduce a new implant, researchers should go beyond proving equivalency by demonstrating the distinct advantages of using an new construct over existing ones. Only after thorough assessment, with specific surgical indications, and comprehensive pre-clinical biomechanical testing should a new product be considered for clinical testing. With the prepared pre-clinical testing checklist and a comprehensive testing protocol, products developed using this process will be mechanically validated for consideration in clinical trials.

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