FATIGUE TESTING OF A NEW LOCKING PLATE FOR HIP FRACTURES

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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 in the range of 10-30%[1,2,3,4,5]. Major challenges in treating femoral neck fractures can be broken down into two broad categories: biologic and biomechanical. The major biologic 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. Different patient populations and injury mechanisms demonstrate variations in fracture pattern. Typically, elderly patients demonstrate fractures with a low Pauwel's angle in osteoporotic bone whereas younger patients demonstrate a more vertical fractures with a higher Pauwel's angle in stronger, non-osteoporotic bone. Recent research into functional outcome measures in hip fracture patients has identified that despite currently accepted union rates, many patients demonstrate unacceptable functional impairments as a result of their healed hip fractures[6]. The purpose of this study was to develop biomechanical test model to test a new orthopedic implant designed to improve union rates and decrease functional impairments in hip fracture patients.

METHOD

Testing Protocol Development

There is no standardized testing protocol for development of new orthopedic trauma products. Government regulatory approval is required before products can be brought to market for commercial use, however, development of products for use in clinical trials largely relies upon the discretion of the attending surgeon and their local health institution. In an effort to develop a comprehensive testing protocol for development of a new orthopedic implant we prepared a 9-point checklist to serve as a reference through the development process.

New Trauma Product Development Checklist

1. **Establish need for new product**
   - A. identify surgical indications
   - B. specific fracture type
     - *specific demographic*
     - *specific patient factors*
   - C. needs assessment
     - *currently available implants*
     - *previous implants*
     - *establish need for new implant*
2. **Literature search**
3. **Conceptual design**
   - A. Establish design criteria
     - *surgical*
     - *engineering*
4. **Prototype design**
   - A. engineering consultation
   - B. prototype manufacture
5. **Model Design**
   - A. Model design
     - *static / fatigue*
     - *load direction, magnitude, modeling*
     - *clinically relevant testing parameters (cycle count, magnitude, physiologic loading)*
     - *synthetic vs cadaveric substrate*
     - *existing standardized testing protocols.*
     - *failure criteria - stiffness, displacement, strength, fatigue life*
   - B. Pilot testing
     - A. Observe mode of failure (type, load, cycles, location)
     - B. Evaluate modeling relevance
       - *determine output parameters (displacement, stiffness, failure criteria)*
     - C. Iterative model development
7. **Pre-clinical biomechanical testing**
   - A. Validated modeling criteria
   - B. Larger sample sizes
     - *power, cost, time*
   - C. Statistical analysis
   - D. Cadaveric vs Synthetic
   - E. Reporting of resultS
8. **Peer Review**
   - A. surgical indications
   - B. pre-clinical testing results
   - C. critical surgical review
     - *potential failure*
     - *remediation*
     - *technical considerations*
   - D. cost
   - E. sample size
     - *Inclusion / exclusion criteria*
     - *Power analysis*
9. **Clinical Testing**

Figure 1 - Product development checklist

The checklist was followed and a prototype implant was developed. The design was felt to include the favorable attributes of the currently accepted gold standard treatment for femoral neck fractures - 3 cancellous screws - and incorporate that with a locking plate on the lateral cortex of the femur. This incorporates familiar surgical technique, with it's well researched fixation into the femoral head, and combines that with resistance to varus collapse at the femoral neck provided by a lateral locking plate.

Pilot testing

Static Mechanical Testing

Pilot testing began with static testing of new construct against the currently accepted gold standard - 3 cancellous screws. This testing was undertaken to evaluate how the new construct would perform in the situation of catastrophic loading of the femoral neck. Nine paired cadaveric femora were instrumented with either 3-cancellous screws or the newly designed locking plate and loaded until failure. Left and right femora served as their own control. Specimens were positioned in 10 deg of adduction, potted in bismuth alloy, and axially loaded in an Instron 8874 (High Wycombe, UK) at 5mm/s until failure. Force and displacement and time were recorded. Failure was defined as increasing displacement with significantly decreasing load, as observed from the force displacement curve[7].

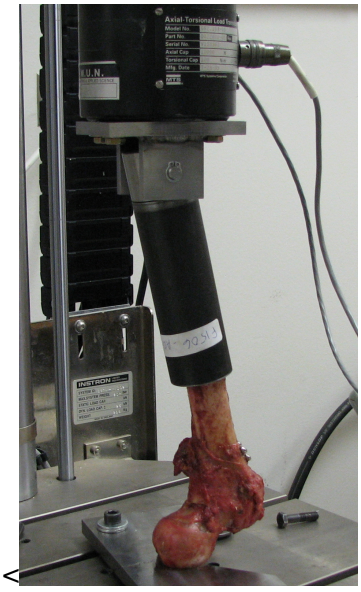

Figure 2 - Static mechanical testing.

Fatigue testing

A fatigue testing protocol was developed to evaluate the performance of constructs under cyclical loading. Test protocol was adapted from ISO 7206 which was developed for testing of arthroplasty prostheses[8]. Using a linear bearing load plate (Figure 3) , samples were loaded axially with femora positioned in 10 deg adduction and 9deg flexion to represent single leg stance. Samples were cycled at 1 Hz. Fatigue life was set at 500, 000 cycles which represents 12 weeks recovery for a hip fracture patient at a typical reduced activity level. Synthetic bone (4th generation Sawbones) were instrumented with either 3-cancellous screws or the locking plate construct. Samples were potted in bismuth alloy and positioned in a 2-axis vice prior to being loaded in to an Instron 8874 (High Wycombe, UK) test frame with load cell and linear bearing load plate (Figure 3). Load was initially set at 700N (1 x Body Weight for 70kg patient). Force, displacement, and time were recorded.

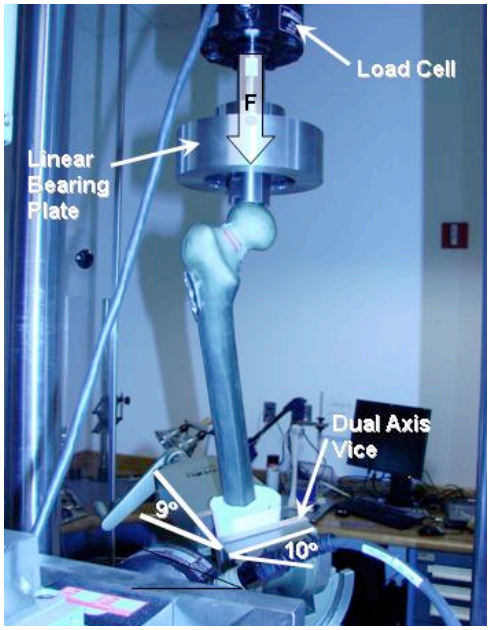

Figure 3 - Fatigue model testing.

In the first set of tests femora were instrumented using the standard technique for the 3-cancellous screw samples. The Locking plate plate samples were as installed in situ without compression across the fracture site. Instrumented femora were incrementally loaded, starting at 700N, for 500,000 cycles. If samples survived 500,000 cycles the load was incrementally increased until

failure was observed. Force, displacement, and cycle count was recorded.

The second set of tests were preformed on samples instrumented with the fracture site in compression. The 3-cancellous screw femora were installed with hardware using standard technique. The locking plate femora were installed by first installing a single standard 7.0mm screw into the superior hole in the locking plate to get compression across the fracture site. Remaining hardware was then installed. Finally, the non-locking screw in the most superior hole was then exchanged for a locking screw. Samples were incrementally loaded, starting at 1500N for 500, 000 cycles until failure was observed. Force, displacement, and cycle count was recorded.

RESULTS

Results of the static mechanical testing are listed in Table 1. The results were then tested for statistical significance using the Students paired t-test. This showed a significant increase in the maximum force to failure when using the new locking plate compared with cancellous lag screws ($p = 0.027$).

Table 1 - Static Mechanical Testing - Specimens loaded to ultimate failure.

Sample	Cancellous Screws (N)	Locking Plate (N)
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**

Results of the first pilot test are listed in Table 2. The mode of failure was similar in both the cancellous screw and locking plate group despite the locking plate sample failing after fewer cycles. There was considerable fretting observed at the fracture site and toggling around the screws in both constructs. The locking hardware was plastically deformed. There was no deformity of the hardware identified in the cancellous screw sample.

Table 2 - Fatigue testing data - locking plate implant installed *without* compression

Load	Locking Plate (cycles)	3-Cancellous Screws (cycles)
700 N	500,000	-
1000 N	500,000	-
1500 N	500,000	500,000
1700 N	90,000	250,000

The second pilot test, with both constructs installed to achieve compression at the fracture site, is listed in Table 3. The locking plate sample was still intact after loading at 1700 N for 500,000 cycles which satisfied the fatigue life specified in the design criteria. Failure occurred at 2000N after 200,000 cycles. The 3-cancellous screw sample failed after 250,000 cycles. As previously observed, failure of the hardware was through toggling of hardware at the fracture site. No appreciable deformation of hardware was identified.

Table 3 - Fatigue testing - Implants installed *with* compression

Load	Locking Plate (cycles)	3-Cancellous Screw (cycles)
1500 N	500,000	500,000
1700 N	500,000	250,000
2000 N	200,000	-

DISCUSSION

Results of testing the locking construct without compression across the fracture site highlights the important role of compression to resist fretting at the fracture site. The mechanical substrate (4th Generation Sawbones) has a very hard, and effectively wear-resistant, outer cortex which permits considerable motion at the fracture site without shortening or varus collapse. We felt that the early failure of the locking plate group was directly attributed to lack of compression and subsequently decreased resistance to motion at the fracture site. Comparison of the two constructs demonstrated considerably more fretting in the locking plate sample immediately upon loading.

The second round of testing, with both constructs demonstrating a similar degree of compression at the fracture site, revealed the locking plate construct to the 3-cancellous screw construct. This difference was attributed to the added rigidity of a fixed angle construct provided by the locking plate. Additionally, the reduced cross-sectional diameter of the 3-cancellous screw hardware (7.0mm) compared to the locking plate hardware (7.3mm) was felt to provide less resistance to fretting.

Sample sizes in this study are insufficient to develop any significant conclusions about 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 which is sufficiently powered to establish statistical significance, if one exists, between the two constructs.

There is no shortage of orthopedic implants available to treat femoral neck fractures. We feel that in order to introduce a new implant, the burden of proof should go well beyond proving equivalency, and extend to demonstrating the distinct advantages of using a new construct. Only after thorough needs assessment, with specific surgical indications, and comprehensive pre-clinical biomechanical testing, should a new product be considered for clinical testing. By development of a pre-clinical testing checklist and an comprehensive testing protocol we feel that products emerging from this process will be mechanically validated for consideration in clinical trials.

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