Multiplane Pin Fixation of Comminuted Proximal Humerus Fractures in Osteoporotic Bone - an in vitro Simulation

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INTRODUCTION:

Comminuted, intra-articular fractures of the proximal humerus in osteoporotic bone are becoming more common as the population ages. Surgical stabilization of these fractures is difficult with conventional techniques. Multi-plane fixation with pins has been effective in other joints, but until now, hardware to accommodate such configurations has been very limited. The NBX device (Nutek Orthopaedics, Inc.) provides the unique opportunity to apply multiple pins in multiple planes of fixation to allow the surgeon to fix the fracture in a fragment-specific manner. The hypothesis of this study is that with the NBX device, multiple plane fixation with multiple pins can be obtained and will provide stable fixation for an adequate time to achieve healing.

METHODS:

The fracture modeled was an OTA 11-C3.3, 5 fragment fracture, (Fig. 1). Sawbones #1019 bones were used to simulate osteoporotic bone. Using a biopsy needle, a 1.5 mm bead was placed in each fragment to measure fragment movements in fluoroscopic videos of the model during cyclic loading. The NBX used 5 – 3 mm diameter pins in the metaphyseal fragments to assure that at least 2 pins, not parallel to each other, passed through each fragment, (Fig. 2). Six similarly prepared constructs were tested.

The rationale for the loading was based upon those established by Lil[1], Duda[2] and Saitoh[3]. A fixture with a glenoid component was used to compress the fragments of the articular surface of the humeral head and a tension band to the lateral side of the humerus to simulate the pull of the deltoid, (Fig 3). The load to create a 4 mm displacement of the 100 mm lever arm (the displacement applied by Duda) was measured and used as the peak load applied for 50,000 cycles in load control for the test. 50,000 cycles was based upon ASTM F1541 for construct tests of external fixators. Test Resources electro-mechanical machine, IMTC 2350-MC, applied the cyclic loads and recorded all 50,000 cycles. Cycles were analyzed at 10, 50, 100, 500, 1K, 5K, 10K and 50K cycles to detect creep or loosening.

At the completion of each test, the NBX fixator, with the pins in place, was separated from the bones and mounted on an MTS 858 machine. Each pin was pulled out of its individual ball joint to detect any loosening that may have occurred during the cyclic testing. New pins in new ball joints were also applied and pulled out to establish a baseline for well fixed pins.

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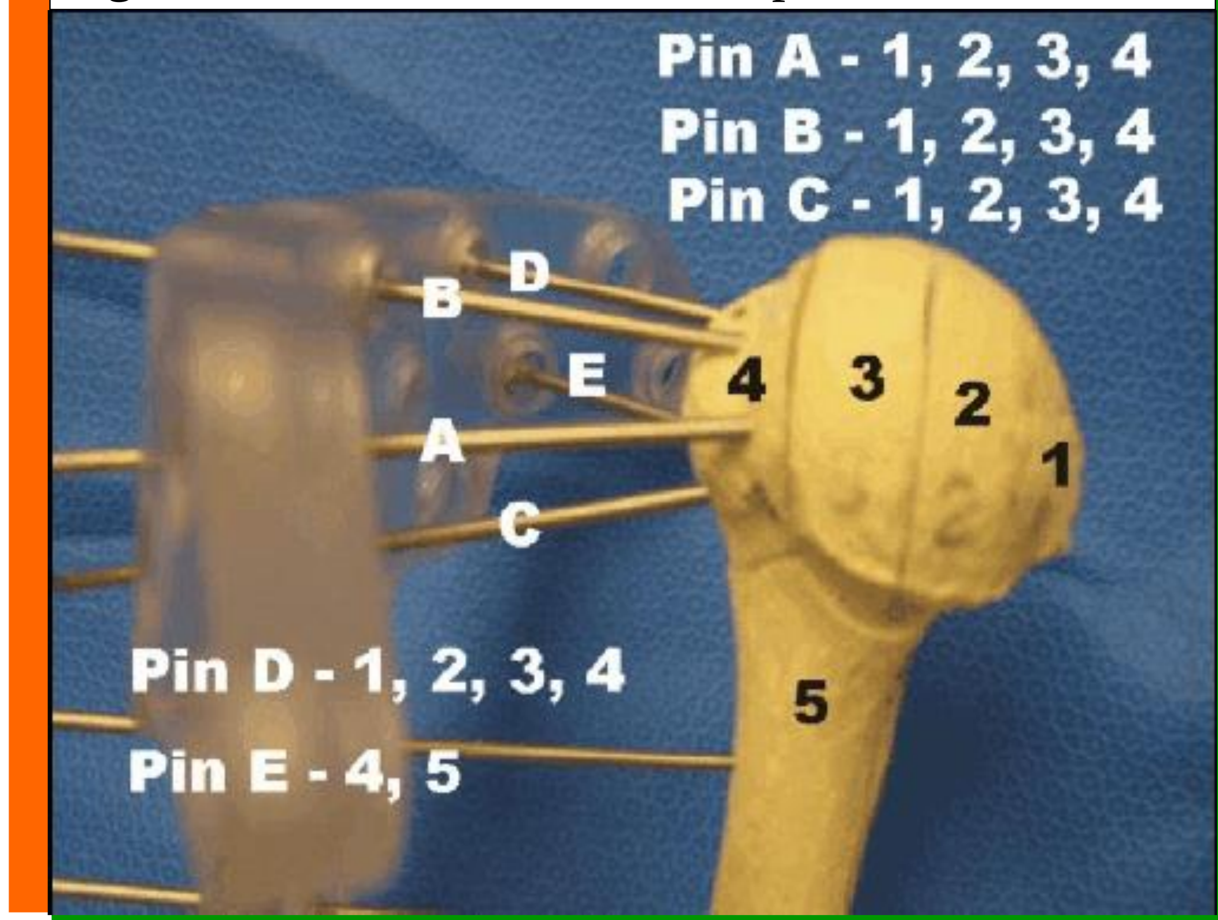
Figure 1-Fracture and Pin Set-Up.



Figures 2-One frame of the fluoroscopic video showing the beads; Figure 3 - the glenoid-like mold with medial lever arm and lateral tension band.

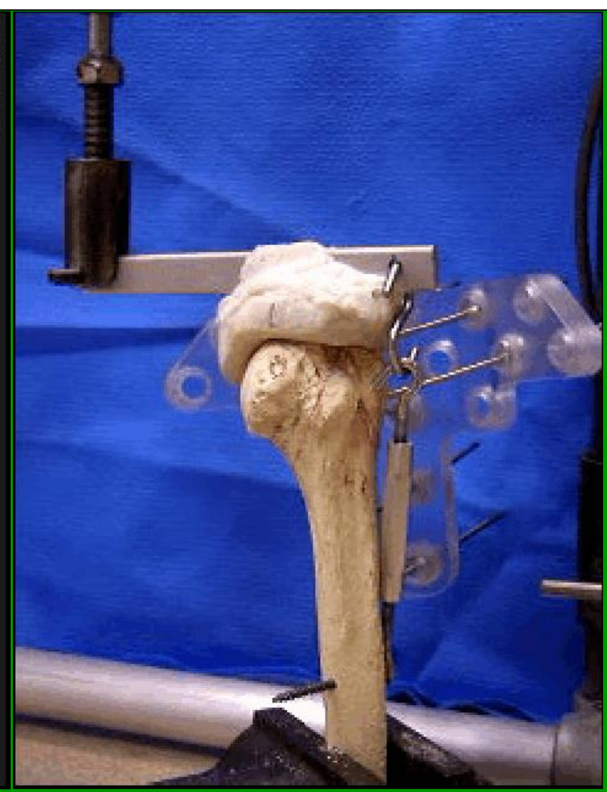
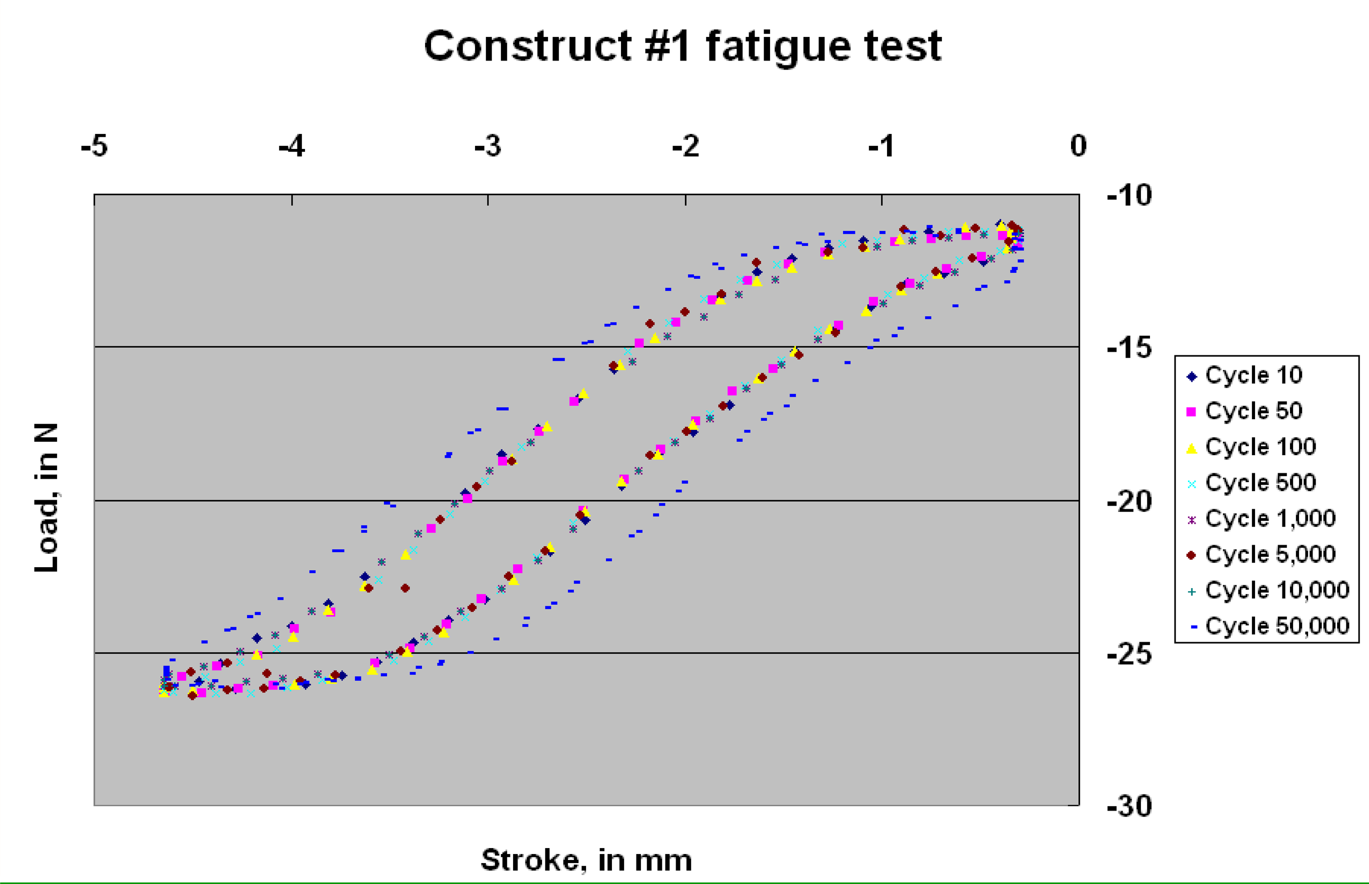
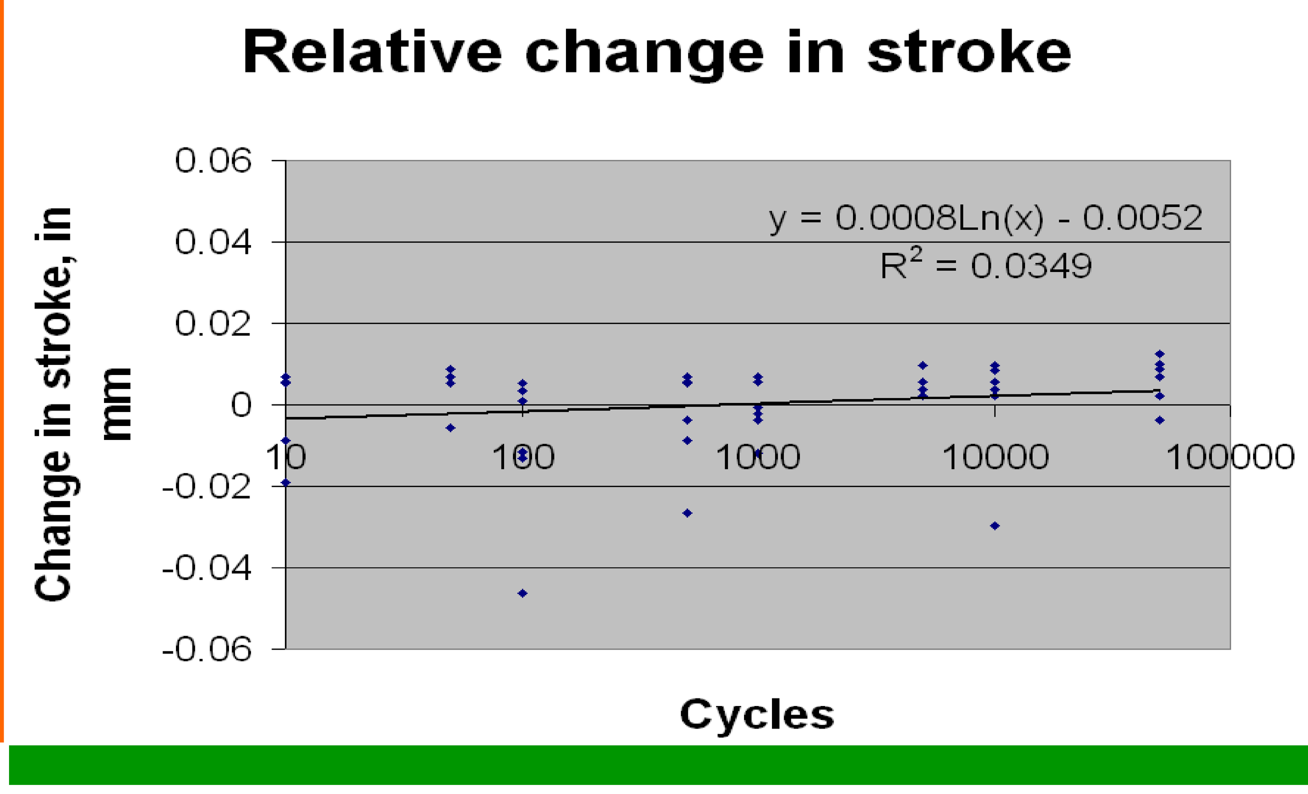


Figure 4 - A typical scatter plot of selected cycles to demonstrate creep.



REFERENCES: 1) Duda, GN, et al. Acta Orthop., 2007, 78-3:430-35; 2) Lil, H, et al. Arch Orthop. Trauma Surg., 2003, 123:74-81; 3) Saitoh, S., et al. J Shoulder Elbow Surg. 1994;3-4:234 –42.

Figure 5 - The plot of all 6 constructs tested to 50,000 cycles. Very little increase in stroke was detected.



RESULTS

Within the accuracy of the image measurement system, there were no measurable relative movements between the bone fragments that could be detected on the fluoroscopic images.

No changes in stroke could be found within the accuracy of the measurement system for up to 50,000 cycles of load control compression and varus loading. Figure 4 shows the plot of the 10th, 50th, 100th, 500th, 1,000th, 5,000th, 10,000th and 50,000th cycles superimposed over each other. Any drift in the cycles was too small to measure with the electromechanical machine.

Most of the deflection appeared to occur in the diaphyseal bone during the cycling. There was no gross evidence of loosening. Analysis of the change in maximum stroke for all 6 constructs revealed a very slight trend for increase over the cycles, but this again was too small to be significant with the measurement accuracy available, (Fig. 5).

The maximum torque that caused some plastic deformation in the ball joint mechanism was 4.7 ± 0.75 N-m. The torques applied to the constructs tested in this study averaged about 3.7 ± 1.0 N-m and that resulted in pin slippage averaging 148 ± 67 N which was comparable to new pins applied to new ball joints, 156 ± 27 N-m, and appeared to be adequate for this type of application.

CONCLUSION:

There was no evidence that loosening occurred in the NBX device for this difficult type of fracture under loading up to 50,000 cycles (more than enough to expect healing). The loading was more than one would expect for a patient with a fracture and the associated soft tissue injuries that is less than 8 weeks old. The fixation was visibly secure and it maintained that security after loading to 50,000 cycles.