Locking Cap Designs Improve Fatigue Properties of Polyaxial Screws in Upper Extremity Applications

Introduction

The advent of polyaxial screw and locking plate systems has provided a new framework for fragment-specific fixation of upper extremity fractures. Previous research has suggested that the ultimate failure strengths of polyaxial screws can be compromised due to excessive screw angulation or inferior locking design. Although this information is valuable, clinical failure of these implants is more likely due to fatigue from cyclic loading rather than an acute event. There is a paucity of data regarding fatigue properties of these implants. This study sought to examine fatigue characteristics of two implant types: 1) locking cap (LC) designs, and 2) cross-threaded (CT) designs. Our goal was to compare LC and CT implants at 0, 10, and 15 degrees of angulation to determine the effect of locking mechanism on screw-plate interface failure. We hypothesized that LC implants would have superior fatigue properties in comparison to CT designs and that increased angulation of the screw would have a negative impact on the fatigue life of CT implants, but would not have any effect on LC implants.

Materials and Methods

A total of 72 screws were tested in four upper extremity implants. Two implants were LC designs (Miami Device Solutions (LC1), Zimmer Biomet NCB (LC2)) and two implants were CT designs (Smith and Nephew PERI-LOC VLP (CT1), Stryker VariAx (CT2)). Using a Bose 3550 with a 49Nm torque cell, screws were locked into place with a rotational speed of 45 degrees/sec and a linear speed (mm/sec) that was determined by the pitch of the threads on the shaft of the screw. All screws were aligned with a custom-built jig to 0, 10 or 15 degrees relative to the plate and torqued to exact manufacturer specifications (n = 6 for each group). Screw-plate assemblies were potted in a low temperature metal alloy (Cerralow 117) such that there was 10mm of vertical clearance between the surface of the alloy to the center of the screw head. The potted implant was securely held within the test frame such that a hardened steel actuator with a 3mm diameter cylindrical tip had a line of action 4mm away from the nearest face of the implant. Implants were fatigue tested on a Bose 3350 universal test frame with a 4450N load cell. For fatigue testing, a staircase method consisting of 11 steps was employed. The first step imparted a 100N cyclic force on the screw for 5000 cycles at a rate of 2Hz. Each subsequent step increased the linear force by 50N, increasing the moment applied to the screw-plate interface by 0.2 Nm up to 2.4Nm. Failure of the implant was defined as screw displacement exceeding 5 degrees from the original axis. If the implant survived

Figure 1. Comparisons of survived cycles before failure. In all but one case (LC2 vs CT2 at 0 degrees), the LC designs sustained a significantly higher number of cycles in comparison to CT designs. With the exception of one case (CT2 at 0 and 10 degrees), there was no significant decrease in survived cycles due to changes in angulation for a particular design. Error bars are +/- 1 standard deviation.
the fatigue test, a ramp to failure was performed at a rate of 0.1mm/s. Cycles to failure were statistically compared using one-way analysis of variance and Tukey honestly significant difference post hoc comparisons with a critical significance level of \( \alpha = 0.05 \).

**Results**

Fatigue testing demonstrated that both LC designs were consistently able to sustain a significantly higher number of cyclic loads than either of the CT designs (Figure 1). There was only one comparison (LC2 and CT2 at 0 degrees) in which the LC design did not sustain a significantly higher number of cycles. Further, there were no significant differences in the number of cycles sustained by LC designs due to changes in screw angulation.

**Discussion and Conclusions**

Likely because of the spherical screw head geometry, LC fatigue characteristics are not influenced by the orientation of the screw relative to the plate. Application of a locking cap in the operating room requires extra time, but provides significantly more robust fixation of the screw to the plate and provides a more predictable and consistent result. It should be noted that this study was limited to upper extremity implants. Lower extremity implants may perform differently than those in this study and warrant further investigation.