BIOMECHANICAL EVALUATION OF Z-FIBER® TECHNOLOGY IN FRACTURE FIXATION

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ABSTRACT

Background and Methods: Plate osteosynthesis has undergone considerable evolution over time, and the purpose of this study is to evaluate the effectiveness of a novel device in fracture fixation. The objective of the Z-fiber® plate construct is to achieve enhanced "biologic fixation" and employ minimally invasive plate osteosynthesis (MIPO) principles in the setting of comminuted osteoporotic fractures. The Z-fiber® plates were compared biomechanically to conventional dynamic compression plates (DCPs) using several techniques. We have performed finite element analysis, axial pull-out testing in synthetic cancellous bone models, and four-point bending and compression testing in a cadaveric canine radii fracture model. ***Results***: Preliminary results indicate based on finite element anaylsis that the Z-fiber® plates may offer enhanced distribution of Von Mises stress over the area of the plate. Axial pull-out demonstrated that the Z-fiber® construct had 165% ($p<0.004$) of the pullout strength of conventional 3.5mm cortical screws. ***Conclusions***: According to initial biomechanical investigation, Z-fiber® plating may offer a viable method of fracture fixation. Further study is required, including greater sample sizes with cadaveric testing and in vivo experimentation.

INTRODUCTION

Plate osteosynthesis has undergone considerable evolution over time and is recognized currently as the mainstay of treatment for most articular fractures, many metaphyseal fractures, and certain diaphyseal fractures (such as the forearm)[1]. Robert Danis, generally regarded as the father of modern osteosynthesis, stated that the goals of rigid fracture fixation were to achieve early active limb mobilization, complete bone restoration, and primary bone healing.[2]

Applying Danis' priniciples of osteosynthesis, the Arbeitsgemeinshaft fur Osteosynthesefragen (AO), has advocated four main principles in the treatment of fractures: anatomical reduction, rigid fixation, preservation of blood supply, and early active mobilization.[3] The Dynamic Compression Plate (DCP) was introduced in 1969 by Allgöwer et al. as a self-compressing plate for the treatment of fractures.[8] The DCP provides axial compression via an eccentrically placed screw with a spherically under-shaped head in an inclined plate hole.[1] However, success of the DCP relies on precise fracture reduction in order to achieve rigid stabilization. During the advent of dynamic compression plating, wide surgical exposure was undertaken in order to achieve this reduction and often the soft tissues were stripped off of fracture fragments compromising blood supply as well as debridement of osteogenic tissues around the fracture site.[1,14] Additionally, the rigidity of this construct was dependent on bicortical screw fixation and friction between the plate and underlying bone.[9]

The observation of radiographic bone loss beneath plates, initially attributed to stress shielding,[10] was thought by Perren et al. to be a result of disturbed circulation to the underlying bone due to periosteal compression by the plate.[10] These assumptions, led to the development of the Limited Contact-Dynamic Compression Plate (LC-DCP) as well as the Point Contact Fixator (PC-Fix) [11,12,13] in an attempt to address these circulatory concerns. These plates were machined with ridges or points respectively on the underside to limit contact areas between the plate and the underlying bone and periosteum. As such, the concept of 'biological fixation' began to gain greater attention and surgical techniques of fracture fixation evolved to enable better preservation of the soft tissues and thereby maintain circulation to the bone.[4]

In order to minimize soft tissue stripping the minimally invasive plate osteosythesis (MIPO) technique was developed. This technique involves indirect fracture reduction to avoid devitalizing and debriding the osteogenic tissues surrounding the fracture site. The plate is percutaneously inserted and secured at distances proximal and distal to the fracture.[14] An example of such a device designed to facilitate this technique is the Less Invasive Stabilization System (LISS).[5] With this system, stability of the construct is not dependent on anatomical reduction of the fracture as with conventional plating techniques.[7] The plate is introduced through a small incision and unicortical locking screws (self-drilling and self-tapping) are placed via small stab incisions using an attached screw

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guide. Threaded screw heads lock into the plate, therefore no compression of the fixator onto the bone is required to achieve stability,[6] and the blood supply to the bone under the fixator is preserved.[5] Cadaver arterial injection studies have provided some objective evidence that the MIPO technique is superior to the conventional plate technique in mainlining arterial femoral vascularity and perfusion.[14]

Seeking to further evolve fracture fixation, we are investigating a novel method of fixation that would integrate these principles of "biological fixation" and potentially improve upon current MIPO technique. In situations where there is poor bone quality and fracture comminution, such as distal radius articular fractures in the elderly, current plating techniques often provide suboptimal fixation. The goals of such a device would be: (1) incorporate multiple points of fixation for enhanced stability in osteoporotic bone and comminuted fractures, (2) diminish soft tissue trauma by shortening the length of the plate without compromising construct stability, (3) utilize locking components to enable unicortical fixation, and (4) preserve vascularity of underlying periosteum and bone through application of indirect reduction techniques.

In cooperation with the engineering firm Foster-Miller Inc. of Waltham, Massachusetts, we have investigated the use of a technology that is used currently in the aerospace industry for the fixation of prefabricated composite materials. Foster-Miller developed and patented Z-Fibers® to be used as an alternative to conventional metal/screw fasteners. Z-Fiber® technology increases delamination resistance by greater than five-fold and increases mechanical strength of composite parts by more than 50 to 100 percent (according to classified U.S. Government studies). Current use of this technology includes US Airforce and commercial aircraft, NASA space vehicles, and Formula 1 racecars. Z-Fibers® (so named for their orientation in the 'Z-axis' direction) can be machined using a variety of materials including carbon, stainless steel, and titanium and then arranged in a preset array of pins within a foam core support structure (Figure 1,2).

Figure 1.
Electron micrograph of Z-Fiber® orientation within composite material

Figure 2.
Diagram of Z-Fiber® pin array on laminate surface.

The fiber array can be customized to pin diameter, density and depth of penetration. Pins are inserted into the composite materials using an ultrasonic pressure device, which is also available as a hand-held instrument (Figure 3). Z-Fiber® technology has never before been applied within the healthcare industry for the purpose of orthopedic fracture fixation. The present investigation encompasses not only the design phase of the Z-Fiber® fixation device but also the biomechanical testing of a prototype.

Figure 3.
Hand-held Z-Fiber® ultrasonic driver (20kHz operation).

FINITE ELEMENT ANALYSIS

In order to assess the feasibility of applying Z-Fiber® technology to the field of fracture fixation, a finite element analysis was performed to compare a Z-Fiber® plate construct to a traditional DCP plate in the setting of a long bone fracture with a gap at the fracture interface.

A finite element analysis was performed using the CAEFEM finite element software (Concurrent Analysis Corporation, Thousand Oaks, CA). This software package utilizes three-dimensional elements and linear models. Bone is a non-linear, anisotropic, nonhomogenous material with time-dependent viscoelastic properties.[15] For the purposes of this study we considered bone as a homogeneous linearly elastic material according to established protocols in the literature.[16,17] Two models were generated: (1) The control model consisted of a human femur bone with a fracture gap of 1 mm bridged by a 6-hole stainless steel DCP plate 73 x 10 x 5 mm compared to (2) the same fractured femur bridged by a Z-Fiber® stainless steel pins and plate of similar dimensions. Both models were placed under a four-point bending maximum load of 300 N. Von Mises stress diagram was generated.

The peak load of 300 N with four-point bending yielded equivalent strength when comparing the conventional DCPs and the Z-Fiber® constructs in this fracture model (neither construct failed under this load). However, this analysis demonstrated higher peak stresses at the screw plate interfaces of conventional DCP when compared to our Z-Fiber® construct which distributed stresses more evenly across the plate. Also noted were high stress concentrations just beyond the ends of each plate construct.

Based on this comparison to conventional DCP plating, we believe that the Z-Fiber® plate construct may be a feasible method of fracture fixation. The more even distribution of stress across the plate may be seen as an advantage over traditional plating techniques. We suspect that under cyclical loading conditions, the conventional plate may be prone to failure at the plate screw interface, leading to shearing of the screws or fracture of the plate through the holes. Both fracture constructs demonstrated high Von Mises stress concentrations proximal and distal to the plates which may indicate susceptibility to periprosthetic fracture under these biomechanical conditions. In fact this prediction was verified later during 4-point bend testing using fresh frozen canine radii.

As mentioned previously, the finite element analysis was preformed merely to confirm the feasibility of the Z-Fiber® plate construct in fracture fixation, and more extensive modeling would be of interest in future investigations.

AXIAL PULL-OUT TESTING

In order to assess axial pullout strength of the Z-Fibers®, an array of fibers anchored within a Teflon® PolyTetraFluoroEthylene (PTFE) plate was constructed. The Teflon® PTFE plate was used as a substrate to pull on the array of titanium pins, which had a sum diameter approximately equal to a 3.5mm cortical screw.

Figure 4. Z-Fibers® Titanium pin insertion was performed manually with the handheld ultrasonic device through the Teflon® PTFE plate into the Sawbone® #1522-02 cancellous-like material.

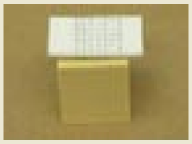

Figure 5. Completed pin/plate test structures had titanium pins holding PTFE plates to Sawbone® blocks.

The Z-Fiber® array consisted of a 7 x 7 arrangement (49 total) of titanium headless pins (.2mm diameter x 10mm length) driven through Teflon® PTFE plates measuring 0.90” x 1.65” x 0.13”. The Z-Fiber® constructs were inserted into synthetic bone blocks simulating the properties of cancellous bone (Sawbones® #1522-02, Sawbones Inc., Vashon WA). The Z-Fiber® constructs were inserted using the hand-held ultrasonic device at operational frequency of 20kHz (Figures 4,5).

Cortical screw control blocks consisted of one 3.5mm conventional self-tapping cortical screw (204.814 Synthes, West Chester, PA) inserted into the same Sawbones® cancellous-like bone block in accordance with American Society for Testing and Matierials (ASTM) Bone Screw Insertion Standards (A3.4.1). A special test fixture was machined to assess pull-out strengths of the Z-Fiber® constructs and cortical screws using an MTS system (Instron 5582). Axial pull-out force was applied in accordance with ASTM Axial Pullout Strength Standards (A3.4.2) (Figure 6). Six titanium Z-fiber® and six cortical screw constructs were tested in axial pullout. Students two-tailed t-test was used to calculate the statistical significance between these samples.

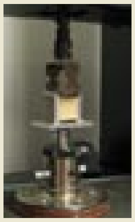

Figure 6. A special test fixture was manufactured to pull out screws and pinned plates from the Sawbone® cancellous-like material in the Instron 5582.

Results from the testing of the Z-fiber® construct showed that the titanium pins were well retained in the Teflon® PTFE plates even though the pins did not have heads holding them in place. During axial pullout testing, we observed noticeable bending at the edges of the plates. This phenomenon may have affected the measured pull-out behavior since it may have introduced non-axial loading.

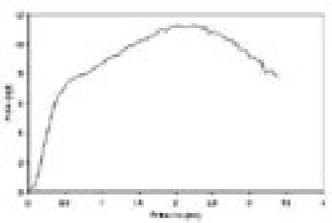

Figure 7. Load vs. extension measured from Z-fiber® sample

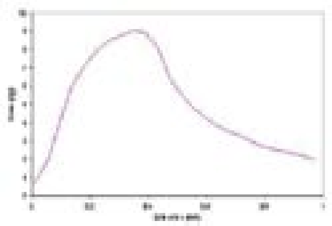

Figure 8. Load vs. extension measured from cortical screw sample

Failure of the Z-fiber® constructs appeared to occur more gradually and the samples continued to carry some load after reaching a peak. In contrast, failure of the samples with screws in them occurred rapidly, usually accompanied by an audible snapping noise. There was a sharp drop-off in load carrying capability after failure. Typical plots showing the load vs. extension measured from the different samples are shown in Figures 7,8.

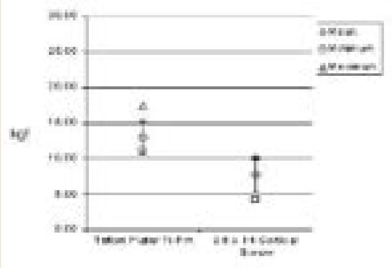

Figure 9. Mean measured maximum forces are plotted for each fixation type along with the measured ranges. Standard deviation is shown using error bars.

Testing results are summarized in Figure 9, plotted as mean values with error bars representing the measured standard deviations. Minimum and maximum values are also plotted for each set of data to illustrate the range and scatter in the data. The 3.5 mm x 14 mm cortical bone screws produced a measured retention force mean of 7.8 kgf with a range from 4.2 kgf to 10.3 kgf. The Z-Fiber® pins produced a mean retention force of 12.9 kgf, with a measured range from 11.1 kgf to 17.3 kgf. The Z-Fiber® pin array had a statistically significant higher pullout strength ($p<0.004$) compared to 3.5mm cortical screws.

Results from initial testing indicate that arrays of titanium Z-Fiber® pins inserted ultrasonically can provide fixation force comparable to 3.5mm cortical screws in cancellous bone-like material. In particular, an array of pins with a holding area equivalent to a 3.5 mm screw provides higher retention force than 3.5 mm cortical screws. Screw failure occurs catastrophically with a limited load carrying capability after failure. In contrast, pin failure occurs less radical with an apparent ability to continue to carry load after the pins have partially been pulled out. However, the observation of the Teflon plate bending as well as angular placement of titanium pins in each sample, may have prevented pure axial pull-out. This may have resulted in an elevated maximum load capacity and increased load carrying after peak loading. Additional testing with rigid metallic plates would likely provide additional control over pin insertion angle and placement. Metal plates should reduce any apparent mechanical moment applied to the pins and keep the pins straight during the insertion process.

DISCUSSION

According to this preliminary biomechanical investigation, Z-fiber® plating may offer a viable method of fracture fixation. Axial pull-out studies demonstrated that the Z-fiber® construct, consisting of titanium pins in Teflon® PTFE plates, had statistically significant higher pullout strength of conventional 3.5mm cortical screws. However, during axial pullout testing, the observed bending at the edges of the PTFE backing may have introduced non-axial loading and affected pull-out behavior. Use of a metal plate to uniformly pull on an array of headed Z-fiber® pins would likely reduce both non-axial insertion of Z-fibers® into bone models and non-axial pull-out loading during future studies.

Canine cadaveric testing of the stainless steel Z-fiber® construct versus conventional dynamic compression plating (DCP) has also been performed and will be published separately. Plates were compared according to ASTM standards in four point bend and compression. Preliminary results indicate that the Z-fibers® perform with similar biomechanical strength in comparison to 50% longer DCPs.

Concern with respect to the host bone response to Z-fiber® insertion *in vivo* will also be addressed in future experiments. These studies will be performed in collaboration with investigators from the University of Iowa, and will compare performance of Z-fiber® plating and conventional DCPs in bilateral canine radii. Histologic sections and radiographic studies will be used to evaluate efficiency of fracture healing and host bone response.

Retrieval techniques of the Z-fiber® constructs are currently under investigation. We suspect that the Z-fiber® pins may produce less damage than screws to host bone, as illustrated by the greater elasticity of the cadaveric Z-fiber® repair constructs tested in compression. Just as the finite element analysis demonstrated enhanced distribution of Von Mises stress in the Z-fiber® constructs, a similar pattern will likely be observed in host bone after hardware removal. We speculate that the stress concentration within host bone after removal of hardware will be greater at bone defects created by conventional screw holes compared to the defects resulting from Z-fiber® insertion. The use of bioabsorbable materials for the Z-fiber® components is also under investigation, thus potentially minimizing the need for retrieval of the hardware from patients.

In summary, the objective of this study is to critically evaluate a novel technology in fracture fixation using well accepted and established methods of biomechanical evaluation. The biomechanical testing in this study conforms to ASTM standards, and the preliminary nature of these results reflects the fact that this technology is still in evolution of design. More investigation is need, but these studies support our hypothesis that Z-fiber® plating may offer a viable method of fracture fixation.

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