A Mechanical Evaluation of the Interfragmentary Compressive Forces of the Arcus Staple System

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Abstract

The objective of this study was to quantify the maintenance of the compressive forces applied by the Arcus® Staple System across a simulated fracture site for static hold and dynamic cyclical bending. The Arcus Staple System was implanted across a simulated fracture site using polyurethane foam with mechanical properties analogous to bone. The staple was installed across a fracture site (Figure 1) with two thin film force sensors placed between the composite fracture model to measure the forces across the fracture site during induced staple compression upon installation and after cycling. Each staple construct was cycled resulting in bending of the staple and the compressive forces recorded pre and post cycling. The Arcus Staple System successfully maintained compressive forces across a simulated fracture site and exceeded the compressive forces of competitive bone staples. Additionally, there was no loss of compressive force measured for the simulated fracture fixation.

Introduction

The use of surgical implants for bone stabilization has given the surgeon a means of internal fixation and immobilization during bone healing. Compression bone staples have been a conventional form of internal fixation and serve as internal splints that are easily installed. Although screw fixation is often the preferred choice for fracture fixation, there are many surgical situations where screw fixation is not feasible due to lack of bone space to allow for multiple implants for added stability, thus providing ideal environments for the use of compression staples. Such staples will compress across a fracture site to provide stabilization and immobilization of fractures, osteotomies, and allow for arthrodesis of small bones, such as in the foot and ankle. However, the extent and holding power of the applied compressive force under repetitive cycling may differ for various fixation systems. Therefore, the objective of this study was to quantify the compressive forces applied by the Arcus Staple System across a simulated fracture site for both quasi-static and dynamic cycling. Additionally, the compressive integrity for the Arcus Staple System was compared to compressive forces measured for competitive staples found in published literature.[1]

Methods

The Arcus Staple System was implanted across a simulated fracture site consisting of two densities of polyurethane foam (Grade 40pcf and Grade 20pcf, Sawbones Pacific Research Laboratories, Vashon Island, WA), which simulated a composite model of cortical bone and cancellous bone

(Figures 1-6). Six composite bone constructs were implanted with the Arcus compressive staple (Size 5) across the simulated fracture site, with each staple installed evenly across the staple bridge in the fracture model. Two Tekscan FlexiForce sensors (Tekscan Inc., South Boston, MA) ranging from 0lbs. to 100lbs. were initially calibrated per the manufacturer's specifications and placed between the composite fracture model into the two halves of foam, with the primary force sensor placed across the Grade 40 pcf halves proximal to the staple bridge. The sensors for each test construct were used to measure the real time compressive forces across the fracture site during staple compression upon installation, at ten and fifteen minutes after installation, and after 600 cycles of dynamic loading.

Each construct was centered between grips that were mounted to an MTS electromechanical materials test machine with a 1kN load cell and dynamically cycled in tension between 0N to 100N for 600 cycles which induced a bending of the staple (Figures 3 and 4). The compressive forces were recorded proximally during cycling (closest to bridge). The loading algorithm for the instrumented construct prior to cycling followed the methods of Shibuya et al.[1] for direct comparisons of compressive loads measured for competitive product after staple installation. Figures 1 through 5 show the construct, test, and sensor setup. Descriptive statistics and a one-way repeated measure Analysis of Variance at an alpha of 0.5 with a Neuman-Keuls comparison was conducted on the sample test results using GraphPad Prism 5, Version 5.03.

FIGURE 1: THE ARCUS COMPRESSION STAPLE (SIDE VIEW)

FIGURE 2: THE STAPLE IMPLANTED ACROSS THE FRACTURE SITE

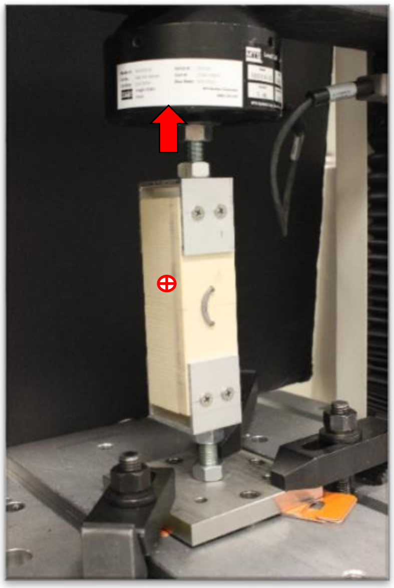

FIGURE 3: IMPLANTED CONSTRUCT MOUNTED IN MTS TEST MACHINE. CENTER OF GRIP ALIGNED WITH LOAD CELL (⊕) STAPLE IS ANTERIOR TO CENTERLINE.

FIGURE 4: FRONT VIEW OF CONSTRUCT WITH FLEXIFORCE SENSORS IN THE FRACTURE SITE AND MOUNTED ON MTS TEST MACHINE

FIGURE 5: CLOSER VIEW OF THE TWO FLEXIFORCE SENSORS (1-PROXIMAL, 2-DISTAL) WITHIN THE CONSTRUCT

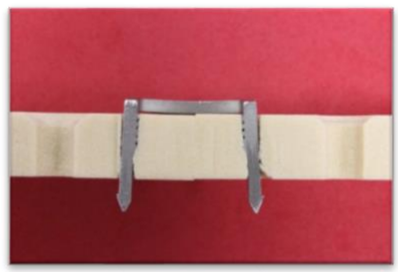

FIGURE 6: COMPRESSION STAPLE LONGITUDINAL SECTION SHOWING TINE AND FOAM APPOSITION AT THE DISTAL END OF TINE COMPRESSION

Results

The mean compressive forces measured during the series of testing is shown in Figure 7. There was no statistically significant loss in applied compressive force from the initial force measured at installation and the forces measured after ten minutes after installation and prior to cycling, which was measured at least fifteen minutes after installation. Additionally, there was no statistically significant loss in compressive force across the fracture site after six hundred dynamic cycles of staple bending, with no statistically signficant loss in compression force when the construct was removed from the test machine and in a relaxed state (Figure 8).

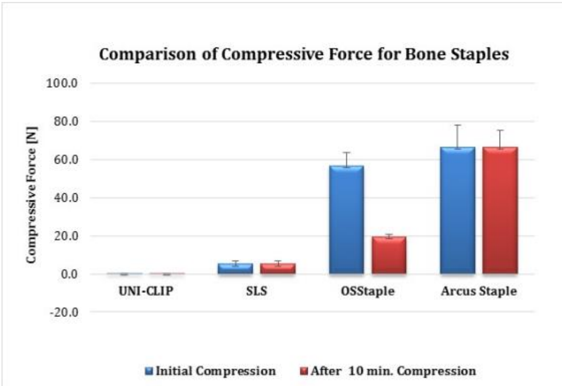

FIGURE 7: COMPARISON OF THE COMPRESSIVE FORCES FOR THE ARCUS COMPRESSION STAPLE BEFORE AND AFTER TEN MINUTES OF STATIC HOLD TO THREE STAPLE FIXATION SYSTEMS (SHIBUYA ET AL.)

NOTE: The compressive forces for the competitive staples shown in the graph above were extracted from the work of Shibuya et al.[1] The Nextremity Solutions Arcus Staple was tested in the same fashion following the methods published by Shibuya et al. and does not represent direct side by side testing to competitive product.

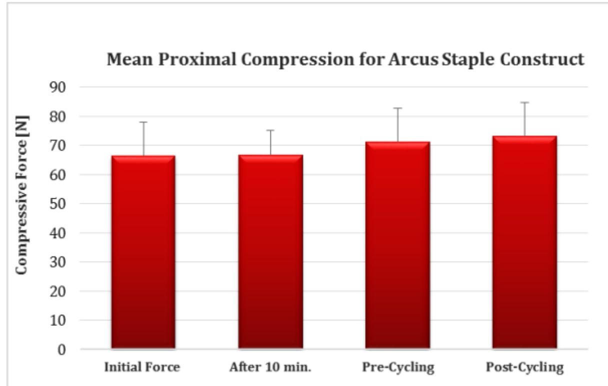

FIGURE 8: MEAN COMPRESSIVE FORCES FOR THE ARCUS STAPLE DURING THE LOADING SERIES

Discussion

The Arcus Staple System successfully maintained compressive forces across the simulated fracture site after ten and fifteen minutes of relaxation and after cyclic bending of the staple. The Arcus Staple System (Nextremity Solutions, Inc.) exceeded reported[1] compressive forces of competitive bone staples* Uni-Clip (Integra LifeSciences), mechanically altered shape; SLS (Smith & Nephew), traditional staple; OSStaple (BioMedical Enterprises), nitinol alloy; and demonstrated its compressive integrity across the fracture site with no statistically significant loss of compressive force during repeated staple bending under supraphysiological loading. (Figure 8)

References:

1. "A Compression Force Comparison Study Among Three Staple Fixation Systems", Shibuya et al., *J. Foot and Ankle Surgery*, Vol. 46, No. 1, 2007.

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**Bench testing is not necessarily indicative of clinical performance.*