J Shoulder Elbow Surg (2016) 25, 949–953

ELSEVIER

JOURNAL OF SHOULDER AND ELBOW SURGERY

www.elsevier.com/locate/ymse

BASIC SCIENCE

Biomechanical analysis of intramedullary vs. superior plate fixation of transverse midshaft clavicle fractures

David J. Wilson, MD[a,*], William F. Scully, MD[b], Kyong S. Min, MD[c], Tess A. Harmon, BA[d], Josef K. Eichinger, MD[a], Edward D. Arrington, MD[a]

[a]*Madigan Army Medical Center, Joint Base Lewis McChord, WA, USA*
[b]*Martin Army Community Hospital, Ft. Benning, GA, USA*
[c]*Brian Allgood Army Community Hospital, Yongsan, South Korea*
[d]*Loma Linda University School of Medicine, Loma Linda, CA, USA*

Background: Middle-third clavicle fractures represent 2% to 4% of all skeletal trauma in the United States. Treatment options include intramedullary (IM) as well as plate and screw (PS) constructs. The purpose of this study was to analyze the biomechanical stability of a specific IM system compared with nonlocking PS fixation under low-threshold physiologic load.
Methods: Twenty fourth-generation Sawbones (Pacific Research Laboratories, Vashon, WA, USA) with a simulated middle-third fracture pattern were repaired with either an IM device (n = 10) or superiorly positioned nonlocking PS construct (n = 10). Loads were modeled to simulate physiologic load. Combined axial compression and torsion forces were sequentially increased until failure. Data were analyzed on the basis of loss of rotational stability using 3 criteria: early (10°), clinical (30°), and terminal (120°).
Results: No significant difference was noted between constructs in early loss of rotational stability ($P > .05$). The PS group was significantly more rotationally stable than the IM group on the basis of clinical and terminal criteria ($P < .05$ for both). All test constructs failed in rotational stability.
Conclusions: When tested under physiologic load, fixation failure occurred from loss of rotational stability. No statistical difference was seen between groups under early physiologic loads. However, during load to failure, the PS group was statistically more rotationally stable than the IM group. Given the clavicle's function as a bony strut for the upper extremity and the biomechanical results demonstrated, rotational stability should be carefully considered during surgical planning and postoperative advancement of activity in patients undergoing operative fixation of middle-third clavicle fractures.

The views expressed are those of the authors and do not reflect the official policy of the Department of the Army, the Department of Defense, or the U.S. Government.
This study was funded through an institutional grant from the Madigan Army Medical Center (MAMC), Department of Clinical Investigation (DCI). All tested implants were purchased using these funds through the MAMC DCI. This research was made possible through material and facility support from the Andersen Simulation Center at MAMC.
This study was approved by the Institutional Review Board of Madigan Army Medical Center, Department of Clinical Investigation (reference No. 211087).
*Reprint requests: David J. Wilson, MD, Orthopaedic Surgery, Bassett Army Community Hospital, 1060 Gaffney Road #7400, Fort Wainwright, AK 99703-7400, USA.
E-mail address: david.j.wilson268.mil@mail.mil; dav.j.wilson@gmail.com (D.J. Wilson).

1058-2746/$ - see front matter Published by Elsevier Inc. on behalf of Journal of Shoulder and Elbow Surgery Board of Trustees.
http://dx.doi.org/10.1016/j.jse.2015.10.006

Level of evidence: Basic Science Study; Biomechanics

Keywords: Clavicle fractures; intramedullary fixation; biomechanical testing; shoulder; middle-third clavicle fractures; intramedullary implant stability

Clavicle fractures account for 2% to 4% of all adult fractures.[8] Of these, approximately 80% occur within the middle third of the clavicle.[7,17] Recent studies indicate that operative repair of selected clavicle fractures may improve rate of healing and prevent problems associated with malunions.[2,9,11,17,21]

When surgical treatment is indicated for a displaced midshaft clavicle fracture, a variety of implants may be selected, including plate-screw (PS) constructs and intramedullary (IM) devices. Clavicle plates can be further categorized by both the plate's location-matching contour (superior, anterior-superior, anterior, and anterior-inferior) and the presence of locking or nonlocking screw options. Examples of the IM devices available for treatment of middle-third clavicle fractures include the 4.5-mm Herbert screw (Zimmer, Warsaw, IN, USA), the Rockwood (DePuy, Warsaw, IN, USA) or Hagie pin (2.5-, 3.0-, 3.8-, and 4.5-mm options; Smith & Nephew, Memphis, TN, USA), a 6.5-mm partially threaded cancellous screw, and the Sonoma CRx device (Sonoma Orthopedic Products Inc, Santa Rosa, CA, USA).[1,12,16,22,23]

Given the unique flat S shape of the clavicle, the complex deforming forces about the middle third of the bone, and its near-subcutaneous position, these various implant types have differing pros and cons. For example, superiorly positioned plates have been shown to be biomechanically superior to anterior and anterior-inferior plates, whereas the latter options offer safer drilling trajectories, affording the opportunity to place longer screws. Alternatively, IM implants are less prominent than plates and can be placed through smaller incisions with less soft tissue disruption.

The Sonoma CRx nail is a relatively new implant that strives through unique design and features to maintain the advantages of IM clavicle fixation while improving the torsional resistance at the fracture site. The Wavibody design of the nail allows flexibility during implantation for ease of entry into the sinusoidal bone. On appropriate positioning, the nail can then be "actuated," causing the implant to be become rigid once it is contoured to the clavicle. The actuating mechanism also triggers talons or grippers on the medial end of the implant to expand outward 8 mm to gain endosteal purchase. The lateral end of the implant is secured with a 2.7-mm cortical screw. This process not only confers rotational stability on either side of the fracture but also generates compression at the fracture by the manner in which the grippers engage the surrounding bone.

Previous studies have evaluated the biomechanical differences between these various fixation options. Most studies have used 3- and 4-point bending models to stress the hardware constructs, simulating a repeated injury mechanism.

Recently, 4 cases of early hardware failure were reported involving IM fixation using the Sonoma CRx device, raising concerns about the stability of this construct under low-demand conditions, as is generally experienced during early rehabilitation.[13,23]

Several authors have described this low-threshold physiologic stress and quantified it for the middle third of the clavicle. Taylor et al sought to qualify the normal physiologic forces across the midshaft of the clavicle during movements of the upper extremity required to feed oneself.[19] The process of bringing the hand to the mouth was tested with a digitally simulated highly comminuted midshaft clavicle fracture (at a peak of 50° of internal rotation of the humerus, 15° of glenohumeral abduction, and 45° of forward flexion) using a computational model. The resulting computer analysis found that this complex movement produced axial compression and a rotational bending moment at the fracture site, resulting in downward and posterior displacement of the lateral fragment. Iannolo et al further quantified the magnitude of forces across the middle of the intact clavicle during shoulder motion using both computational and cadaveric biomechanical modeling.[5] Their study found that during shoulder abduction, there was significantly more axial compression and torsion than with internal and external rotation of the humerus, producing pressures that reached, on average, a peak of 34 N of compression and 0.398 N·m of torque about the middle third of the clavicle.[5]

The objective of this study is to evaluate the ability of the Sonoma CRx nail to resist combined axial compression *and* torsion in a simulated midshaft clavicle fracture in comparison to a PS construct.

Methods

The fourth-generation Sawbones (Pacific Research Laboratories, Vashon, WA, USA) model of the human clavicle was used for this biomechanical evaluation. This current model closely matches the modulus of elasticity and, as a result, the torsional and compressive stiffness of living human cortical and cancellous bone and has previously been successfully used to evaluate component stability of middle-third clavicle fracture models.[14,15] A simulated interdigitating, transverse, middle-third fracture pattern was created in each of the 20 Sawbones models used. Equal groups of 10 clavicles were then fixated with either the Sonoma CRx IM device or a superiorly positioned nonlocking PS construct (3.5-mm reconstruction plate; DePuy Synthes, West Chester, PA, USA).

All samples were then mounted in plaster of Paris and tested using a dynamic servohydraulic loading device (8521