Quantifying Simulated Syndesmotic Malreduction Forgiveness Using a Multi-Stage Stabilization System

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INTRODUCTION: Malreduction following a syndesmotic injury can be detrimental to the long-term health of the ankle joint. Prior studies have shown the potential of a rigid fixation, such as a transsyndesmotic screw, to produce tibiofibular malreduction. Flexible implants, although capable of allowing forgiveness in these situations, does not produce sufficient stability for every syndesmosis injury pattern. The objective of this study was to assess the potential for syndesmotic malreduction forgiveness of the R3ACT™ Stabilization System (Paragon 28), a rigid screw-type fixation that transitions to a semi-constrained device state similar to a suture-type fixation upon weightbearing. We hypothesized that the released configuration of the device would allow for significant recovery of a syndesmotic malreduction.

METHODS: Weightbearing Computed Tomography (WBCT) scans were obtained for each of 22 below-knee matched specimens (44 limbs) in a radiolucent frame with an applied static axial load of 350N under three conditions: (C) native control, (M) rigid device malreduction, and (R) released device timepoints. A lateral approach was used to destabilize the joint in four controlled malreduction conditions: 5mm anterior displacement (n=10), 5mm posterior displacement (n=11), 5° internal rotation (n=10), and 140N overcompression (n=9). Fixation was performed with a single implant 20mm proximal to the ankle joint. The device was manually released using manufacturer guidelines to allow for semi-constrained motion of the syndesmosis, reproducing the release that would occur when a patient starts weightbearing. Anatomic axes of the tibia and fibula were extracted from WBCT scans using Bonelogic™ Software (Disior). Custom MATLAB code was used to calculate tibiofibular joint pose using extracted anatomic bony axes with an established orthogonal joint coordinate system representation [1]. All produced information was normalized to the control states and compared across specimens and malreduction strategies. A Student's paired t-test was used to assess statistical differences between rigid device malreduction (M) and released device (R) timepoints.

RESULTS: Anterior (+) and posterior (-) malreduction specimens demonstrated +2.5±1.4mm and -5.0±2.2mm of average malreduction at the rigid malreduced timepoint (M). The released device condition (R) resulted in average recovery of -1.8±1.4mm (72%) and +1.7±1.1mm (33%) toward the control position of the joint, respectively. Rotational malreduction specimens demonstrated 2.4±2.1° of average absolute rotational malreduction at the rigid timepoint (M), with 2.0±3.4° (81%) of recovery at the released device timepoint (R). Overcompression (+) specimens demonstrated average medial translation of 0.9mm at the rigid timepoint (M), and the released device condition (R) had 0.74±0.78mm (82%) of joint pose recovery. Statistically significant malreduction recovery was found for anterior (p=0.0034), posterior (p=0.0006), and over compression (p=0.0224) malreduction strategies, with a notable correlation for internal malreduction (p=0.07) (Table 1).

DISCUSSION: This study considered four different types of syndesmotic malreduction, with applied malreduction targets larger than those expected clinically [2], to assess the ability of the R3ACT screw to accommodate a broad range and direction of malreduction. The injured and malreduced models were capable of producing the desired malposition as planned, providing an objective comparative status. As hypothesized, the implant was able to provide malreduction recovery in the different scenarios after the semi-constrained device state was activated. The produced data could support the use of this system to mitigate potential surgical tibiofibular malreduction when load is applied to the joint.

SIGNIFICANCE/CLINICAL RELEVANCE: Correctly reducing the ankle syndesmosis in a surgical environment is challenging and has been demonstrated to result in possible variable amounts of malreduction [2] which can have a detrimental effect on joint mechanics and recovery. This paper has sought to quantify malreduction forgiveness using a commercially available multi-stage syndesmotic repair system. It is our hope the results of this study can stimulate additional scrutiny of syndesmotic repair strategies to better understand surgical treatment and post-operative care.

REFERENCES: [1] Grood and Suntay. *J Biomech Eng*. 105(2): 136-144. 1983. [2] Boszczyk et al. *Foot and Ankle International*. 39(3): 369-375. 2017.

ACKNOWLEDGEMENTS: Funding for this research was provided by Paragon 28.

			(C)ontrol		(M)alreduced		(R)eleased		M-R
	dof	n	μ	σ	μ	σ	μ	σ	p-value
Anterior (mm)	A(+)P	10	0	0	2.50	1.37	0.71	1.04	0.0034
Posterior (mm)	A(+)P	11	0	0	-5.04	2.23	-3.35	1.52	0.0006
Internal (deg)	IE	10	0	0	2.44	2.09	0.46	2.70	0.0707
Over-compression (mm)	ML(+)	9	0	0	-0.89	1.10	-0.16	0.49	0.0224

Table 1: Mean and standard deviation of the Control, Malreduced, and Released joint pose information. Anterior, posterior, and internal malreduction results are described along the respective degree of freedom, overcompression is described along the medial-lateral degree of freedom.
Figure 1 (middle): R3ACT Stabilization System graphic demonstrating semi-constrained device state.
Figure 2 (right): Bony geometries of the tibia, fibula, and talus for malreduced (M-grey) and released (R-purple) WBCT timepoints aligned to tibia for the anterior (right) and internal (middle) malreduction study arms.