R3ACT™
STABILIZATION SYSTEM

PERFORMANCE ANALYSIS OF DYNAMIC SYNDESMOSIS REPAIR STRATEGIES IN CYCLIC LOADING

Paragon 28® Research & Development

Exclusively foot & ankle
Paragon 28®

Introduction

Acute ankle sprains account for 628,026 emergency department visits in the United States each year (data reported 2002–2006)[1]. 40% of patients report ankle instability 6 months after injury likely caused by an increase in length or rupture of the syndesmotic ligaments[2]. Injury to the ankle syndesmosis can lead to changes in joint kinematics[3], increases in cartilage contact pressures[4], and delay in return to activity. Several strategies exist which seek to restore the support provided by the syndesmotic ligaments after trauma.

Paragon28® has developed a two-phase soft tissue fixation system called the R3ACT Dynamic Syndesmosis Screw. The device allows for a period of initial rigid fixation for soft tissue healing at the joint and is then released through weight-bearing to engage a suture-bumper construct nested inside the screw. The suture-button construct provides stabilization of the joint and allows for a dynamic support mechanism. Several competitive suture-based syndesmotic repair strategies exist which also seek to support the syndesmotic joint while allowing for natural motion between the tibia and fibula to occur.

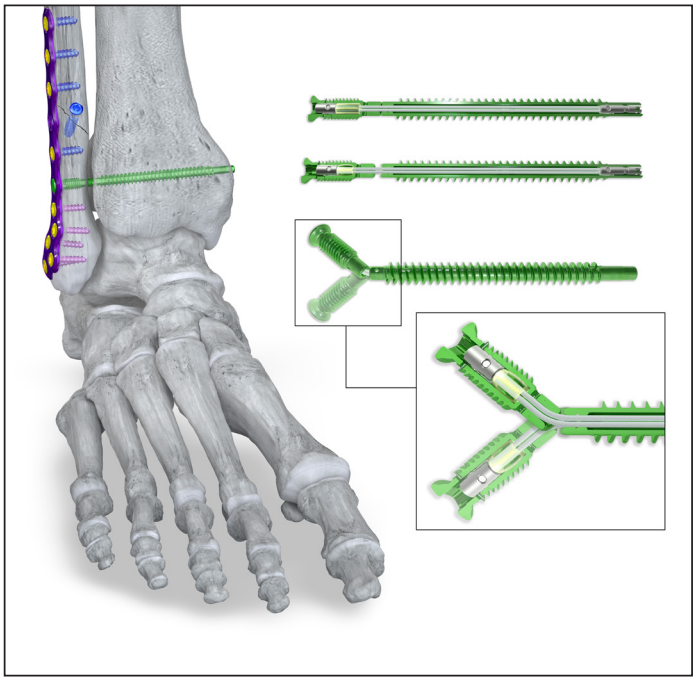

Figure 1 Paragon28's R3ACT Dynamic Syndesmosis Screw

Native motion of the tibiotalar joint has been reported to range between 0mm and 3.08mm in vivo when applying 7.5Nm external rotation moment[5]. Mean tibiotalar displacements have been reported ranging from 0mm to 3.3mm during dynamic activity (i.e. box jump)[6]. These reports indicate a functional range of 0–3.5mm of displacement at the joint for native function. Therefore, a dynamic stabilization system which can maintain support through this kinematic range is paramount to the success of the system. The goal of this study was to test the R3ACT Dynamic Syndesmosis Screw against two competitive solutions in cyclic loading and unloading to assess changes in functional response of the device throughout the lifecycle.

Methods

Three syndesmotic repair strategies were tested in cyclic loading for 300,000 cycles:

- R3ACT Dynamic Syndesmosis Screw
- Knotless Suture Button Device (C1)
- Knotless Suture Fixation Device (C2)

The devices were each placed in a testing fixture attached to a cyclic loading test frame. All devices were implanted via their respective surgical techniques. The test frame applied loading between 22N and 166N for 300,000 cycles. These loading conditions were derived from data reported by Markolf et al. of resultant forces acting on the distal tibia in a cadaveric model[7]. Relative displacements of each device were measured during the test to quantify change in length of the construct throughout the loading regime at a single load.

Results

Displacement results were recorded at five distinct points in the loading cycle (N=1, 300, 1k, 3k, and 300k) where the applied force was the cyclic mean force (F=92 N, range 90–94 N). The recorded displacements were placed into three bins: 0–3.5mm (purple), 3.5–5.0mm (gray), and values greater than 5mm (red). Binned results for each construct can be found in Table 1.

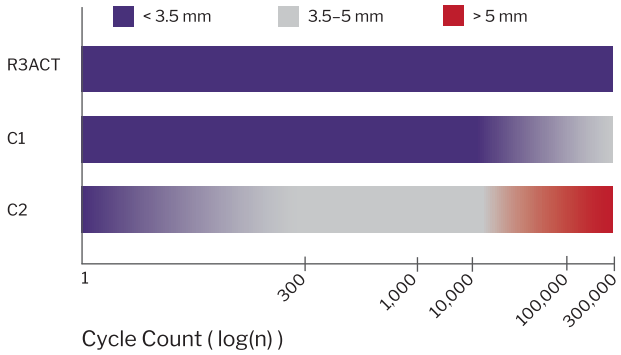

Figure 2 Displacement of devices at half load during cyclic testing (range: 90–93N). Color corresponds to device displacement: 0–3.5mm (purple), 3.5–5.0mm (gray), 5.0mm+ (red).

Discussion

The R3ACT Dynamic Syndesmosis screw provided consistent support throughout the entire 300k cyclic loading procedure. Suture construct C1 provided initial stabilization in the healthy functional range but then settled in a larger displacement range of 3.5–5.0mm. Suture construct C2 lengthened significantly throughout the testing procedure, lengthening more than 300% of its originally installed construct length.

Providing consistent support within the functional range of the syndesmotic joint is paramount to the success of a dynamic syndesmotic repair. Paragon 28's R3ACT Dynamic Syndesmosis screw provided the necessary support required by the joint to maintain healthy motion.

References

1. Waterman, B. R., Owens, B. D., Davey, S., Zacchilli, M. A. & Belmont, P. J. The epidemiology of ankle sprains in the United States. J. Bone Jt. Surg. — Ser. A 92, 2279–2284 (2010).
2. Hermans, J. J., Beumer, A., De Jong, T. A. W. & Kleinrensink, G. J. Anatomy of the distal tibiofibular syndesmosis in adults: A pictorial essay with a multimodality approach. J. Anat. 217, 633–645 (2010).
3. Hagemeijer, N. C. et al. Range of Normal and Abnormal Syndesmotic Measurements Using Weightbearing CT. Foot Ankle Int. 40, 1430–1437 (2019).
4. Hunt, K. J., Goeb, Y., Behn, A. W., Criswell, B. & Chou, L. Ankle Joint Contact Loads and Displacement with Progressive Syndesmotic Injury. Foot Ankle Int. 36, 1095–1103 (2015).
5. Beumer, A. et al. Kinematics of the distal tibiofibular syndesmosis: Radiostereometry in 11 normal ankles. Acta Orthop. Scand. 74, 337–343 (2003).
6. Hogg-Cornejo, V. et al. Normal Kinematics of the Syndesmosis and Ankle Mortise During Dynamic Movements. Foot Ankle Orthop. 5, 247301142093300 (2020).
7. Markolf, K. L., Jackson, S. & McAllister, D. R. Force and displacement measurements of the distal fibula during simulated ankle loading tests for high ankle sprains. Foot Ankle Int. 33, 779–786 (2012).

R3ACT™

STABILIZATION SYSTEM

P80-WP-0002 Rev A

Paragon 28, Inc.
14445 Grasslands Dr.
Englewood, CO 80112 USA
(855) 786-2828

Exclusively foot & ankle

Paragon 28®

www.Paragon28.com