R3LEASE™ Stabilization System Post-Op Protocol

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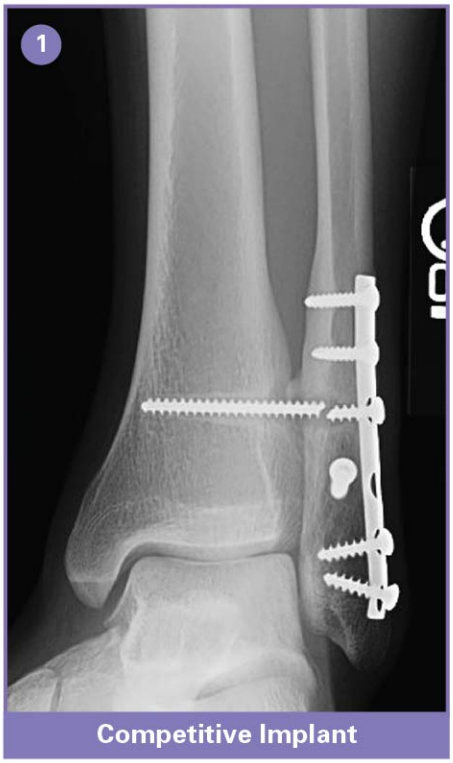
Paragon 28® Gorilla® R3LEASE™ Stabilization System

PRODUCT RATIONALE:

The Paragon 28® Gorilla® R3LEASE™ Stabilization System was designed to offer surgeons an improved design over traditional screws when used for syndesmotic fixation. After syndesmotic healing and with the resumption of postoperative weightbearing, it is common for traditional syndesmotic screws to loosen or break. While typically of little clinical consequence, the location of screw breakage can be unpredictable with some breakage causing osteolysis from adjacent bony erosion leading to pain and difficult removal.[1] (Figure 1) Furthermore, well-fixed screws have been demonstrated to lead to worse outcomes due to limiting normal physiologic motion.[2] Although several studies have demonstrated no clinical benefit to syndesmotic screw removal postoperatively, it remains common practice to remove them mainly due to patient and/or surgeon concerns of screw breakage. While usually a relatively benign procedure, secondary screw removal has been associated with an overall 22.4% complication rate as well as additional time and cost burden to the patient and health-care system in general.[3]



Competitive Implant

Figure 1:
38 year old male with broken syndesmotic screw causing painful fibular erosion.

For suture-button devices, the main purported advantage is allowing for stabilization of the syndesmosis during healing yet allowing for physiologic motion thereafter without the need for a secondary removal surgery. While demonstrated to have clinical effectiveness, suture-button devices may be suboptimal for certain injuries and the significant additional implant cost may make its use prohibitive to many surgeons.[4] Furthermore, recent studies have demonstrated that the use of screws is more cost-effective as compared to suture-button devices only when a secondary removal procedure for the screw is not required.[5,6]

The Paragon 28® R3LEASE™ Stabilization System was designed to offer surgeons an effective alternative to traditional syndesmotic screws and suture buttons. While offering the rigidity of a traditional metal screw, if breakage occurs, the design allows for screw breakage cleanly in the syndesmotic clear space. Furthermore, breakage allows for the restoration of motion. If removal is desired either before or after screw breakage, specific design features of the R3LEASE™ Stabilization System and its instrumentation allow for facilitated removal either through a lateral or medial approach.

TECHNOLOGY OVERVIEW:

The R3LEASE™ Stabilization Systems was designed so that if screw fracture occurs, the screw breaks cleanly and in the syndesmotic clear space. To properly target the clear space, two notch lengths (14 mm and 17 mm) were developed. The Breakaway Screw is available from 40 mm – 45 mm in 5 mm increments and 48 mm – 64 mm in 2 mm increments. Two mm increments from 48 - 64 mm allows the surgeon to target the medial cortex of the tibia for quadricortical fixation, if desired. Static bending strength and stiffness of the Gorilla® R3LEASE™ Stabilization exceeded that of a comparable 3.5 mm solid screw as well as a 4.0 mm cannulated screw made of the same material.*

CLINICAL CONSIDERATIONS AND POSTOPERATIVE PROTOCOLS:

The need for syndesmotic fixation is based on standard indications as related to injury pattern, clinical findings and radiographic parameters demonstrating syndesmotic diastasis and/or malalignment of the ankle mortise.

In general, my patients requiring syndesmotic fixation (whether associated with a concomitant ankle fracture or in isolation) follow the postoperative protocol as described below:

- **Day of surgery:** After surgery, patients are placed in a well-padded short leg plaster AO splint in neutral position and made non-weightbearing. This dressing is maintained until their first postoperative visit.
- **POD 7:** Clinical examination performed. The splint is removed and surgical wounds examined. Patients are placed back into a short leg plaster AO splint in neutral position with continued non-weightbearing status.
- **POD 14:** Repeat clinical and radiographic examination is performed. The splint is removed and if amenable, sutures are removed. Patients are placed in a removable fracture boot and allowed to touch-down weight bear if they are able to effectively modulate/protect their weightbearing status. Formal physical therapy is initiated and both passive & active range of motion exercises started immediately.
- **6 weeks after surgery:** Repeat clinical and radiographic examination performed. If doing well, patients are allowed to advance to 50% partial weightbearing in their fracture boot per their tolerance. Range of motion exercises are continued and strengthening exercises are initiated.
- **10 weeks after surgery:** Repeat clinical and radiographic examination performed. If doing well, patients are allowed to advance to full weightbearing in their fracture boot and wean out of the boot into a regular comfortable shoe in 2 weeks time. Range of motion and strengthening exercises are continued and light, non-impact cardiovascular exercises are emphasized.
- **4-6 months after surgery:** Repeat clinical and radiographic examination performed. If doing well, patients are allowed to advance to full physical activity without restrictions.

There exist many patient and injury-based factors that may effect this postoperative protocol. For example, patients with medical comorbidities (ie. diabetes, peripheral vascular disease, rheumatoid arthritis, tobacco use, etc.) which may affect soft-tissue and osseous healing may have physical therapy and/or advancement in weightbearing delayed. Patients who undergo concomitant fixation of a large posterior malleolus fracture, who require supplemental deltoid ligament repair and/or syndesmotic augmentation may similarly have an altered postoperative course. Patients with subtle syndesmotic injury may be progressed faster than those with significant disruption of the syndesmosis. As with any injury, the postoperative protocol should be tailored to the patient's specific needs.

DISCLOSURES:

John Y. Kwon, MD is the Chief of Foot & Ankle Surgery at Beth Israel Deaconess Medical Center, Boston, MA and Assistant Professor at Harvard Medical School. He is a paid consultant and receives royalties from Paragon 28®.

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