CASE SERIES

Bimalleolar Ankle Fracture Open Reduction Internal Fixation Using a Novel Syndesmotic Screw

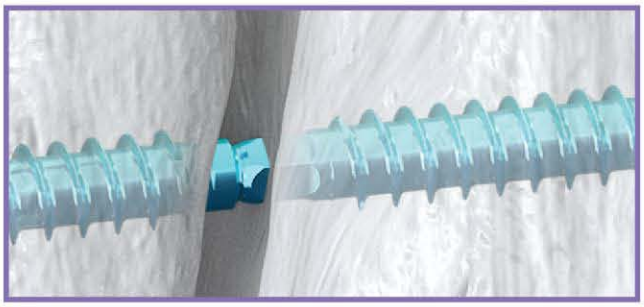
Surgeon Author: John Y. Kwon, MD
Assistant Professor, Department of Orthopedic Surgery, Harvard Medical School
Chief, Foot & Ankle Service, Beth Israel Deaconess Medical Center,
Boston, Massachusetts, USA

FEATURED PRODUCTS: Paragon 28® Gorilla® Ankle Fracture Plating System, Paragon 28® R3LEASE™ Stabilization System

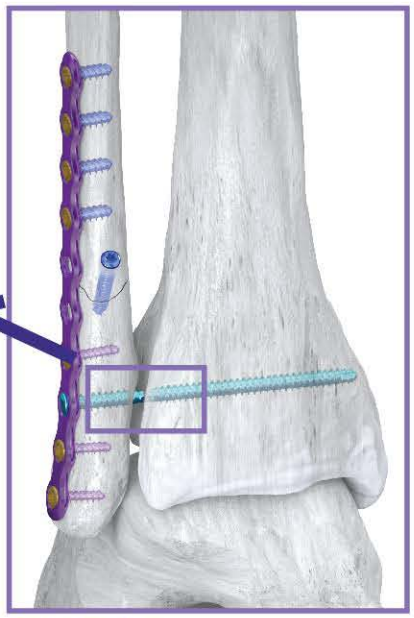
Introduction

The Paragon 28® R3LEASE™ Stabilization System was developed to offer surgeons an improved design over traditional screws used for syndesmotic fixation. After syndesmotic healing, it is common for traditional syndesmotic screws to loosen or break with resumption of post-operative weightbearing. 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] Furthermore, intact well-fixed screws have been demonstrated to lead to worse outcomes due to limiting normal physiologic motion.[2] Syndesmotic screw removal remains common practice, however, due to patient and surgeon preference, the fear of screw breakage, or limitations in range of motion causing future problems. While usually a relative 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 healthcare system in general.[3]

The Paragon 28® R3LEASE™ Screw was designed to offer surgeons an effective alternative to traditional syndesmotic screws and suture buttons. While offering the rigidity of a traditional metal screw, should breakage occur, 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.



Break Point of R3LEASE™ Screw



R3LEASE™ Screw

CASE 1:

Presentation

The patient is a healthy 43 year old female who sustained a twisting injury on ice. She was evaluated at our institution where she was found to have a closed bimalleolar ankle fracture with concerns of syndesmotic disruption. On examination, she had swelling around the ankle but her skin was intact. She was tender over the malleoli. Her compartments were soft. Light touch sensation was intact in all dermatomes and was otherwise well perfused.

Figure 1: Radiographs demonstrating bimalleolar ankle fracture: (**A**) anteroposterior and (**B**) lateral.

Radiograph Examination

Three views of the ankle were obtained at the time of injury. A bimalleolar ankle fracture with a subluxed mortise was visualized demonstrating a supination adduction fracture pattern as described by Lauge-Hansen. There was noted to be a vertically aligned medial malleolus fracture with significant comminution at the fracture site and a relatively low transverse fracture of the distal fibula (Figure 1).

Initial Management and Decision Making

Treatment options were discussed with the patient and surgical fixation was planned given the fracture displacement, instability and malalignment of the mortise.

Surgical Technique

The patient was placed in the supine position with a small bump underneath the ipsilateral hip. A non-sterile tourniquet was used on the thigh. The patient was prepped and draped in normal sterile fashion. First, we turned our attention to the lateral malleolus. A 6 cm incision was made over the distal fibula. Deeper dissection was performed using Stevens scissors. Care was taken to avoid any cutaneous nerves which were carefully retracted out of the way. The fracture was noted to be a relatively short oblique fracture at the level of the syndesmosis. The fracture site was identified and cleaned of any hematoma using irrigation and curettes. A bovie was used to remove soft-tissues and periosteum around the fracture site. The fracture was anatomically reduced using a pointed reduction clamp. A Paragon 28 intra-fragmentary 3.5 mm Mini-Monster® Solid Screw was placed in standard, lag fashion. A Paragon 28 Gorilla Anatomic Fibular Locking Plate was pre-trialed and held with olive wires and checked under fluoroscopy. Once appropriate position was verified, the plate was affixed with multiple 3.5 mm locking screws distally as well as a single 3.5 mm non-locking screw proximally. Next, a curvilinear incision was made over the medial malleolus. Deeper dissection was performed using Stevens scissors to avoid the saphenous neurovascular bundle. The fracture site was gently cleaned as described above. The fracture was anatomically reduced and assessed under intraoperative fluoroscopy. Once anatomic reduction was achieved, the Paragon 28 Medial Malleolus Plate was pre-trialed and held with olive wires. Once plate position was adequate, the plate was affixed with multiple 4.2 mm non-locking screws proximally and 3.5 mm locking screws distally.

Next, given the suspected syndesmotic injury, a radiographic Cotton test was performed. With the foot positioned in a perfect mortise position, a pointed reduction clamp was placed around the distal fibula and lateral-posterior distraction was applied. There was noted to be changes in tibia-fibula overlap, tibia-fibula clear space and medial clear space under fluoroscopy, consistent with a syndesmotic injury. Therefore, with the mortise anatomically reduced by inverting the foot, a 2.8 mm drill bit was used to drill from the fibula into the tibia slightly dropping the hand from the axial alignment. Fibular width was measured and overall screw length was measured. Next, a 50 mm length x 14 mm breakpoint 4.0 mm R3LEASE Screw was inserted in standard fashion completing the syndesmotic stabilization. Repeat intraoperative stress testing under fluoroscopy was performed demonstrating enhanced stability. All wounds were thoroughly irrigated out and closed in standard fashion.

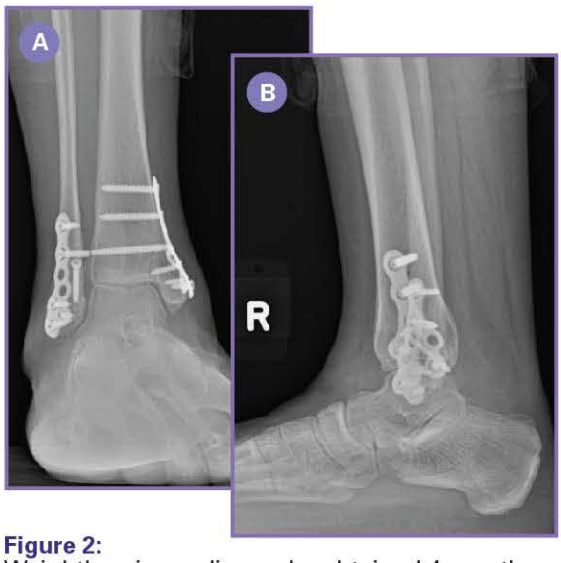


Figure 2:
Weightbearing radiographs obtained 4 months post-operative demonstrating healed ankle fracture with R3LEASE Screw broken at the appropriate break point: (**A**) anteroposterior and (**B**) lateral.

Post-Operative Protocol

The patient was placed in a well-padded splint at the time of surgery and was made non-weightbearing. She returned 2 weeks after surgery, at which time her sutures were removed. She was then placed in a removable fracture boot and physical therapy was initiated. The patient remained non-weightbearing.

The patient was then evaluated 4 weeks later at the 6-week time point. Repeat radiographs demonstrated excellent osseous alignment and no failure of internal fixation. The patient continued physical therapy with range of motion and strengthening exercises initiated. She was advanced to partial weight bearing with assistive devices. The patient was re-evaluated 4 weeks later at the 10-week time point postoperatively. Clinically and radiographically the patient was doing well and was allowed to fully bear weight as tolerated in her boot. She was told to wean out of her boot two weeks thereafter. The patient was evaluated at 4 months post-operative and was fully weightbearing in a regular shoe with no pain and excellent range of motion. X-rays revealed a fractured R3LEASE Screw at the break point (Figure 2).

The patient presented at her one year follow-up visit, had no pain, supple range of motion and was doing well.

CASE 2:

Presentation

The patient is a healthy 24 year old male who sustained a dirt bike accident resulting in a twisting injury to his left ankle. He was found to have a closed bimalleolar ankle fracture and was indicated for surgical fixation (Figure 3). Surgical treatment was performed as described above using a Paragon 28 Gorilla 8 Hole Straight Fibula Plate with a R3LEASE Screw for the syndesmotic repair, and two headless 4.0 mm Mini-Monster Screws for the medial malleolar fracture. At 4 months post-operative, the patient was weightbearing as tolerated and found to have a broken R3LEASE Screw (Figure 4). At 6 months post-operative, he was doing well, had no pain and had returned back to full physical activity.

Figure 3: Radiographs demonstrating bimalleolar ankle fracture: (**A**) anteroposterior and (**B**) lateral.

Figure 4: Radiographs obtained 4 months post-operative demonstrating healed ankle fracture with R3LEASE Screw broken at the appropriate break point: (**A**) anteroposterior and (**B**) lateral.

CASE 3:

Presentation

The patient is a healthy 42 year old female who sustained a twisting injury to her left ankle falling down stairs. She was found to have a closed bimalleolar-equivalent ankle fracture and was indicated for surgical fixation (Figure 5). Surgical treatment was performed as described above using a Paragon 28® Gorilla® 9-Hole Anatomic Fibula Plate with two R3LEASE™ Screws for the syndesmotic repair. At 6 weeks post-operative, radiographs were taken showing intact R3LEASE™ Screws (Figure 6). She was made weightbearing as tolerated approximately 10 weeks post-operative and was found to have a broken and loose R3LEASE™ Screw at approximately 4 months post-operative (Figure 7). At 6 months post-operative, she was doing well, had no pain and had returned back to full physical activity.

Figure 5: Bimalleolar-equivalent ankle fracture demonstrating widening of the medial clear space consistent with deltoid ligament disruption.

Figure 6: 6 week post-operative mortise radiograph demonstrating anatomic mortise alignment and intact R3LEASE™ Screws.

Figure 7: 4 month post-operative mortise radiograph demonstrating a broken inferior R3LEASE™ Screw with appropriate loosening of the proximal R3LEASE™ Screw.

1. Riedel MD, Briceno J, Miller CP, Kwon JY. Technical tip: Removal of a broken tri-cortical syndesmotic screw using a "perfect" circle technique. *Injury*. 2018;49(4): 877-880.
2. Manjoo A, Sanders DW, Tieszer C, MacLeod MD. Functional and radiographic results of patients with syndesmotic screw fixation: implications for screw removal. *J Orthop Trauma*. 2010;24(1):2-6.
3. Schepers T, Van Lieshout EM, de Vries MR, Van der Elst M. Complications of syndesmotic screw removal. *Foot Ankle Int*. 2011;32(11):1040-1044.

Exclusively foot & ankle Paragon 28®

Paragon 28, Inc.
4B Inverness Ct. E, Ste. 280
Englewood, CO 80112, U.S.A.
855.786.2828 | www.paragon28.com

Paragon 28 Medical Devices Trading Limited
43 Fitzwilliam Square West
Dublin 2, D02, K792, Ireland
+353 (0) 1541 4756

CE 2797