CASE SERIES

Traumatic Syndesmosis Injuries Treated with a Novel Flexible Syndesmotic Device

Surgeon Author: Lauren E. Geaney, MD

Associate Professor of Orthopedic Surgery, UConn Health
UConn Musculoskeletal Institute
Farmington, Connecticut, USA

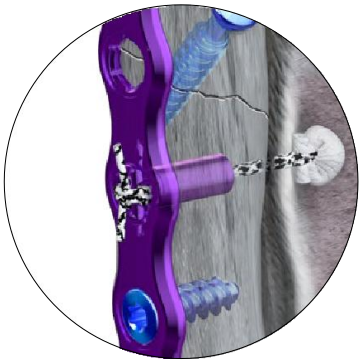
Paragon 28® a ZIMMER BIOMET company

Featured Products: Paragon 28® R3FLEX® Syndesmotic Stabilization System and Gorilla® Ankle Fracture Plating System

Introduction

Ideal syndesmotic reduction and fixation continues to be a challenge even for the most experienced foot and ankle surgeons. Despite open reduction and advances in imaging technology, there continues to be high rates of syndesmotic malreduction with some studies even reporting up to 50% incidence.[1,2,3] While historically rigid fixation was more universal, there have been clear benefits demonstrated with the use of flexible fixation.[4] Amongst these, the lack of return to the operating room as well as the ability for malreduction forgiveness [5,6] has encouraged many surgeons to prefer flexible fixation over rigid options. However, previous flexible implants have still faced challenges, **specifically interference with medial fixation, the possibility of injury to medial neurovascular structures, the inability to tension the implant as well as the possibility of implant loosening**.[7,8]

The R3FLEX® Syndesmotic Stabilization System was designed to offer the benefits of flexible fixation while simultaneously minimizing the complications with more traditional suture button devices. Specifically, the R3FLEX device provides fixation on the lateral cortex of the tibia, avoiding interference with medial hardware or the medial neurovascular structures. The innovative tensioning device on the inserter also provides reproducible tensioning of the implant. Furthermore, the shorter working length between the fibular component and the tibial component as well as the tensioning device minimize the potential for loosening.[8] There are multiple options for fixation into the fibula including the Gorilla Ankle Fracture System, Gorilla Syndesmosis 2-hole Plate, or a washer.



Tri-cortical All-Suture Fixation

R3FLEX STABILIZATION SYSTEM

CASE 1:

Presentation

The patient is a 26-year-old male presenting with a chief complaint of a one-month history of left ankle pain. He reports that he was wrestling competitively when his opponent grabbed his left ankle. He had immediate pain and a sensation of popping in the ankle. He had difficulty bearing weight. Since that time, the pain had improved, but he continued to have challenges with running and any high-impact activity. On exam, he had mild swelling over the lateral ankle. He had maximal pain over the distal syndesmosis at the AITFL. He has pain which is reproduced with external rotation of the foot in the mortise. He has a negative anterior drawer and no pain over the fibula. He has full strength and was neurovascularly intact.

Radiograph Examination

Weightbearing views of the ankle were obtained at the time of injury which were negative for any obvious pathology. An MRI subsequently performed revealed a full-thickness tear of the anterior-inferior tibiofibular ligament (AITFL), full-thickness tear with periosteal sleeve avulsion of the posterior inferior tibiofibular ligament (PITFL), tear of the anterior bundle of the deep fibers of the deltoid ligament. Note the fluid tracking up the posterior tibia on sagittal T2 imaging consistent with a PITFL tear.

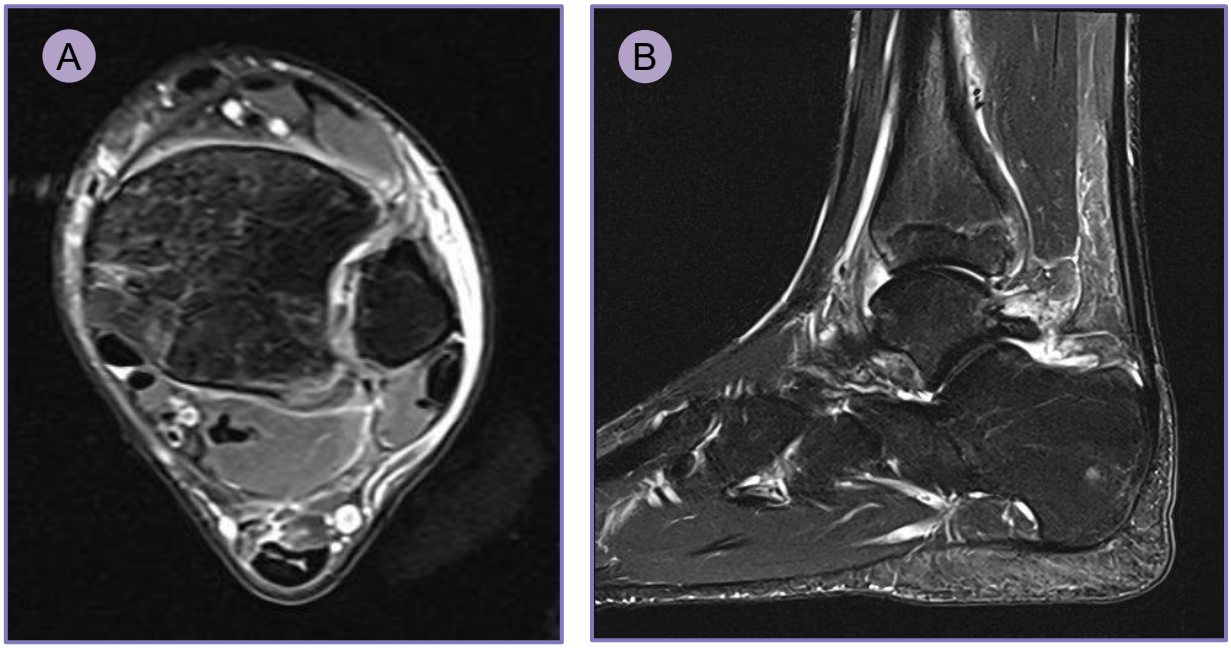


Figure 1: MRI demonstrating ligamentous injuries: **(A)** transverse and **(B)** sagittal.

Initial Management and Decision Making

Treatment options were discussed with the patient. Considering his high level of activity, the full thickness tears of the AITFL and PITFL and the deltoid ligament the decision was made to proceed with ankle arthroscopy and evaluation of the syndesmosis, open reduction internal fixation of the syndesmosis, and open deltoid repair.

Surgical Technique

The patient was positioned in a supine position with a bump underneath the left hip. A nonsterile tourniquet was applied to the left upper thigh. An AP and lateral x-ray was taken of the opposite side as reference for reduction of the syndesmosis. The left lower extremity was then draped and prepped in the normal sterile fashion. First, I proceeded with an ankle arthroscopy through an anterior medial portal. The arthroscopy confirmed complete tear of the deltoid ligament as well as instability of the syndesmosis. The synovitis was debrided and the camera was removed.

An incision was made directly over the fibula laterally. We dissected through the soft tissue to the periosteum. The periosteum was then split and elevated to expose the lateral fibula. I then dissected anteriorly to the anterior aspect of the syndesmosis. Pre-reduction imaging confirmed opening of the syndesmosis which was asymmetrical to the opposite side (Figure 2). A large periarticular clamp was used to reduce the syndesmosis and AP and lateral x-rays were then taken to confirm symmetry to the opposite side. The periarticular clamp was placed centrally over the fibula in the anterior 1/3 of the tibia medially through a separate incision. The syndesmosis was also directly visualized through the incision and with the arthroscopic camera to ensure anatomic reduction.

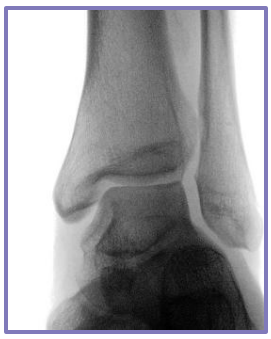


Figure 2: X-ray of the injured ankle and widening of the syndesmosis.

The Gorilla Syndesmosis 2-hole Plate was then placed over the lateral cortex and held in place with an olive wire. AP and lateral x-rays were taken confirming appropriate positioning of the plate. The drill guide for the R3FLEX was placed into the proximal hole of the syndesmotic plate. A mortise x-ray was taken and under fluoroscopic guidance, the 2.8 mm drill was then used to drill into the tibia directed in a center-center position by dropping the hand and drilling to the stop on the drill. The drill and the drill guide were then removed, and the 3.8 mm drill was used to drill through the fibula. The drill into the fibula was in nearly the same trajectory as the 2.8 mm drill, but the implant allows some forgiveness for the fibular portion of the implant to sit flat within the plate and avoid prominence. The implant was then inserted with gentle pressure into the tibia. Taps with a mallet were necessary due to the patient's bone quality to insert the implant past the lateral tibial cortex. The inserter tip was disengaged from the inserter, and the implant was seated against the lateral cortex of the tibia by pulling on the inserter handle (Figure 3).

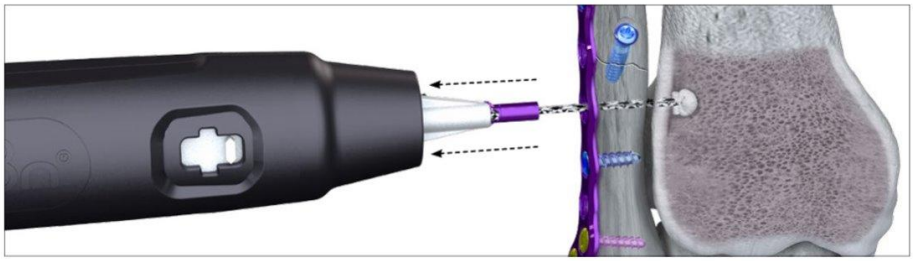


Figure 3: All-suture anchor fixation set on the lateral cortex of the tibia by pulling on the R3FLEX inserter handle.

Surgical Technique (Cont.)

The fibular portion of the implant was seated into the plate by pulling back on the purple loop while simultaneously advancing the grey portion of the inserter to guide it into the hole (Figure 4). Final tensioning was provided by rotating the purple handle until the tensiometer was centrally aligned (Figure 5). Prior to releasing the implant, the ankle was ranged through range of motion and additional tension applied after the suture in the repair was balanced. The white button was pushed to release the implant. AP and lateral x-rays were taken showing full seating of the fibular component. A second implant was then placed in the second hole using a similar technique.

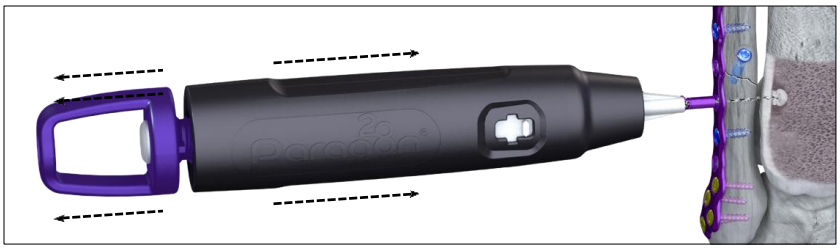


Figure 4: The purple loop is pulled towards the user while the grey handle is simultaneously pushed towards the patient to seat the lateral implant.

Figure 5: The purple loop is rotated clockwise to increase tension across the repair. It can be rotated counter-clockwise to decrease the tension.

The medial side was then opened by creating an incision extending from just proximal to the tip of the medial malleolus distally in an oblique fashion. We dissected through the soft tissue to the superficial deltoid. The superficial deltoid was released off of the medial malleolus and deep to this, the deep deltoid was torn anteriorly. The tip of the medial malleolus was debrided and an all-suture anchor was placed into the medial malleolus. A mattress suture was passed through the deep and superficial deltoid with the foot held in a neutral position. All wounds were thoroughly irrigated out and closed in a standard fashion.

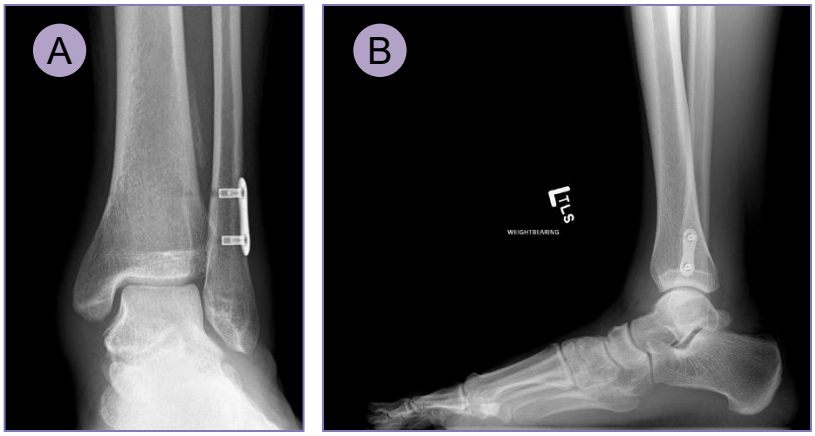


Figure 6: 3-month post-op X-ray with the Syndesmosis 2-hole Plate and 2 R3FLEX implants: **(A)** A/P and (**B**) Lateral.

Post-Operative Protocol

The patient was placed into a well-padded splint with the ice machine embedded into the splint. The patient was non-weightbearing. He returned to the office 2 weeks after surgery and the splint and sutures were removed. X-rays were obtained and a removable walking boot was provided. He was allowed to progress to full weightbearing with the boot. He began active dorsiflexion and plantarflexion at the 2-week interval and was allowed to increase walking to tolerance. At 6 weeks, he returned to the office at which point he progressed out of the boot with physical therapy. At 3 months postoperatively, he was allowed to progress without restriction and was able to do a single-leg heel raise.

CASE 2:

Presentation

The patient is a 47-year-old female presenting to the office for after a fall down the stairs. She presented initially to the emergency department and then subsequently to the office. X-rays revealed a Weber B fibula fracture in addition to a Mason Type 1 posterior malleolus fracture[9] identified on CT scan (Figure 5 A,B,C). Based on the posterior malleolus fracture, the syndesmosis was presumed to be unstable. Intraoperatively, an external rotation test was performed confirming syndesmotic instability. The patient was treated with surgery including a Paragon 28 Gorilla Anatomic Fibular Plate with reduction of the fracture in a standard fashion. The syndesmosis was fixed using the previous technique described and a R3FLEX Syndesmotic Stabilizing device. At the patient's 6-month postoperative visit, she had returned to all previous level of function (Figure 6 A,B).

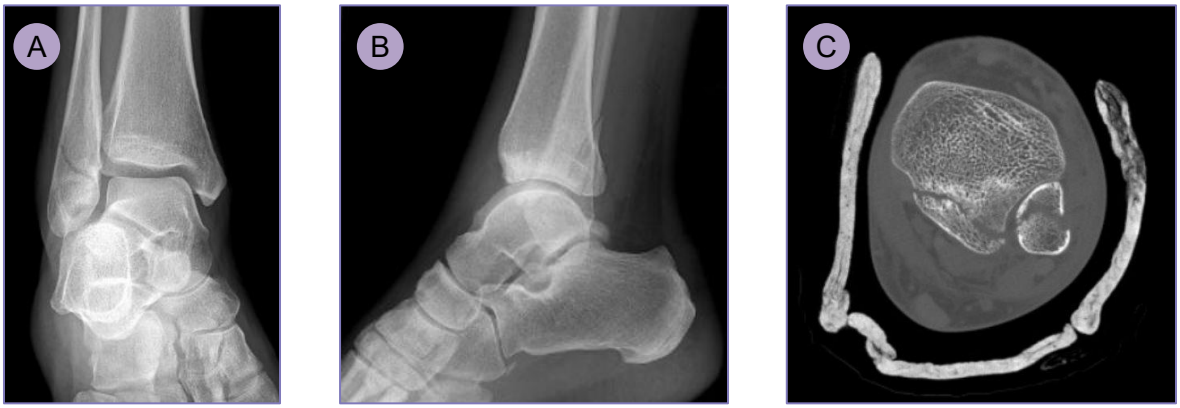


Figure 7: Injury X-rays and CT scan: **(A)** A/P X-ray **(B)** Lateral X-ray **(C)** Axial CT.

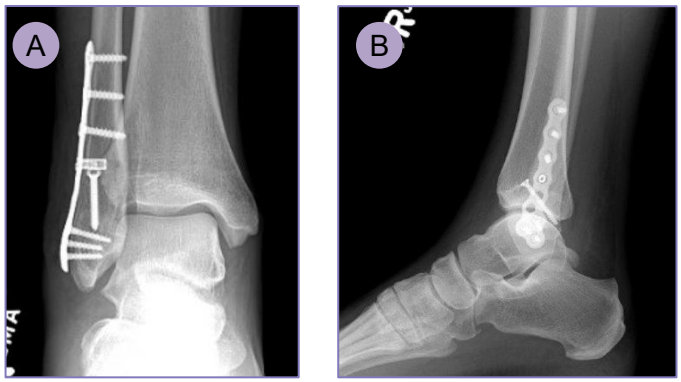


Figure 8: 6-month post-op X-rays with the Gorilla Anatomic Fibular Plate and R3FLEX: **(A)** A/P **(B)** Lateral.

CASE 3:

Presentation

81-year-old female presenting with a bimalleolar ankle fracture and syndesmotic injury following a motor vehicle collision. Non-weightbearing X-rays revealed a comminuted Weber B fibula fracture and a sagittal split to the medial malleolus with syndesmotic widening. CT scan also showed a Chaput fracture anteriorly (Figure 8 A,B,C). The patient was treated with open reduction internal fixation of the fibula using a Paragon 28 Gorilla Anatomic Fibular Plate in addition to fixation of the medial malleolus and the Chaput fragment using 4.0 mm partially-threaded cannulated Mini-Monster® Screws. The R3FLEX syndesmotic system was also utilized after fixation of the other fractures. This was particularly helpful in that it avoided interference with the other tibial fixation (Figure 9).

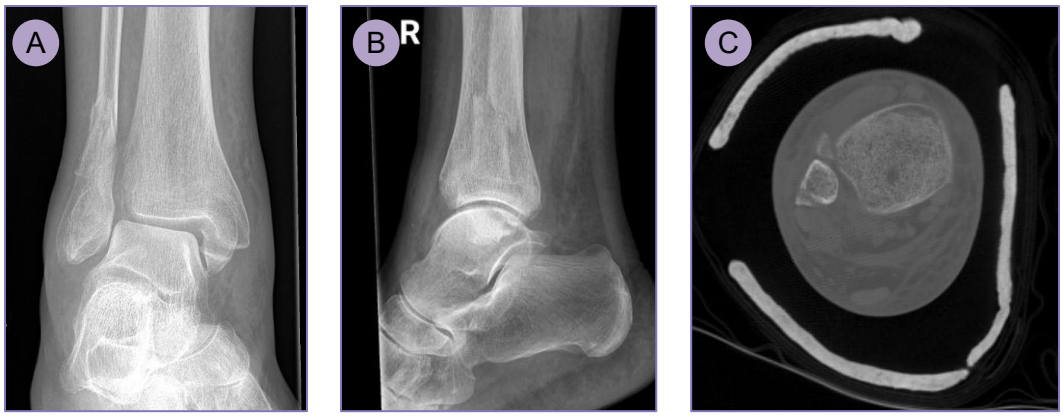


Figure 8: Injury X-rays and CT scan: **(A)** A/P X-ray **(B)** Lateral X-ray (**C**) Axial CT.

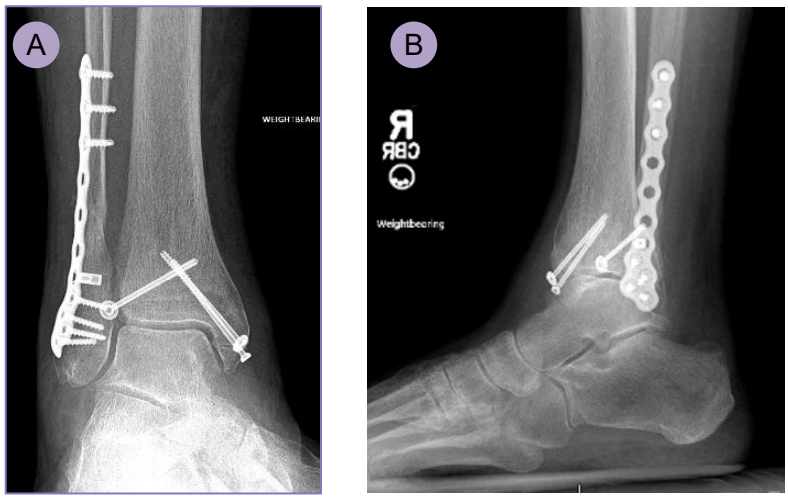


Figure 9: 3-month post-op X-rays with the Gorilla Anatomic Fibular Plate, Monster Screws, and R3FLEX: **(A)** A/P **(B)** Lateral.

Surgical Pearls

Do not place the R3FLEX into the lateral fibula without a washer or a plate to prevent stress fractures.

The 3.8 mm fibula drill should be performed in a similar trajectory as the 2.8 mm drill to facilitate implant insertion but has some flexibility to minimize implant prominence.

Position the plate more posterolateral on the fibula to minimize prominence of the R3FLEX fibular implant.

You don't need to always advance all the way down to the inserter tip. In small patients, just make sure that the flat part of the inserter enters the tibia (Figure 10).

Insert the implant by hand first if possible, followed by gentle taps with a mallet.

Range the ankle through a range of motion after tensioning to balance the suture and add additional tension if needed (Figure 11).

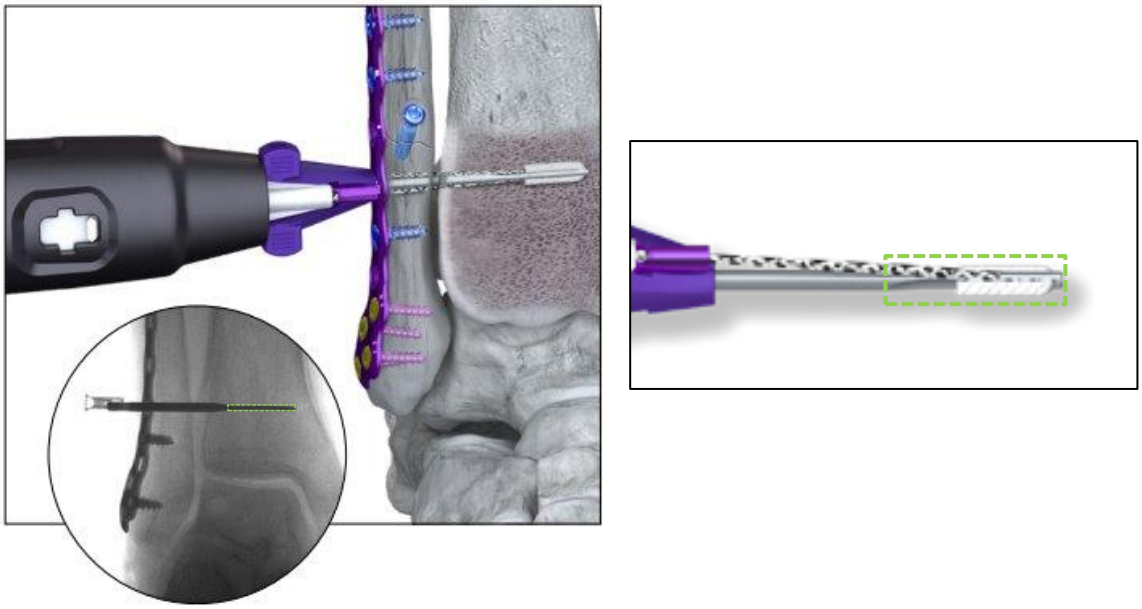


Figure 10: In smaller anatomies, only the flat portion highlighted in green needs to enter the tibia. The all-suture anchor is half-way down this portion.

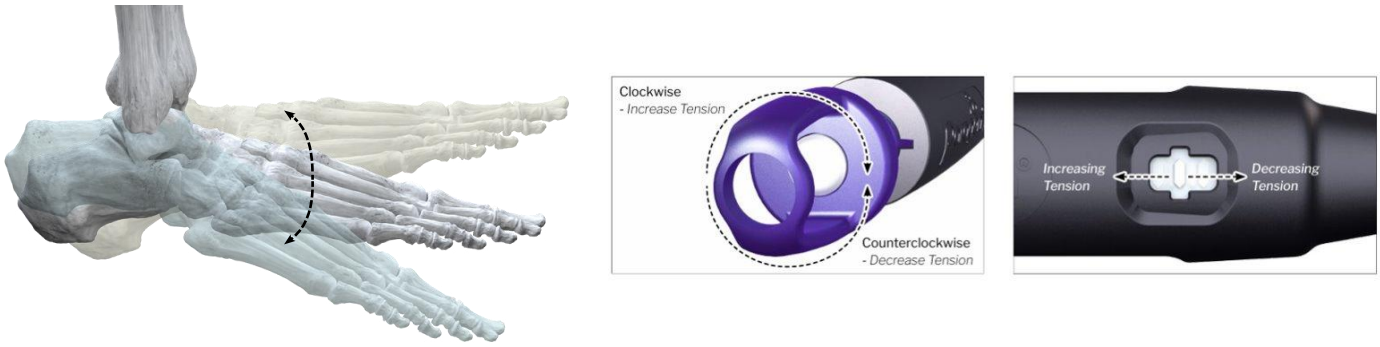


Figure 10: Plantarflex and dorsiflex the foot (range the ankle) to balance the sutures in the R3FLEX. Add additional tension as needed if the indicator decreases.

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www.Paragon28.com

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

Paragon 28® Medical Devices Trading Limited
First Floor Block 7 Beckett Way
Park West Business Park
Dublin 12
D12 X884
Ireland
+353 (0) 1588 0350

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