CASE SERIES

FIBULINK™ Syndesmosis Repair System Radiographic Case Series in 40 Patients Undergoing Ankle Fracture Repair with Syndesmotic Stabilization

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Retrospective radiographic follow-up of 40 patients undergoing stabilization of the distal tibiofibular syndesmotic complex with the DePuy Synthes FIBULINK™ Syndesmosis Repair System. The purpose of this review was to evaluate maintenance of reduction of the ankle mortise and report on fixation failure which was not observed.

1. INTRODUCTION

The syndesmotic complex is a fibrous joint composed of 4 main ligaments. The anterior tibiofibular ligament (AITFL), the interosseous ligament (IO), the posterior tibiofibular ligament (PITFL) and the deep transverse ligament.[1] Historically, the posterior ligaments were taught to be the main stabilizer of this complex; however, previously published studies evaluated the ligaments with lateral translation testing only (Ogilvie-Harris 1994).[2] Clanton et al recently re-evaluated the syndesmotic complex, finding that the AITFL was the strongest ligament out of the syndesmotic complex when testing for resistance of external rotation forces rather than lateral translation.[1] Injuries associated with syndesmotic complex typically result in lower energy forces, subjecting the tibiofibular joint and ankle joint to an external rotation moment. The external rotation energy will invariably result in an "open book" anterior to posterior disruption resulting in first tearing of the AITFL, followed by the interosseous ligament then the PITFL.[1] Traditionally, this dense fibrotic mobile syndesmotic complex was stabilized with a rigid internal screw. Although this method of stabilizing the syndesmotic joint can be successful, studies have shown undesired compilations such as hardware failure (i.e.,screw breakage), mal-reduction, decreased ankle joint range of motion and potential need for second surgeries for hardware removal.[3]

Advancements in flexible suture button fixation has significantly diminished many of these potential side effects; however, it also has its disadvantages. Complications such as lack of stability in the sagittal plane, medial neurovascular incarceration, loss of reduction, and rarely tibialis anterior tendon irritation can result in fixation shortcomings.[4]

The DePuy Synthes FIBULINK Implant System is a solution in advancing fixation of the syndesmotic complex by affording the surgeon tibial metaphyseal fixation without violating the medial tibial surface. The device allows for gradual controlled uniform stabilization using tethered suture screw fixation and ability to increase or decrease tension.

The following is a case series of 40 patients undergoing ankle fracture repair including internal osseous fixation with flexible syndesmotic stabilization using DePuy Synthes FIBULINK Implant System. The purpose of this research was to radiographically evaluate syndesmotic reduction of the ankle mortise and report on the maintenance of reduction and postoperative complications.

2. METHODS

Forty patients were retrospectively reviewed radiographically. Radiographs were evaluated by using the immediate postoperative x-rays compared to final postoperative x-rays. Maintenance of correction was confirmed by using the following 3 parameters; **1.** The lateral aspect of the tibial screw in relation to the lateral tibia cortex on the medial oblique view; **2.** The tibiofibular clear space on medial oblique view; and **3.** The medial clear space on anterior posterior projections (Figure 1). Inclusion criteria included closed uni-malleolar, bi-malleolar and trimalleolar ankle fractures.

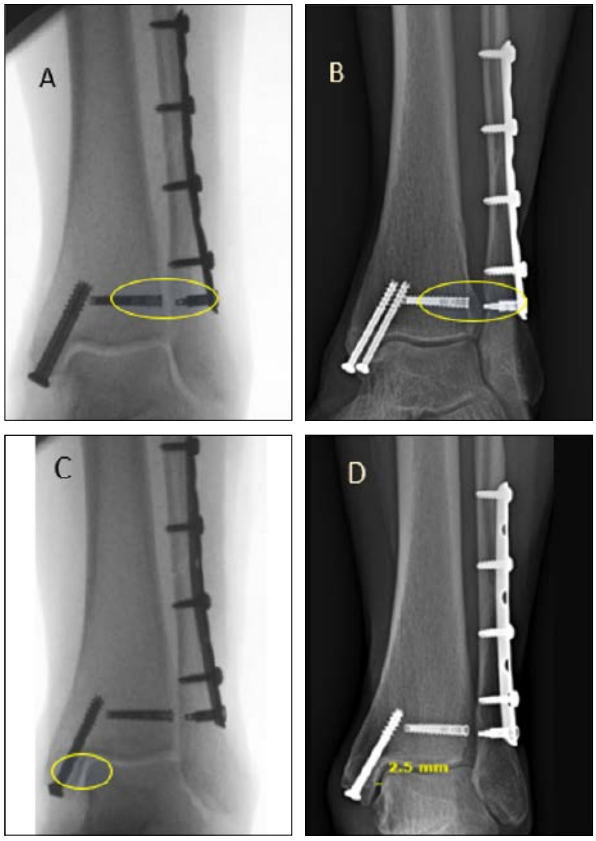

Figure 1.

1. Tibial screw remains constant to lateral tibia cortex immediate post-op (A) and final post-op (B).

2. Tibiofibular clear space remains <6mm on MO view in both (A) and (B).

3. Medial clear space remains constant in both (C) and (D).

3. SURGICAL TECHNIQUE

Preoperative assessment of injuries included plain radiographs and computed tomography when deemed appropriate by the treating surgeon. Once osseous components were stabilized with open reduction and internal fixation, the ankle joint was placed through a dorsiflexion and external rotation stress exam to evaluate the competency of the syndesmosis. Direct intraoperative evaluation of the syndesmosis along with radiographic parameters were used to determine syndesmotic competency. An increase in tibiofibular clear space, as well as medial clear space widening, were deemed a candidate for syndesmotic stabilization using the DePuy Synthes FIBULINK Implant.

The syndesmosis was debrided and either manually reduced or reduction was achieved using a large point to point tenaculum. This was at the discretion of the treating surgeon. A K-wire was then placed at least 2 cm proximally to the ankle joint in the standard 20° to 30° projection from lateral to medial. Again, reduction was confirmed directly as well as with multiplanar fluoroscopy. The K-wire was inserted through both cortices of the fibula and into the tibial metaphysis without violating the medial tibial cortex. AP and lateral x-rays were used as confirmation of proper wire placement.

SURGICAL TECHNIQUE continued

A step drill was then used to create a 3 mm pilot hole in the tibia along with a 4 mm hole in the fibula.

The tibial screw is then inserted until the lateral aspect of the screw is flush with the lateral tibial wall This must be confirmed on a medial oblique mortise view. The fibula tensioning cap is then advanced by clockwise rotation of the knob, which will increase tension, while counterclockwise rotation will reduce tension of the device. This allows the surgeon to perform fine adjustments of the FIBULINK Implant System to ensure an anatomic reduction. Direct inspection of the fibula at the incisura, as well as fluoroscopy, is used to confirm. When the surgeon is content with the syndesmosis reduction, the silver tube, followed by the gold tube, then tensioning knob are each pulled laterally to remove (Figure 2).

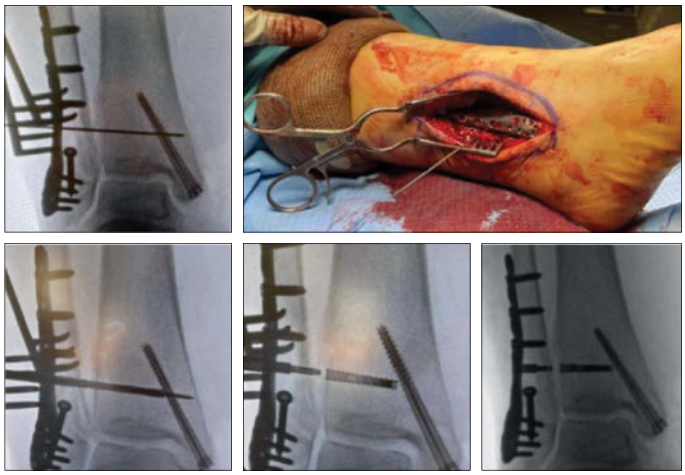

Figure 2. Sequential steps using the DePuy Synthes FIBULINK Syndesmotic Repair System.

4. RESULTS

Forty patients were retrospectively reviewed. There were 16 male and 24 female patients (N=40). Average age was 51 years old (17 to 82 years old). The mean follow-up was 5.7 months. Fracture patterns observed: 12 PER, 27 SER, and 1 SAD ankle fracture.

Maintenance of reduction was verified by comparing immediate postoperative x-rays and final postoperative x-rays. Maintenance of reduction was defined as: **1.** No change in position of the tibial metaphyseal screw using the lateral tibial cortex as a reference; **2.** Less than 6 mm of tibiofibular clear space; and **3.** <4 mm of medial clear on both immediate postoperative x-rays and final x-rays.

We observed no change in position of initial tibial screw placement. All final x-rays-maintained reduction of the tibiofibular clear space (<6 mm) as well as no propagation of medial clear space widening (<4 mm). We observed no final postoperative complications requiring further surgical intervention and no hardware related complications such as FIBULINK Implant loosening, breakage, allergic reaction or infection (Figure 3).

Figure 3. Maintenance of correction following ankle fracture ORIF with syndesmotic stabilization at 270 days.

5. DISCUSSION

As our understanding of the syndesmotic complex deepens, medical device advancements will aid in surgeons' ability to better address this complicated tibiofibular joint. Progression of stabilization has come a long way from rigid fixation of the mobile fibrous distal articulation of the tibia and fibula, which has been shown to potentially have undesirable outcomes. The DePuy Synthes FIBULINK Implant affords surgeons the ability to "dial in" the fibula within the tibial incisura in a controlled fashion without violating the medial tibial cortex. Many devices currently available require a separate incision to ensure proper medial button placement on the medial face of the tibia, which can result in incarceration of the medial neurovascular structures. The FIBULINK Implant allows for a shorter working length with metaphyseal and lateral tibial cortex fixation using a metal screw which will increase the overall strength of the syndesmotic construct. Figure 4 shows a radiographic example before and after implantation of FIBULINK Syndesmosis Repair System. Additional radiographs are available in the Supplemental Section (Figures 5-7).

Figure 4. Example of a 50-year-old female with a PER 4 type ankle fracture with a high proximal Maisonneuve fracture and evident medial clear space widening. Seven-month follow-up radiographs show excellent maintained reduction of the syndesmosis and medial clear space.

6. CONCLUSION

This retrospective case review of 40 patients undergoing syndesmotic stabilization using the DePuy Synthes FIBULINK Implant System adequately maintained anatomic reduction of the ankle mortise at a final follow-up at 5.7 months. We observed no loss of ankle joint radiographic parameters including both tibiofibular clear space and medial clear space. Lateral tibial cortex and metaphyseal screw placement was maintained on all x-rays reviewed, with no screw migration or device failure.

7. SURGEON PROFILES

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8. REFERENCES

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2. Ogilvie-Harris DJ. Disruption of the ankle syndesmosis: diagnosis treatment by arthroscopic surgery. *Arthroscopy.* 1994;10(5):561-568.
3. Laflamme M, Belzile EL, Bédard L, et al. A prospective randomized multicenter trial comparing clinical outcomes of patients treated surgically with a static or dynamic implant for acute ankle syndesmosis rupture. *J Orthop Trauma.* 2015;29:216-223.
4. Desai S. Syndesmotic injuries treated with an aperture fixation device. *Techniques in Foot & Ankle Surg.* 2020;19(2):96-103.

9. SUPPLEMENTAL FIGURES

Figure 5. Examples of six ankle fractures fixated with the FIBULINK Syndesmosis Repair System showing the correct tension achieved intra-operatively.

Figure 6. Examples of two SER 4 and one PER 4 closed high energy ankle fractures with significant displacement. Anatomic reduction and maintenance of reduction was achieved with the FIBULINK Implant System.

Figure 7. Images of a 63-year-old female with a PER 4 ankle fracture with visible syndesmotic rupture/widening. 6-month follow-up radiographs show excellent alignment and maintained reduction of the syndesmosis.

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

Please refer to the instructions for use for a complete list of indications, contraindications, warnings, and precautions.

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