TITLE

Evaluation of Safety and Performance Outcomes of the Fibulink Syndesmosis Repair System with Early Full-Weight Bearing

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Trauma/CMF Investigator Initiated Study Protocol Template

Version 1.0

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Complete Sections 1.0 – 12.0 to create the Protocol for Submission.

SECTION 1.0: Protocol Background

1.1 Full Protocol Title	Evaluation of Safety and Performance Outcomes of the Fibulink Syndesmosis Repair System with Early Full-Weight Bearing Protocol
1.2 Version and Date	5 /9 /22
1.3 Principal Investigator	Dr. Amr Abdelgawad
1.4 Institution and Address	Maimonides Medical Center, 4802 10th Ave, Brooklyn, NY 11219
1.5 Sub-Investigators (if applicable)	Dr. Aaron Lam, Dr. Mitchell Ng, Dr. Adam Gordon, Dr. Ahmed M. Thabet
1.6 Multi-center Institutions and Address (if applicable)	Texas Tech University Health Sciences Center, El Paso, Texas

SECTION 2.0: Statement of Compliance

2.1 Include a statement that the study will be conducted in accordance with specific provisions of the associated IRB/IECs, and in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with Good Clinical Practice (GCP) and the applicable national and regional regulatory requirement(s)	The study will be conducted in accordance with specific provisions of the associated IRB/IECs, and in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with Good Clinical Practice (GCP) and the applicable national and regional regulatory requirement(s).

SECTION 3.0: Background Information and Scientific Rationale

3.1 Identification and description of the study product and its intended purpose	Fibulink Syndesmosis Repair System is a multi-component anchor system designed for the treatment of syndesmotic disruption in the setting of unstable ankle fractures. It composes of a suture bridge within a screw fixation system. Previous methods of fixation include trans-osseous screw fixation and suture-button technique. However, limitations of screw fixation include delayed weight bearing, risk of screw breakage and need for subsequent screw removal.[1] The use of suture button technique improved on the limitations of screw fixation by allowing earlier weight bearing and more physiological motion at the syndesmotic joint.[2] Despite the success, limitations of the suture button technique include the lack of tension control within the suture system[3] and the need to make a separate medial incision. The Fibulink Syndesmosis Repair System combines the advantages of the previous two fixation techniques to allow for a more precise and anatomic syndesmotic fixation.
3.2 Description of the intervention and/or procedures for which the study product is intended	The study product is intended to adjunct open reduction and internal fixation of ankle fractures with concomitant disruption of the syndesmosis.
3.3 Description of the populations and indications for which the study product is intended	Adult patients (***ages 22 yo and older***) who sustained ankle fractures with disruption of the syndesmosis. This includes patients with syndesmotic sprain (without fractures) who demonstrates instability on stress radiographs, bimalleolar equivalent ankle fractures with syndesmotic disruption, bimalleolar ankle fractures with syndesmotic injuries, Maisonneuve fractures, trimalleolar ankle fractures without the need for posterior malleolus fixation and ankle fracture dislocations.
3.4 A summary of relevant previous pre-clinical and clinical studies (as applicable)	The Fibulink Syndesmosis Repair System has been evaluated and compared to the Arthrex Syndesmosis TightRope in a biomechanical study.[4] When assessing the total medial to lateral displacement at the syndesmosis during dynamic testing at 300,000 cycles, TightRope was found to have a statistically significant higher average displacement when compared to the Fibulink (2.07 mm v 0.61mm, P<0.001). During static load-to-failure testing, Fibulink system

	was found to require a statistically significant higher average load at 2 mm displacement and ultimate load. In a 14 patient case series using the Fibulink system, short term outcome measures (AOFAS and VAS) were favorable with no reported complications.[5]
3.5 A summary of potential risks and benefits (including steps that will be taken to control or mitigate risks)	Benefits of the Fibulink system include the avoidance of a medial-sided incision which would eliminate the risk of injury to the nearby neurovascular structures (ie: saphenous vein) and possible soft tissue entrapment. In addition, the Fibulink system is designed to allow for setting and adjusting the desired tension at the syndesmosis. This allows for better control in optimizing the final syndesmotic gap. Risks of the Fibulink system includes the loss of reduction and the maintenance of the syndesmosis reduction and difficult removal, planned or unplanned. To control the risks, we will have set time points where we evaluate the syndesmosis via standard radiographs. If there is a loss of reduction or maintenance of the reduction, the study will end for the affected patient. Revision surgery will be performed.
3.6 References to literature and data that are relevant to the study and that provide background for the study	Please see section 12.0

SECTION 4.0: Study Objectives/Design

4.1 Describe the purpose of the study	The purpose of the study is to evaluate the ability of the Fibulink Syndesmosis Repair System to maintain reduction of the ankle syndesmosis. Appropriate reduction of the syndesmosis is critical due the changes in tibiotalar contact pressure observed in cadaveric studies.[6,7] Malreduction and instability of the distal tibiotalar joint can lead to chronic instability, increased articular damage and ultimately degenerative arthritis.[7,8] Medial to lateral translation of distal tibia and fibula of 2 mm or more has been considered pathologic.[9] Earlier biomechanical study demonstrated the Fibulink system is superior in maintaining displacement of less than 2 mm.[4] Given the improved strength, we also look to evaluate the outcomes of initiating full weight bearing **(100%)** with CAM boot at 4 weeks postoperatively. One of the big limitations for trans-osseous screw fixation is delayed weight bearing due to risk of screw breakage.[1] Suture button technique allowed for early weight bearing with average of 6 weeks postoperatively using TightRope.[2,10–12]By initiating full weight bearing **(100%)** with CAM boot at 4 weeks postoperatively, this would be a significant improvement in current clinical practice.
4.2 Primary Objective	The primary objective is to evaluate the reduction and maintenance of the reduction of ankle syndesmosis in 6 months after initiating full weight bearing **(100%)** at 4 weeks ***or 6 weeks*** postoperatively. ***This will be determined based on comparing the tibiofibular overlap, tibiofibular clear space and medial clear space preop values.***
4.3 Secondary Objective	The secondary objectives include: 1) reduction and maintenance of the reduction of the ankle syndesmosis at 2 weeks, 4-6 weeks, 8-10 weeks and 3 months ***based on the tibiofibular overlap, tibiofibular clear space and medial clear space preop values.*** 2) rate of unplanned re-operation or late-stage revision, 3) operative statistics (i.e. OR time, surgical approach/procedure, type of additional fixation), 4) safety data such as intra- and post-operative complication rates
4.4 Exploratory Objective	Not applicable.
4.5 Rationale for selection of endpoints	The rationale of the endpoints selected is to evaluate the short-term clinical outcomes (6 months) using the Fibulink Syndesmosis Repair System for fixation of a syndesmotic injury. If reduction is maintained at six months, no further displacement should be expected as full healing of the native ligaments is achieved.
4.6 Describe the hypothesis (i.e. non-inferiority or superiority)	Reparation of the syndesmosis with the Fibulink Syndesmosis Repair System will maintain the reduction of the syndesmosis at 6 months follow-up. Initiating full weight bearing **(100%)** in CAM boot at 4 weeks postoperatively is safe (when compared to the standard 6 weeks postoperatively) given that early biomechanical studies have demonstrated superior dynamic and load-to-failure testing when compared to the TightRope system.[4]
4.7 Describe the design of the control group used (i.e. type, prospective, historic), if any	Not applicable.
4.8 Describe the expected duration of subject participation, targeted enrollment duration along with sequence and duration of all study periods, including follow up	The enrollment duration is planned for 2 year. Every patient that is enrolled will have a minimum of 6 months follow-up. The research coordinators will follow-up with study patients to ensure compliance with study and prevent drop out.

4.9 Describe measures to be taken to minimize or avoid bias on the part of subjects, investigators, and analysts including randomization, if applicable. Include process of the randomization procedures	All potential participants will be informed of the study purpose. All treatment options for ankle fractures with syndesmotic injuries will be explained. Risks and benefits of each option will be discussed in full detail. Informed consent will be obtained before enrollment of participants in the study. A separate informed consent for surgery will be obtained. In addition, clear measurement criteria will be determined before the initiation of the study. ***Patients will be randomized into one of two groups: group 1) full weight bearing (100%) initiated at 4 weeks postoperatively and group 2) full weight bearing (100%) initiated at 6 weeks postoperatively. The rest of the study, including operative technique and postoperative protocol, will remain the same for both study groups.*** Computer based systems will be utilized to perform statistical analysis.
4.10 Describe "stopping rules" or "discontinuation criteria" for individual subjects, parts of study, and entire study	For individual subjects: if revision surgery is needed. ***Indications for revision surgery include intra-operative Fibulink breakage, system malfunction, inability to correctly tension the suture system and postoperative complications such as screw/suture breakage, subsidence, and infection.*** For the study: if more than 4 patients develop implant-related complication. ***Implant-related complications include intra-operative Fibulink breakage, system malfunction, inability to correctly tension the suture system and postoperative complications such as screw/suture breakage, subsidence, and infection.***

SECTION 5.0: Study Population

Describe the population to be studied

5.1 As appropriate, include background discussion/details on prevalence, for example: sex/race specific prevalence considerations, diagnosis, treatment patterns, and patients currently undergoing procedure regardless of study participation	The study will be performed at two Level 1 trauma centers, in urban settings with a diverse patient population from age, sex and ethnicity. All patients with ankle injuries/fractures routinely received radiographs of the ankle to assess the extent of the fracture pattern with manual or gravity stress tests if needed. Routine surgical fixation of unstable ankle fractures with or without syndesmotic injuries including distal fibular fixation, medial malleolus fixation (if necessary) and syndesmotic fixation (using trans-osseous screw fixation or suture button).
5.2 List inclusion and exclusion criteria. Include characteristics of subjects by age, sex, and condition.	Inclusion criteria: 1) ***age > 22 yo***, 2) ankle fracture with syndesmotic disruption as assessed with intra-operative cotton test. This includes the following injuries: - Syndesmotic sprain (without fractures) - Bimalleolar equivalent ankle fractures - Bimalleolar ankle fractures - Maisonneuve fractures - Trimalleolar ankle fractures without the need for posterior malleolus fixation - Ankle fracture dislocations Exclusion criteria: 1) previous ankle surgery, 2) active local infection about the ankle, 3) chronic ankle deformity secondary to trauma or congenital, 4) ligamentous laxity, 5) pathologic fractures, 6) peripheral vascular disease, 7) peripheral neuropathy, 8) diabetes neuropathy and charcot, 9) open fractures, 10) poly trauma, 11) inability to provide informed consent, 12) symptomatic ankle osteoarthritis, 12) retained hardware, 13) pregnant, 14) metabolic bone disease, 15) history of chronic steroid use, **16) mal-reduced ankle fractures (this will be determined through the parameters established in section 6.3)**
5.3 Describe withdrawal criteria and procedure(s), and procedures for replacement of subjects	Participants are allowed to withdraw from the study at any time point. Patients will notify the investigators their wish to withdraw from the study. Should the participant request for removal all data collected, it will be honored. New participants will be recruited until the aimed number of participants at each site is achieved.
5.4 Describe the number of investigational sites and number of subjects. Include the minimum and maximum number of subjects to be included from each center in a multi-center study	Number of site: 2 Number of subjects: ***56 (28 subjects in each group)***

SECTION 6.0: Study Procedures and Methodology

6.1 List key materials/devices required to execute the study (i.e. device, fixation, grafting material, sutures, neuromonitoring)	Syndesmosis injury - Fibulink Syndesmotic Repair System Medial malleolus fracture – ORIF with screws Lateral malleolus fractures – ORIF with plate and screws
6.2 Describe the study/surgical procedure and approach	All ankle fractures will be evaluated by the orthopedic team. Standard radiographs including AP, lateral and mortise view of the ankle will be obtained. Manual or gravity stress view will be performed if needed. Treatment options including nonoperative and operative management will be discussed with the patient including the risks and benefits. An informed decision will be made. Two separate informed consent will be obtained. The first will be an informed consent for the surgery, detailing the planned surgical procedure. The second will be an informed consent for the enrollment of the study, detailing the purpose of the study and the use of the Fibulink Syndesmotic Repair System in any cases of syndesmotic injury. Should the patient elects to proceed with surgery, the patient will be informed that fixation of the fractures will be performed first. Direct lateral approach to the distal fibular will be used for fixation of the lateral malleolus. If necessary, direct medial approach will be used for fixation of the medial malleolus. Once the fractures have been fixed, the syndesmosis will be stressed intraoperatively under live fluoroscopy. Based on the parameters described in 6.3, a decision will be made whether fixation of the syndesmosis is required if instability is noted. If fixation of the syndesmosis is required, it will be performed through the direct lateral approach. The research coordinator will be informed of all patients that had the syndesmosis fixed with the Fibulink System. Patients will then be followed at the following time points: 2 weeks, 4-6 weeks, 8-10 weeks, 3 months and 6 months. ***During each follow-up time points, the tibiofibular overlap, tibiofibular clear space and medial clear space will be measured and recorded.*** The postoperative protocol will be as follow: Immediately post-op, patient will be placed in a short leg cast. At 2 weeks postop, the short leg cast will be removed. Suture removal will be performed. Patient will be placed in a CAM boot and instructed to perform early active ankle range-of-motion. ***Depending on the study group, at 4 weeks or 6 weeks postop,*** **full** weight bearing **(100%)** in the CAM boot will be allowed. Physical therapy will begin. At 8-10 weeks postop, **full** weight bearing **(100%)** without CAM boot will begin. Patients will continue to follow-up at 3 months and 6 months. The research coordinator will ensure proper follow-up and will be responsible for data collection and input. After achieving the planned number of participants, the results of the two study sites will be gathered. Appropriate statistical analysis will be performed, and the results will be presented in a full manuscript format.
6.3 Describe all clinical observations/evaluations, medical history assessments, radiographic assessments, patient reported outcomes as applicable	Preop: XRs (AP, lateral, mortise) with manual or gravity stress view if needed Intraoperative: Live fluoroscopy with Cotton test[13] Postop: XRs (AP, lateral, mortise) Radiographic assessments: tibiofibular overlap, tibiofibular clear space, medial clear space widening under normal mortise and manual stress Normal values: 1) Tibiofibular overlap: > 6 mm on AP, > 1 mm on Mortise[14,15] 2) Tibiofibular clear space: < 6 mm on AP and Mortise[14,15] 3) Medial clear space: < 5 mm on Mortise[10] ***Using the above 3 values (tibiofibular overlap, tibiofibular clear space and medial clear space), radiographic assessments of the syndesmosis at preop and the pre-defined time points (at 2 weeks, 4-6 weeks, 8-10 weeks, 3 months and 6 months) will be recorded and compared. At the end of the study period, success of maintaining syndesmotic reduction will be based on comparing the tibiofibular overlap, tibiofibular clear space and medial clear space preop versus at 6 months to the normal values.*** The ac ceptable threshold for changes in width of the syndesmosis is up to 2 mm.[16–18] For each patient, the age, sex, laterality, type of ankle injury/fracture and co-morbidities including BMI, diabetic status, smoking status, alcohol status will be collected.

	The total number and rate of unplanned re-operation or late-stage revision will be collected. The reasons will be documented. Operative statistics to be collected include the total OR time, the surgical approach/procedure, the need for additional fixation. Safety data to be collected include intraoperative complications such as Fibulink breakage, system malfunction, inability to correctly tension the suture system and postoperative complications such as screw/suture breakage, subsidence, and infection. **Pain will be measured (pre-operatively and at last follow-up). This will be measured through the visual analog scale (VAS)**
6.4 Attach Study Calendar to capture section timepoints/visits	See example IIS Study Calendar* Check box to indicate Study Calendar is attached: ☒
6.5 Document criteria for radiographic assessment (i.e. fusion criteria, subsidence) and who will conduct the assessment (i.e. radiologist, 2 independent surgeons)	**Reduction of syndesmosis criteria:** Assessment will be conducted by senior author using standard XRs (AP, lateral, mortise) while evaluating the tibiofibular overlap, tibiofibular clear space, medial clear space as described in 6.3. ***This would be performed at the following time points: preop, 2 weeks, 4-6 weeks, 8-10 weeks, 3 months and 6 months.***

SECTION 7.0: Assessment of Safety

Safety parameters should be clearly outlined in this section. As appropriate for the study, state applicable definitions.

7.1 Describe the management and reporting of device and procedure related Adverse Events (AEs) and safety data	The management and reporting of device and procedure related adverse events and safety data will be conducted by our department's research fellow, Dr. Adam Gordon. Appropriate authorities will be notified if any adverse events occurred.

SECTION 8.0: Methods of Quality Control

8.1 A general outline of the methods of quality control of data should be outlined here	The primary objective of the study is to evaluate the reduction and maintenance of the reduction of the ankle syndesmosis at 6 months***. In addition, the quality and maintenance of the reduction at 2 weeks, 4-6 weeks, 8-10 weeks, and 3 months postop will be assessed as well.*** This will be determined through objective measurements described in other published papers via standard radiographs (AP, Lateral and Mortise) to measure syndesmotic reduction. These measurements include the tibiofibular clear space, tibiofibular overlap and medial clear space.[10,15] The review of the radiographs will be performed the same for each subject. Internal quality control audits will be performed after recruitment of cohorts of 5 patients to ensure the data is accurate and reliable. The senior authors (Dr. Amr Abdelgawad, Dr. Ahmen Thabet) and sub-investigator (Dr. Aaron Lam) will interpret and determine the reduction of the syndesmosis from the acquired radiographs.

SECTION 9.0: Statistical Methodology

Include a description of the analyses which will be performed including planned analyses when applicable (i.e. 12 months planned analysis), safety assessment, and the final analysis plan. This may include,

9.1 Provide a description of how the sample size for the study was determined. If appropriate, show sample size derivations and/or statistical power estimates for each appropriate endpoint, and estimate the overall power for successfully meeting all endpoints. This section may include a statement about the number of sites and/or the number of subjects at each site	**Non-inferiority study** **If there is truly no difference between the standard and experimental treatment (90% in both groups), then 56 patients (28 per group) are required to be 80% sure that the upper limit of a one-sided 95% confidence interval (or equivalently a 90% two-sided confidence interval) will exclude a difference in favor of the standard group of more than 20%.**

9.2 Expected drop-out rates	25%. The research coordinators will follow-up with study patients to ensure compliance with study and prevent drop out.
9.3 Provisions for planned analyses	Calculate rate of unplanned re-operation and/or late-stage revisions, intra- and post-operative complication rates Calculate operative stats including: mean OR time
SECTION 10.0: Ethics/Protection of Human Subjects	
10.1 State the requirement to obtain IRB/IEC approval prior to execution of the protocol and IRB documentation required or provided rationale	The study will be conducted in accordance with specific provisions of the associated IRB/IECs, and in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with Good Clinical Practice (GCP) and the applicable national and regional regulatory requirement(s). Each site will obtain full approval by their own institutional research ethics boards prior to the initiation of the study.
10.2 Describe the general requirements for obtaining informed consent, including providing subjects with new information as needed.	Patients who meet the study's inclusion criteria will be informed of the nature of the syndesmotic injury and the reasons for fixation. Patient will be informed of the types of fixation available including the standard trans-osseous screw, TightRope system and the Fibulink system. Patient will be informed of the planned study. ***They will be informed that there will be two study groups: full weight bearing (100%) at 4 weeks postop versus full weight bearing (100%) at 6 weeks postop. Assignments will be random. Patient will be informed of the standard weight bearing protocol (6 weeks postop) and reasons why earlier weight bearing is considered (4 weeks postop).*** With the patient's approval, two separate informed consent will be signed: one for the actual planned surgery and one for the use of the Fibulink Syndesmotic Repair System.
10.3 State that a copy of the protocol, informed consent forms, and other information to be completed by participants, such as survey instruments or questionnaires, and any proposed advertising or recruitment materials will be submitted to the IRB/IECs for written approval. Additionally, the investigator must submit and obtain approval from the IRB/IEC for all subsequent amendments to the protocol, informed consent documents, and other study documentation referenced above.	A copy of the protocol, informed consent forms, and other information to be completed by participants, such as survey instruments or questionnaires, and any proposed advertising or recruitment materials will be submitted to the IRB/IECs for written approval.
10.4 Describe methods used to protect subject confidentiality	All data will be collected and stored on site at Maimonides. PHI will not be disclosed to persons outside of the Medical Center. Identifiable information will be stored in a secure manner (password protected database) accessible only to research study investigators. Forms used for recording data for this study will not have any participant identifiers. The study team will use coded information which does not have any elements of PHI. No photocopies will be made of any patient chart, lab or other clinical information. All research files including the physical paper consents will be stored in a locker with the key kept by the research coordinator while they are unsupervised. We will keep electronic data stored in password protected files and will not email any information unless it can be encrypted. All PHI will be used only on site at MMC and will not be disclosed to any outside entity. All computers that will be used are password protected.

SECTION 11.0: Data Handling and Record Keeping	
General procedures for data management should be included within the protocol.	
11.1 Describe data management procedures, where the data will be stored, from example, data collection (specify whether via electronic data capture or paper records), data handling, review, electronic data systems verification/validation, and data retention	All data will be collected and kept in a password protected file. All physical papers including consents will be stored in a locker with the key kept by the research coordinator.

SECTION 12.0: Scientific References

List references as applicable to the background and scientific principles of the study

Thornes B, Shannon F, Guiney AM, et al. Suture-button syndesmosis fixation: Accelerated rehabilitation and improved outcomes. *Clinical Orthopaedics and Related Research*. 2005;431:207–212.

DeGroot H, Al-Omari AA, el Ghazaly SA. Outcomes of suture button repair of the distal tibiofibular syndesmosis. *Foot and Ankle International*. 2011;32:250–256.

Morellato J, Louati H, Bodrogi A, et al. The Effect of Varying Tension of a Suture Button Construct in Fixation of the Tibiofibular Syndesmosis - Evaluation Using Stress Computed Tomography. *Journal of Orthopaedic Trauma*. 2017;31:103–110.

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Ramsey PL, Hamilton W. Changes in tibiotalar area of contact caused by lateral talar shift. *JBJS*. 1976;58.

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Thornes B, McCartan D. Ankle syndesmosis injuries treated with the TightRope™ suture-button kit. *Techniques in Foot and Ankle Surgery*. 2006;5:45–53.

Latham AJ, Goodwin PC, Stirling B, et al. Ankle syndesmosis repair and rehabilitation in professional rugby league players: a case series report. *BMJ Open Sport & Exercise Medicine*. 2017;3:e000175.

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Harper MC, Keller TS. A radiographic evaluation of the tibiofibular syndesmosis. *Foot & ankle*. 1989;10:156–160.

Leeds HC, Ehrlich MG. Instability of the distal tibiofibular syndesmosis after bimalleolar and trimalleolar ankle fractures. *JBJS*. 1984;66.

Rigby RB, Cottom JM. Does the Arthrex TightRope® provide maintenance of the distal tibiofibular syndesmosis? A 2-year follow-up of 64 TightRopes® in 37 patients. *The Journal of foot and ankle surgery : official publication of the American College of Foot and Ankle Surgeons*. 2013;52:563–567.

Mukhopadhyay S, Metcalfe A, Guha AR, et al. Malreduction of syndesmosis--are we considering the anatomical variation? *Injury*. 2011;42:1073–1076.

APPENDIX

Please mark X below (as appropriate)

IIS Study Calendar – Trauma/CMF

Procedure	Visit 1 Baseline	Treatment Day 0	Visit 2 2 weeks	Visit 3 4 -6Weeks	Visit 4 8-10 Weeks	Visit 5 3 Months	Visit 6 6 Months
Informed Consent	X						
Demographics	X						
Medical History	X						
Physical Exam	X						
Device / Procedure Related Adverse Events		X					
Surgical Details		X					
Patient Reported Forms (i.e.. VAS)		X					
X-ray	X		X	X	X	X	X
MRI							
CT							
Add additional info below (if applicable)							

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