Short term results of a novel suture-button construct for acute ankle syndesmotic injuries

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Abstract

Introduction
The importance of the syndesmosis in ankle stability is well recognized. Numerous means of fixation were described for syndesmotic injuries including the suture button technique. Owing to cost-effectiveness issues, it is difficult to use the commercially available options freely in our institution. We, eventually, designed an alternative construct.

Patients and methods
In this study, we aim to assess the results of using a novel suture-button construct in treatment of syndesmotic ankle injuries. Fifty-four - 34 males and 18 females- patients fulfilled our preset inclusion/exclusion criteria. Seven patients were lost during follow-up. The remaining 47 patients were successfully followed up to a minimum of 24 months.

Results
The American Orthopedic Foot and Ankle Society scores (AOFAS) improved significantly from a mean of 32.4 to 94.5 (p 0.005). Radiologically, the medial clear space (MCS), tibio-fibular clear space (TFCS) and tibio-fibular overlap (TFO) measurements showed a significant improvement postoperatively (p 0.005). Patients showed good satisfaction rate with 96% survival rate (95% CI: 94.0% to 99.3%).

Conclusion
This novel suture button construct is an efficient and safe treatment option for acute syndesmotic injuries. Good anatomical reduction and durable physiologic fixation of the syndesmosis were achieved with this technique.

Key words
ankle trauma, ankle syndesmotic injury, suture button technique.

Introduction

The distal tibiofibular syndesmosis is considered crucial for ankle stability which is compulsory for adequate weight transmission and, subsequently, walking. The syndesmosis encompasses the anterior-inferior tibiofibular ligament, posterior-inferior tibiofibular ligament, inferior transverse tibiofibular ligament, and the interosseous ligament. This complex steadies the mortise by securing the fibula in the fibular notch [1-3]. Syndesmotic injuries are frequently associated with malleolar fractures [1], nevertheless, it may occur independently without these fractures especially in sports injuries [4,5].

Syndesmotic injuries ought to be transfixed if found unstable after fixation of malleolar fractures to prevent instability and subsequently preclude the development of ankle osteoarthritis [OA]. Syndesmotic injuries are anticipated to occur in 10% of fractures around the ankle and up to 20% of fractures that requires operative intervention [6]. The standard fixation technique as recommended by the AO foundation is to transfix the syndesmosis by a 3.5 mm syndesmotic screw [7]. Numerous means of fixation were described over the years including the suture button technique. Recently, fixation by the suture button technique, also known as Tightrope, was initially popularized commercially by Arthrex (Arthrex Inc., Naples, FL, USA). Recent in-vitro biomechanical studies have advocated this technique as a sturdy mean of fixation and it was purported to be as potent as syndesmotic screws mechanically. This method allowed more flexibility resulting in a physiologic movement of the distal tibiofibular joint as demonstrated in some studies [8, 9]. Owing to cost-effectiveness issues, it is arduous to use the commercially available options easily in our institution. Consequently, the need to design an alternative similar construct was substantial.

Our assembly comprised a couple of two-holed mini plates deployed as buttons and polyester braided (No.5) surgical sutures as ropes. In this study, we aim to assess the results of using a simply fashioned suture-button construct in treatment of syndesmotic an-

kle injuries. Thus it provides a newly modified notion for treating these injuries with a minimally invasive, secure, physiologic and more economic technique. Moreover, by using this technique early weight bearing can be safely allowed, and the need of another operation for removal of the hardware is reduced.

Our aim is to describe a novel Suture-Button Construct for Acute Ankle Syndesmotic Injuries. Additionally, we aim is to evaluate the effectiveness of the suture-button assembly described here in treating distal tibiofibular syndesmotic diastasis injuries.

Patients and Methods

This study was carried prospectively between January 2011 and April 2012. Fifty-four patients were recruited for this study (35 males and 19 females) with a mean age of 38.2 (18-55) years. Seven patients were either withdrawn or lost to follow-up while the remaining 47 patients continued their regular follow-up up to a minimum of two years post surgery. The study was carried out in in our trauma center serving a 5 million population, after being approved by our institutional research board (IRB). This study was carried out as a multi-surgeon single centre study, using the same technique in all recruited patients.

The study received approval by the Research Ethics Board at our institution before its initiation. A minimum 24-months post-operative follow-up period for each patient was originally envisaged. We report a mean follow-up of 26.35 (24 to 32) months. 47 patients fulfilled our pre-set selection criteria. Our inclusion criteria included male and female patients in all age groups presented to our institution with distal tibiofibular syndesmotic diastasis injuries with or without the association of ankle malleolar fractures, without medical contraindications to surgery, and were committed to provide informed consent. All patients had syndesmotic diastasis injuries that were radiologically determined by a tibiofibular clear space (TFCS) more than 6.0 mm on the anteroposterior or mortise radiographs, medial clear space (MCS) more than superior clear space or 5.0 mm on the anteroposterior radiographs, or tibiofibular overlap (TFOL) less than 6.0 mm on the anteroposterior radiograph or less than 1.0 mm on the mortise radiographs [1, 7]

The exclusion criteria were patients with pathological fractures, open or potentially infected ankle fractures, multiple injuries in the same limb, uncontrolled diabetes mellitus, neuropathic arthropathy or Charcot joint patients, neuropsychiatric and other disorders that may let patients unable to comply with instructions. All patients were given information sheet and asked to sign consent prior to inclusion to the study. All patients were invited to complete an American Orthopaedic Foot and Ankle Society (AOFAS) ankle scores prior to and at one and two-year interval post-surgery. Both (M.N.) and (A.M.) assessed the eligibility of all patients pre-operatively before recruitment in the study.

Construct Structure:

We used polyester braided Ethibond (size 5) sterile surgical sutures and a pair of mini plates (size 2 mm) with two holes. Polygalactin 910 sutures Vicryl (size No.2), drill pit 4 mm, and 15cm long suture needle with slotted end were additionally required. The assembly was intraoperatively fashioned using comprehensive aseptic technique. Two polyester ropes were delivered through the two holes of the first plate; by using the folding technique four threads were recruited to transfix the syndesmosis. Afterwards, we utilized the Vicryl sutures as temporary guiding ropes to deliver the main passing plate. This was achieved by knotting a single thread at both tips of this plate (Fig 1: A, B, and C).

a  b  c 

Figure 1: A- Preparation of the construct before application. A- A slotted 15 cm straight needle was lodged by the double Vicryl guiding threads and passed through this tunnel until retrieved percutaneously from the medial aspect of the tibia.1B- Assembly of the construct. 1C- Construct passed through both the tibia and fibula.

Surgical technique and postoperative care:

Pre-operative antibiotics and antibiotic regimens were the same as per local trauma protocol. All operations were performed in laminar airflow theatres. Post-operative rehabilitation regimens were carried out at the same manner for all patients. Using spinal anesthesia, patients were positioned supine on the operative table. Initially a tourniquet is applied at a pressure of 300 mmHg. The associated fractures, if present, were fixed using the standard AO philosophies of osteosynthesis. Spontaneous reduction of ankle syndesmotic diastasis usually ensues after open reduction and internal fixation (ORIF) of malleolar fractures. Nevertheless, some diastasis remains disrupted after the ORIF of associated fractures, which was reduced primarily with reduction clamps. If no fracture exists, an incision of approximately 2-3 cm is made on the lateral aspect of the fibula, about 2-5 cm proximal to the plafond level. This is followed by drilling of a tibiofibular tunnel with a diameter of 4 mm parallel to and away from joint line for about 2-5 cm in a direction that is 30° posteroanterior in the horizontal plane from fibula to tibia. These steps were performed guided by fluoroscopic image intensifier. Afterwards, the slotted 15 cm straight needle was lodged by the double Vicryl guiding threads and passed through this tunnel until retrieved percutaneously from the medial aspect of the tibia. By pulling one of the two threads the plate could be directed through the tunnel until passing out on the medial aspect. Thereafter, pulling the other thread would secure the plate transversely anchoring on the medial tibial cortex. Finally, the polyester threads were passed through the second mini plate on the fibular side (two threads on each hole) and were knotted tightly together on the plate if satisfactory syndesmotic reduction is achieved (Fig. 2 and 3). Wound closure after cutting off the remaining vicryl threads was done and patients were immobilized in a below knee plaster cast for the first two weeks. Partial weight bearing in a walking cast or air cast boot was allowed directly post-surgery if no fractures was associated. Nonetheless, if associated malleolar fractures were present, the patient was kept non-weight bearing for four weeks. Full weight bearing was started six weeks postoperatively.

Clinical and radiological assessment:

The cohort of patients was followed up in the fracture clinic in a regularly scheduled fashion (at 6 weeks, 6 months, 12 months and 24 months) postoperatively. Final clinical and radiographic evaluation was undertaken at 24 months. AOFAS ankle hindfoot scores evaluated the clinical outcome of the operated ankles. Radiologically, Syndesmotic competency was checked-up by measuring TFCS, TFOL and MCS on the radiographs of the affected ankles by two independent observers.

Figure 2: Post-Operative Radiograph of the construct in isolated syndesmotic injury 2A- Antro Posterior View 2B- Lateral view

Figure 3: Post-Operative Radiograph of the construct in syndesmotic injury associated with Lateral Malleolus fracture 3A- Antro Posterior View 3B- Lateral view

Statistical analysis:

The data were collected, tabulated and analyzed using the "Statistical Package for the Social Sciences (SPSS) 16 for windows program. Student t-tests was used to compare the improvement of the ankle scores pre and postoperatively. AP value < 0.05 is considered to be statistically significant.

Results

None of the patients died in the first two years, while seven patients were lost to follow-up. The remaining 47 ankles (28 right and 19 left) were successfully evaluated up to two years. The mean age of patients was 38.2 (18-55) years at time of surgery. The mechanism of injury was falls, road traffic accident and sports injuries in 13, 22 and 12 patients, respectively. Nine patients presented by pure syndesmotic disruption, while the remaining 38 patients had associated malleolar fractures. All patients were full weight bearing comfortably after being immobilized for 6 weeks in a below knee cast postoperatively. The AOFAS score improved significantly from 32.4 (range 21.3-37.2) preoperatively to 94.5 (range 84-98) at 2 years post-surgery (p 0.005).

There were two documented superficial wound infections post-surgery treated successfully with Antibiotics. None required a second surgery. One patient required treatment for deep venous thrombosis. Revision was undertaken as a result of implant failure in two ankles. The first revision was carried out after 10 days in a non-compliant 45-year-old man with a Body Mass Index of 44. He started weight bearing immediately after having an ORIF of a bimalleolar fracture. The patient sustained a fall on the 10th day postoperatively. Revision surgery was carried out to restore of anatomical reduction using a syndesmotic screw.

The second case, was 36-year-old woman, who was revised at 5 weeks. She was one of our early cases recruited in the study, presenting with an isolated syndesmotic injury. Marked widening of the MCS during the direct post- operative follow up X-rays was observed. This failure of syndesmotic reduction was attributed partly to a missed deltoid ligament disruption and additionally due to imperfect tightening of the threads. Repairing of the deltoid ligament, hardware removal and fixation with a syndesmotic screw was undertaken to revise the fixation.

A complete radiographic series was available for 44 ankles (44 patients). The distance of sutures from tibial plafond had a mean of 25.5 (23.2 - 34.3) mm. The MCS significantly decreased from 8.8 (6.7-12.8) mm preoperatively to 3.2 (range 2.6 - 4.1) mm at two years postoperatively (p 0.05). Similarly, The TFCS significantly decreased from a mean of 9.2 mm (6.9-11.8) preoperatively to mean of 4.2 mm (range 3.3-5.2) at two years postoperatively (p 0.05). The TFO in the AP view significantly improved from a mean of 2 (0-5.5) mm preoperatively to a mean of 8 (7-9) mm (p 0.01). Finally, excluding the two revisions, none of the ankles demonstrated evidence of nonunion radiologically. As yet, by using this simple cost-effective minimally invasive technique our patients showed good satisfaction rate with 96% survival rate (95% CI: 94.0% to 99.3%) as shown in (Fig.4).

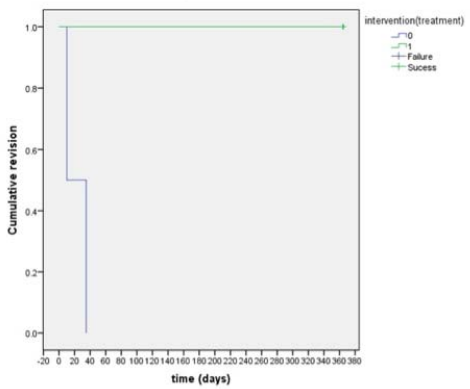

Figure 4: The Kaplan Meier estimate of the percentage of patients free from revision at 2 years was 96% survival rate (95% CI: 94.0% to 99.3%)

Discussion

We have observed excellent survivorship of 47 novel cost effective Suture-Button construct for acute ankle syndesmotic injuries at two-year follow-up. We report a survival rate of 96 % for the reported assembly. The suture button system utilization for management of syndesmotic ruptures has increased swiftly in the last few years. Suture button transfixation of ankle syndesmotic injuries has been proposed as an alternative solution to syndesmotic screws. It provides superior physiological properties when compared to standard syndesmotic screw fixation method [3,8-10].

Cadaveric studies demonstrated that the use of suture button technique provide similar biomechanical strength yielded by screw fixation [10,11]. Lately, it has been reported that Suture button is used in about 10% of all surgical interventions indicated in syndesmotic disruptions in the United States [12]. It provides the required flexibility for the normal gliding movement of the distal tibiofibular joint fort [3,8]. Subsequently, It would lead to faster return to work with comparable outcome compared the both the syndesmotic screw and the bolt fixation [13]

Recently, a systematic review done by Schepers displayed similar AOFAS outcome scores for the management of syndesmotic injuries with a mean of 89 points when the Tight-Rope system was used compared to 86 points when screw fixation was used. The follow-up was 2.2 times longer in the screw group [3]. The rate of implant removal is lower than in the syndesmotic screw group. There is currently insufficient evidence on the long-term effects of the Tight-Rope and more uniform outcome reporting is desirable.

In one study, fixation of syndesmotic injuries using suture button technique, yielded to an AOFAS score of 89.1 postoperatively, at a mean of 19 months post-surgery, compared to 86.3 at 42 months follow-up when the standard syndesmotic screw fixation method was utilized [3,7]. We achieved a mean AOFAS score of 94.5, using our technique at 24 months follow-up.

The need of implant removal was reported broadly in both the Suture button and the syndesmotic screw groups. 22/220 (10%) patients treated with a Tight Rope compared to 449/866 (51.9%) patients treated with a syndesmotic screw or bolt required implant removal with an average follow-up of 16 and 24 months respectively [3]. Furthermore, the relative early rehabilitation together with the absence of the need to remove hardware made this procedure more attractive [10,13]. There is still an ongoing debate on whether to remove the screw or not, which diameter to use and the length to utilize. A common complica-

tion that is seen in everyday practice is the breakage of the screw breakage and the fear of the resulting stiffness. Nonetheless, Schepers published a review of literature about whether to retain or remove the syndesmotic screw. He concluded that there is no functional difference in patients with retained or removed screws [14]. The presence of reported complications ensuing screw removal as recurrent diastasis and infection is also a source of concern [5,15]. Jordan et al undertook a radiological study to gauge the changes of the tibiofibular position and the ankle mortise after removal of syndesmotic screws. They reported high association of integrity loss of the syndesmotic parameters after screw removal [16].

We report two ankles with superficial infection and implant failures in two patients. Complications of stitch abscess, osteomyelitis, painful aseptic osteolysis, Polyethylene debris osteolysis reaction and implant failures have been reported previously [17,18]. Degroot et al recommended guidelines to optimize the surgical technique to avoid these complications. The authors proposed cutting the FiberWire at least 1 cm beyond the knot, so as its sharp end rest flat bordering to the fibula. They also recommended utilizing a small medial incision so as to place the endobutton directly on the tibial cortex to avoid soft tissue interposition, thus precluding rediastasis. In addition, they advocated introducing the tightRope throughout a fibula plate, to elude lateral button pull-through and subsequently rediastasis [17].

Degroot et al evaluated the outcome of suture button technique when used for fixation of syndesmotic injuries at a mean follow-up of 20 months. They reported that the clinical and radiological measurements were improved and returned to normal values for the entire study group postoperatively. Nonetheless, one in four patients required removal of the suture button device due to local irritation or lack of motion. Three patients showed heterotopic ossification, and implant failure due to osteolysis, which was evident in four patients [18]. Dissimilarly, these complications were not observed in our study. However, in our study group complications of failure of fixation in two patients were recorded.

We suppose that more time may be required to reveal similar complications. Although the fact that our simple technique provided us with advantages like decreased cost with increased efficacy, but there are drawbacks. Time consumption - for kit preparation - was one of the major drawbacks of this technique. Additionally, syndesmotic reduction was also difficult using this mounting solely; yet, reduction clamps were satisfactory enough for reduction percutaneously before transfixation with suture button.

On the other hand, Suture buttons were considered more expensive when compared to the sydesmotic screw technique. Nowadays the aging population cause increased pressures on healthcare budgets. In this environment, funders of trauma surgery need to identify the patients for whom surgical intervention will provide most benefit at reasonable expenses. The analysis of the cost-effectiveness of the usage of the suture-button device for the treatment of syndesmostic injuries is scarce. Our proposed technique offers an alternative solution with the same biomechanical and physiological basis but more cost effective. A major advantage of the described technique in this study is the cost-effectiveness aspect. The cost of this construct is about 45 dollars compared to 625 dollars, which is the cost of the commercial available alternative provided by Arthrex (Arthrex Inc., Naples, FL, USA) in our institution. This reduced the expenses for the 54 constructs recruited in this study from 33750 dollars to 2430 dollars. Accordingly, using our construct was significantly cheaper ($p<0.001$). Also, avoidance of the second procedure to remove the screw will save an extra 400 dollars, when the suture button technique is used.

Convincingly, we only used a single construct in all patients, and the need for duplication was not required among this series. As yet, to our knowledge, this technique was not described before. Longer follow-up studies are required for evaluation of the adequacy of this novel technique. Additionally, the next step would be undertaking a biomechanical study to assess the biomechanical adequacy of our construct. We are currently laying down the protocol for a cadaveric study to assess the biomechanical adequacy of this novel construct. We are aiming to undertake a Randomized Controlled trial comparing our technique to the utilization of a syndesmotic screw fixation in management of acute syndesmotic injuries.

Limitations of the study:

A limitation of this study is that MR images were not available for all patients after surgery, to assess the degree of healing of the syndesmosis. Also, we did not study some variables including duration of symptoms, onset of Workers' Compensation, and pending litigation, which might affect the final outcome after surgery. Also, we did not have a control group in which the gold standard (Syndesmotic screw) is used for management of similar injuries.

Conclusions

In the present healthcare financial era, enhanced efficiency and appropriate application of existing re-

sources is crucial. We report excellent survivorship of 47 novel cost-effective efficient Suture-Button constructs for management of acute ankle syndesmotic injuries at two-year follow-up. This Suture button technique delivered satisfactory anatomical reduction and durable physiologic fixation of the syndesmosis. By using this simple economic technique our patients established good degree of function with no need to remove this hardware, as yet.

Competing interests:

This work was funded by Suez Canal University Hospitals. All authors read and approved the final manuscript. The authors declare that they have no competing interests. We would like to thank Dr Ahmed Maaty for undertaking statistical analysis for this study.

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