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Original article

Comparative Study between Syndesmotic Rupture Treated by Suture-Button and Syndesmosis Screw

Mahmoud K. Sharaf, El Sayed M. Ibrahim, Abd El Hamid A. Hussein, Ahmed R. Khames

Department of Orthopaedic Surgery, Faculty of Medicine Benha University, Egypt.

Corresponding to: Abd El Hamid A. Hussein, Department of, Orthopaedic Surgery, Faculty of Medicine, Benha University, Egypt.

Email:

abdoelnems1989@gmail.com

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Abstract

Background: Syndesmosis injury and rupture is quite common in Lauge–Hansen external-rotation type ankle fractures (ERAF). The injured syndesmosis may remain unstable even the fractures are well reduced and fixed. The aim of this work is to compare between Suture-Button and Syndesmosis Screw as treatment of Syndesmotic Rupture. **Methods:** This prospective randomized study was conducted on Forty patients with ankle fracture admitted to Orthopedic Surgery unit., at Benha University Hospitals from Jan 2022 to September 2023. Forty Patients were randomly enrolled, the allocation of the patients into each group was done using a 1:1 computer-generated sequencing placed in sealed envelopes into three groups: Group A SS (N=20): patients were treated with Syndesmosis Screw, Group B SB (N=20): patients were treated with Suture-Button. **Results:** Regarding the mean total score of The American Orthopaedic Foot & Ankle Society (AOFAS), at 3 months, the mean score in group A was 58.5±12.9 and in group B was 64.75±10.9 with p-value 0.05(p-value ≤0.05 is statistically significant). At 6 months, the mean total score in group A was 86.95±11.45 and in group B was 94.15±5.35 with p-value 0.005.**Conclusions:** The dynamic fixation of acute syndesmosis injuries by tightrope gives better clinical outcomes than static fixation at 3 and 6 months follow up. the implant offers adequate syndesmosis stabilization without the risk of screw breakage. Also, it decreases the reoperation rate.

Keywords: Syndesmotic, Rupture, Suture-Button, Syndesmosis Screw.

Introduction

Syndesmotic injuries account for a significant number of ankle injuries, especially in athletic patient populations, with observed incidences as high as 25% in certain sport specific cohorts. The treatment of such injuries ranges from non-operative management of mild injuries to allograft reconstruction for injuries that result in chronic pain and instability [1].

Syndesmosis injury and rupture is quite common in Lauge–Hansen external-rotation type ankle fractures (ERAF). The injured syndesmosis may remain unstable even the fractures are well reduced and fixed. The gold-standard treatment for syndesmotic instability is trans-syndesmosis screw fixation. However, this method is a static fixation and becomes controversial currently because it has a high complication concern and could lead to biomechanics alteration and micro-motion restriction of syndesmosis, which may increase posttraumatic arthritis rate [2].

Therefore, flexible/dynamic fixation has been advocated in more recent literatures, and more effective treatment methods with less complications are expected in the future. The distal syndesmosis is mainly stabilized by syndesmotic ligament complex, in which anterior-inferior tibiofibular ligament (AITFL) and posterior-inferior tibiofibular ligament (PITFL) play the most important roles [3].

In most ERAF, syndesmosis becomes unstable due to the rupture or dysfunction of AITFL and PITFL. Nevertheless, PITFL is rarely ruptured when posterior malleolus is avulsed, and fixation of posterior malleolus fracture will restore the normal function of PITFL. Once the posterior fracture is well fixed, the residual syndesmotic instability in those ERAF mainly results from the AITFL rupture [4].

The current standard operative practice achieves reduction of the syndesmosis via proximally placed trans osseous fixation devices, most commonly using syndesmotic screw (SS) or suture-button (SB) constructs [5].

Syndesmotic screw (SS) is the conventional approach to syndesmotic stabilization. Screw sizes vary from 3.5mm to 6.0mm and can involve either 3 or 4 cortical fixation. Screw fixation may be associated with complications including non-anatomic reduction, metal ware irritation, broken and loose screws and limited range of motion [6].

Suture-button (SB) technique was developed to address some concerns of the SS technique; potential advantages include allowing physiological movement of the syndesmosis, anatomic healing, the ability to commence earlier rehabilitation, and typically avoiding implant removal [7].

The aim of this work is to compare between Suture-Button and Syndesmosis Screw as treatment of Syndesmotic Rupture.

Patients and Methods

This prospective randomized study was conducted on forty patients with ankle fracture admitted to Orthopedic Surgery unit., at Benha University Hospital, from Jan 2022 to September 2023. The study was presented to the research Ethics

Committee of Faculty of Medicine Benha University with approval code (MS 15-10-2022). Informed consent was obtained from the patients before participating in this study.

Study Location: Benha University Hospital

Inclusion criteria were patients aged 18 years to 70 years, patients suffering from an acute syndesmotic injury, patients with or without an OTA/AO type 44 C ankle fracture, ankle fracture with unstable syndesmotic injury.

Exclusion criteria were poly-trauma, open fracture, symptomatic ankle osteoarthritis, neurologic impairment of the lower extremities, vascular injuries, and non-united and mal-united fractures.

Randomization

Forty patients were randomly enrolled, the allocation of the patients into each group was done using a 1:1 computer-generated sequencing placed in sealed envelopes into three groups:

Group A SS (N=20): patients were treated with Syndesmosis Screw, Group B SB (N=20): patients were treated with Suture-Button.

All patients were subjected to the following as complete history taking included (special habits of medical importance, mode of trauma, time of trauma, any history of co-morbidities as diabetes, hypertension, cardiac problems, renal impairment and any allergies), complete examination included general and local examination, radiological investigations plain x-ray was done, A-P & lateral views of affected ankle and leg, and skeletal X- rays survey (chest, pelvis, cervical spine), CT scan was done in selected cases to determine the fracture pattern and the extension of the fracture to the articular surfaces, laboratory investigations included complete blood count (CBC), blood sugar, coagulation profile, and liver and kidney functions

Multidisciplinary consultations were done to control patients' comorbidities and anaesthesia consultation to check for surgical fitness and consent for general anaesthesia. All patients were consented for surgery, possible risks, complication and follow up protocol.

All patients in the study were anesthetized by either general anaesthesia or spinal anaesthesia. Prophylactic broad-spectrum antibiotic (3rd generation cephalosporin) was taken with induction of anaesthesia. Operative time, intraoperative complications were documented in the patient notes.

Surgical technique:

All patients were positioned supine with a sandbag under the affected buttock; tourniquet was placed at the level of the proximal thigh. The image intensifier passage and position were planned, direct lateral approach to distal fibula was done in 10 cases, combined direct medial approach to medial malleolus and direct lateral approach were done in 28 cases and a small incision was done in 2 cases of isolated syndesmosis injury.

Direct lateral approach: a longitudinal direct lateral incision in line with fibula, the dissection plane is between peroneus tertius anteriorly and peroneus longus and

brevis posteriorly, bone exposure was done and soft tissues which interferes with accurate reduction was removed.

Direct medial approach: A longitudinal incision of 10cm was centered directly over the medial malleolus, saphenous vein and nerve were identified and protected, periosteum at the edges of the fracture was elevated and loose bodies inside fracture site were removed with protection of tibialis posterior tendon. For isolated syndesmosis injury: Under fluoroscopy, site of insertion at the central fibula was localized, about 2 cm proximal of the joint line. The skin was incised vertically over about 2 cm and the bony surface of the fibula was prepared and exposed.

Fracture reduction and fixation, lateral malleolus fracture reduction and fixation; The fracture is reduced anatomically. Reduction of both length and rotation was done. A 3.5 mm cortical screw was inserted as a lag screw in some cases

Medial malleolus fracture reduction and fixation; Fracture was reduced anatomically by use of bone clamp; fixation was done either by 2 malleolar screws (4 mm partially threaded screws) or tension band and wiring Syndesmosis reduction and fixation. After ankle fractures fixation and under fluoroscopy the syndesmosis was tested by pulling the fibula laterally using bone hook or bone clamp, then syndesmosis was reduced with pointed reduction clamp.

Syndesmosis fixation: In all cases, syndesmosis screw or tightrope were just proximal to the inferior tibiofibular joint, 30 degrees from posterior to anterior, parallel to the tibial plafond, with the ankle joint in neutral position.

Syndesmosis stabilization by using a 3.5 mm cortical screw: In 20 cases, a 2.5 mm hole was drilled through the lateral cortex of the fibula either from a hole in the plate or from outside it.

The Tightrope device was inserted, and the long needle brought through the skin on the medial side without skin incision, and the button can be flipped easily under the skin using fibre wire sutures attached to the medial button and the lateral button was pulled down to the bone. After removal of the medial needle including the sutures, the pulley was tightened to complete reduction of the tibiofibular joint and then Tightrope was fixed by knots and knots were cut

All patients were assessed postoperatively by wounds closure, below knee slab was applied, limb was elevated, and neurovascular status was examined. Immediate post-operative x rays were done, ankle x ray AP, lateral and mortise views. Patients were prescribed anti-coagulants, intravenous antibiotics, analgesics and anti-oedematous medications.

All patients were followed up at 2 weeks by (removal of stitches, discontinue oral antibiotics, and superficial and deep infection assessment), at 6 weeks by x rays were obtained (ankle x ray AP, lateral views) and radiological assessment, range of motion assessment, syndesmosis screw was removed in screw group under local anaesthesia and sedation, below knee slab was removed and ankle motion was encouraged, and physiotherapy started in the form of ROM exercises and partial weight bearing according to degree of union), at 12 weeks by (all patients were

instructed to start full weight bearing on affected ankle, assessment by AOFAS hindfoot functional score), at 24 weeks by (assessment by AOFAS hindfoot functional score).

Outcomes

The American Orthopaedic Foot and Ankle Society (AOFAS) ankle-hind foot scale. The AOFAS scale is subdivided into subjective and objective categories scored together. AOFAS score range from 0 to 100, with higher scores indicating better function.

Statistical analysis:

Statistical analysis was done by SPSS v26 (IBM Inc., Armonk, NY, USA). Quantitative variables were presented as mean and standard deviation (SD). Qualitative variables were presented as frequency and percentage (%). Pre and postoperative readings were compared using paired Student's t- test. A two tailed P value ≤ 0.05 was considered statistically significant.

Results

The Mean of age of the studied cases were 26.8±4.67 in group A and 28.2±6.3 in group B.

The study included 32 Males, and 8 Females distributed in both groups, in group A, the ratio was 15:5 and 17:3 in group B. 85 % of patients included in study had no co-morbidities,2 patients had hypertension and diabetes mellitus, 1 patient had diabetes mellitus, and 1 patient had Neuromuscular disorder. There was no statistically significant difference between the two groups regarding age, gender, occupation and comorbidities. **Table 1**

Regarding trauma characteristics, twenty-one patients had bi-malleolar fracture and according to Lauge-Hansen classification thirty-two cases came under the category of external rotation injuries. There was no statistically significant difference between the two groups regarding descriptive or Lauge-Hansen classifications and clinical findings Twenty-nine cases had mild foot swelling, 9 cases had severe swelling, 25 cases were operated within 24 hours and 11 cases were operated after 1 week. According to the type of anaesthesia during the surgery, 23 cases received Spinal anaesthesia and 17 cases received general anaesthesia with no statistically significant difference between the two groups. **Table 2**

AOFAS score pain, function and alignment respectively after 12 weeks were 24, 25.1 and 9.90 among group A (screw group) and 25, 30.55 and 9.9 respectively among group B (tightrope group). After 24 weeks mean among group A were 34.5, 42.65 and 9.8 respectively and 38.5, 45.25 and 9.9 among group B. Regarding the mean total score of AOFAS, at 3 months, the mean score in group A was 58.5±12.9 and in group B was 64.75±10.9 with p-value 0.05(p-value ≤0.05 is statistically significant). At 6 months, the mean total score in group A was 86.95±11.45 and in group B was 94.15±5.35 with p-value 0.005. **Table 3**

Regarding post-operative data, the highest rate of complications was for joint stiffness, it represented 22.5 % (9 cases), followed by CRPS and hardware failure

which represented 7.5% (3 cases) for each complication. Table 4

Joint stiffness, hardware failure, CRPS, superficial infection, implant irritation and hardware removal in group A were 5 patients (25%), 2 patients (10%), 2 patients (10%), 1 patient (5%) ,0 patients and 3 patients (15%) respectively, and were respectively in group B 4 patients (20%),1 patient (5%),1 patient (5%), 0 patients ,1 patient (5%) and 0 patients. Complications were lower in the tightrope group than in screw group and this was statistically significant. **Table 5**

Table 1: Demographic characteristics among the studied group

Socio demographic	Classes of Variables	N (%)	Group A	Group B	p-value
Age	**20-30 Y**	28 (70%)	13	15	1
	30-40 Y	7 (17%)	5	2	
	40-50 Y	5 (13%)	2	3	
Gender	**Male**	32 80%	15	17	0.105
	Female	8 (20%)	5	3	
Occupation	**Office**	15 (37.5%)	7	8	1
	Manual worker	20 (50%)	10	10	
	Housewife	5 (12.5%)	3	2	
Co-morbidities	**No Comorbidities**	34 (85%)	15	19	0.889
	HTN	2 (5%)	2	0	
	HTN & DM	2 (5%)	2	0	
	DM	1 (2.5%)	0	1	
	Neuromuscular disorder	1 (2.5%)	1	0	

Data presented as mean ± SD or number (%) *: statistically significant as P value <0.05, BMI: body mass index, HTN: hypertension, DM: diabetes mellitus

Table 2: Pre-operative data and Clinical findings

	Classes of Variables	Group A	Group B	p-value
Assessment of swelling and skin condition	**Mild**	14	15	0.5
	Moderate	1	1	
	Severe	5	4	
Tuning of surgery	**Within 24 hours**	8	17	0.5
	Within 48 hours	3	0	
	After 1 week	9	2	
	After 2 weeks	0	1	
Trauma characteristics				
Anatomical/descriptive	**Lateral malleolus fracture**	6	8	0.5
	Bi-malleolus fracture	11	10	
	Tri-malleolus fracture	1	0	
	Fracture / Dislocation	1	1	
	Isolated syndesmosis Injury	1	1	
According to Lauge-Hansen classification of ankle injuries	**Supination external rotation**	11	10	0.5
	Pronation external rotation	5	6	
	Pronation abduction	3	3	

Data presented as mean ± SD or number (%) *: statistically significant as P value <0.05

Table 3: AOFAS score among studied groups

WEEK	GROUP	Pain	Function	Alignment	Total	p-value
AOFAS 12 weeks after surgery	Group A (screw) (N=20)	24 ± 5.026	25.1 ±10.09	9.90 ±0.447	58.5 ±12.9	0.05
	Group B (Tightrope) (N=20)	34.5 ± 6.04	42.65 ± 3.20	9.8 ±0.61	86.95±11.45	
AOFAS 24 weeks after surgery	Group A (screw) (N=20)	25 ± 5.11	30.55 ± 9.05	9.9 ± 0.44	64.75 ± 10.9	0.005
	Group B (Tightrope) (N=20)	38.5 ± 3.66	45.25 ± 4.11	9.9 ± 0.44	94.15 ± 5.35	

Data presented as mean ± SD or number (%) *: statistically significant as P value <0.05 AOFAS: American Orthopedic Foot and Ankle Score.

Table 4: Post-operative data among studied groups

	Classes of Variables	N
Immediate post-operative	Low grade fever	**1**
	Neurovascular affection	**0**
	Infection (Superficial)	**1**
Two weeks post-operative	Hardware failure	**1**
	CRPS (Complex Regional Pain Syndrome)	**2**
	Ankle Stiffness	**9**
6 weeks post-operative	CRPS	**1**
12 weeks post-operative	Hardware failure	**2**
24 weeks post-operative	Implant irritation	**1**

Data presented as mean ± SD *: statistically significant as P value <0.05, CRPS: Complex Regional Pain Syndrome

Table 5: Complications among studied groups

	Screw Group A	Tightrope Group B	p-value
	N (%)		0.0421
Joint Stiffness	**5 (25%)**	**4 (20%)**	
Hardware failure/mal reduction	**2 (10%)**	**1 (5%)**	
CRPS	**2 (10%)**	**1 (5%)**	
Superficial infection	**1 (5%)**	**0 (0%)**	
Implant irritation	**0 (0%)**	**1 (5%)**	
Hardware removal	**3 (15%)**	**0 (0%)**	

Data presented as number (%) *: statistically significant as P value <0.05, CRPS: Complex Regional Pain Syndrome

Cases

Case 1

36 years old female, presented with fracture dislocation of ankle and syndesmosis injury after twisting trauma, two days later, fixed with SB. Started full weight bearing after 2 months. Time to union was 3 months. - At 6 weeks, the AOFAS was 65. - At 3 months, the AOFAS was 77 at 6 months, AOFAS improved to be 89.

Figure 1: (A): Preoperative X-ray, (B): Post-operative immediately X-ray, (C): Post-operative after 6 weeks, (D):Post-operative after 6 months

Case 2

53 years old female patient presented after twisting injury with SER fixed with SB after 3 days. Started full weight bearing after 3 months. Time to union was 3 months. At 3 months, the AOFAS was 74. At 6 months, she improved markedly after 6 months to be AOFAS 91.

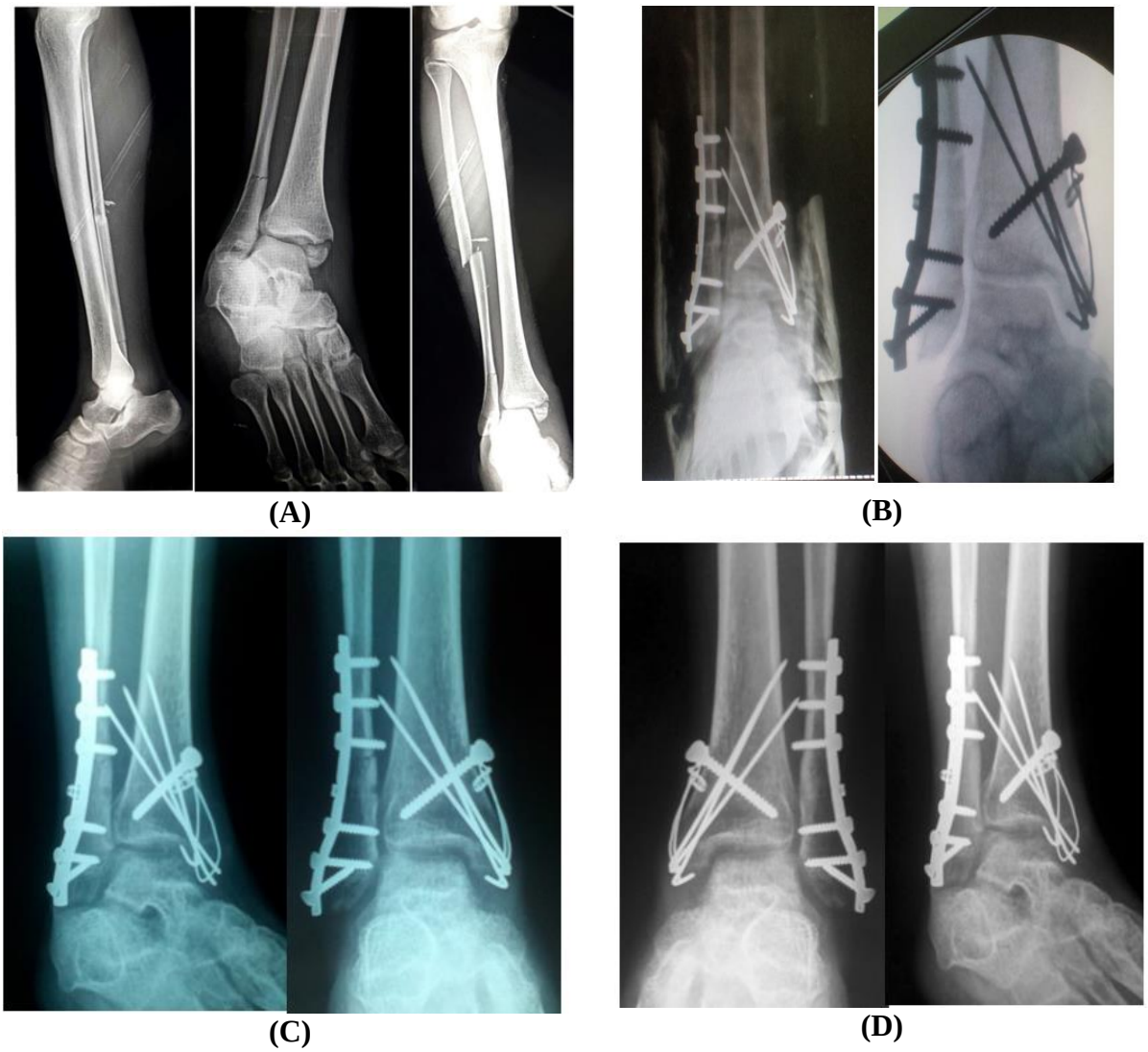

Figure 2:(A): Pre-operative X-ray, (B): Intra-operative and immediate post-op X-ray, (C): Post-operative after 3 months, (D): Post-operative after 6 months.

Discussion

Up to 20% of all ankle fractures form of operative fixation for syndesmosis injury [8].

syndesmotic screw fixation has traditionally been accomplished with transosseous screws, and it remains the most commonly utilized method of fixation for syndesmosis injury [9].

The suture button fixation technique was developed to address some concerns of the syndesmotic screw technique; potential advantages include allowing physiological movement of the syndesmosis, anatomic healing, the ability to commence earlier rehabilitation, and typically avoiding implant removal. Several randomized controlled trials recently showed that The mean age of patients in our study was younger than all other studies. This is probably due to different population characteristics, sports and level of activity. In agreement with other studies there was more males than females.

AOFAS Functional score, Seyhan et al.[10] conducted a study on 32 patients with syndesmosis injury 17 of them were

treated by 4.5 mm cortical screw and 15 patients were treated by tightrope. He found no statistically significant difference between the AOFAS scores in both groups. In disagreement with Seyhan et al.[10] We found that tightrope group AOFAS score was statistically better than screw group.

In agreement with Laflamme et al. [11] who compared clinical outcomes of patients treated by static or dynamic implant in acute syndesmosis injuries. the study included 65 patients and he found that dynamic fixation achieved better clinical outcomes as described with AOFAS especially at three months (p-value:0.016) with no significant difference at 6 months (p-value:0.26).

Thornes et al. [12] published a retrospective cohort study including 16 patients treated with suture-button implant and 16 patients treated with traditional screw fixation. The patients in the suture-button fixation group showed significantly better AOFAS scores at 3 months ($p = 0.01$) and at 12 months ($p = 0.04$) postoperatively and earlier return to work than the screw fixation group (2.8 months versus 4.6 months, $p = 0.02$). In addition, most of the patients were satisfied with the suture-button device while a greater number of fair or poor results existed in patients who had syndesmosis screw fixation. They concluded that the suture-button device could accelerate rehabilitation and improve outcomes.

Adding to the difficulty of comparison, all studies varied in implant which was used in fixation especially in screw group. Coetzee [13] used different types of screws 4,4.5and 6.5 mm screws. Kortekangas [14] used 3.5mm screw with 3 cortices engagement. Laflamme [11] used 3.5 mm screw with 4 cortices engagement. Colcus [15] used 3.5mm screw with 4 cortices engagement. Anderson [6] used 4.5 mm. In our study we used 3.5 mm screw with 3 or 4 cortices engagement.

In our study we have followed up patients till 6 months after surgery, we recommend long term studies to be done and also, we recommend comparative studies to each fracture type and age group.

Regarding complications; Kocadal et al. [16] conducted a retrospective study on 52 patients aged below 65 years and reported 1 patient with a low-grade infection in the suture-button fixation group, 3 patients developed joint stiffness and 1 patient with local irritation. In the screw group fixation 1 patient developed reflex sympathetic dystrophy and 10 cases of implant removal were reported.

Laflamme et al. [11] reported in his study in 2015 which was done on 65 cases with mean age 40 years old that in tightrope group 2 cases were infected and 2 cases of implant removal. But in screw fixation group only one case with hardware failure and no other complications were reported.

In agreement with Kocadal et al. [16] local irritation was reported in our study in tightrope group, hardware removal and failure were higher in screw group than in tightrope group and finally CRPS was reported in screw group with higher rate than tightrope group.

In disagreement with Laflamme [11] we found higher incidence of hardware removal in screw group than in tightrope group.

A meta-analysis study was done by Shimozono et al. [7] It was done on five clinical studies, allowing comparison between 143 patients in the suture button group and 142 patients in the syndesmotic screw group. The suture button group resulted in a lower rate of implant removal (6.0% vs.22.4%, p-value=0.01) and joint mal-reduction (0.8% vs. 11.5%, p-value =0.05) as compared with the screw group.

We recommended that further studies on larger sample size and on large geographical scale to emphasize our conclusion, based on our research, the suture-button fixation group had better functional outcomes (measured on the AOFAS score) and post-operative complication rate compared with the syndesmotic screw fixation group, so the suture-button device could lead to better objective range of motion measurements and earlier return to work. Besides, the suture-button fixation group had lower rate of implant removal, implant failure, and mal-reduction. The key aspects for future research we recommend cost-effectiveness study of the Tightrope.

As function outcomes are influenced by severity of trauma, presence of cartilage injury, soft tissue healing, and subjective sensation of patients and so on, it is more appropriate to assess syndesmotic injuries based on radiologic parameters rather than functional scores. The key point is the accurate anatomic reduction of the syndesmotic injuries. Thus, more high-quality studies comparing the reduction outcomes of screw fixation and suture-button fixation should focus on radiologic evaluation.

Conclusions: The dynamic fixation of acute syndesmosis injuries by tightrope gives better clinical outcomes than static fixation at 3 and 6 months follow up. The implant offers adequate syndesmosis stabilization without the risk of screw breakage. Also, it decreases the reoperation rate.

List of abbreviations:

ERAF	External-rotation type ankle fractures
CBC	Complete blood count
AOFAS	The American Orthopaedic Foot & Ankle Society
AITFL	Anterior-inferior tibiofibular ligament
PITFL	Posterior-inferior tibiofibular ligament
SS	Syndesmotic screw
SB	Suture-button
BMI	Body mass index
HTN	Hypertension
DM	Diabetes mellitus

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