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Efficacy and safety of dynamic fixation by Tightrope versus static fixation by conventional 3.5 mm cortical screw in patients with acute syndesmosis injuries

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***Abstract*---**Background: About 18% of all fractures are ankle fractures. Injury of the ankle with syndesmotic ligaments usually causes instability and may require specific intervention beyond the fixation of the fracture. The syndesmotic injuries, that are isolated without displacement, are not treated surgically. But those with concomitant fractures should be treated surgically. Aim of the study: To assess the outcomes of dynamic fixation by tightrope and static fixation by conventional 3.5 mm cortical screw in patients with acute syndesmosis injuries. Patients and methods: this is a clinical trial conducted on 40 patients with acute syndesmosis injuries recruited from January 2018 to September 2020. Patients were divided into two groups according to the type of treatment. The first group were treated with a conventional 3.5 mm conventional cortical screw (Group A) and the other group were treated by ORIF using an Arthrex tightrope (group B). Results: The average age of the included patients was 26.8±4.67 in Group A and 28.2±6.3 in Group B. The overall AOFAS score was significantly higher in patients in Group B than patients in Group A after 3 months of follow-up (64.75±10.9 versus 58.5±12.9,

respectively) P=0.05 and at 24 weeks follow-up (94.15±5.35 versus 86.95±11.45, respectively) P=0.005. Conclusion: 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*---**Ankle fracture, Ankle injury, syndesmosis, tightrope, screw.

Introduction

The most common cases treated by orthopedic surgeons are patients with acute ankle injuries (1). About 18% of all fractures are ankle fractures (2,3). Injury of the ankle with syndesmotic ligaments usually causes instability and may require specific intervention beyond the fixation of the fracture (4,5). The syndesmotic injury occurs in the form of hyperdorsiflexion of the supinated foot or pronated foot with external rotation of the ankle (6). About 23% of ankle fractures and 10% of all ankle sprains are associated with syndesmotic injuries (7). The rate of the syndesmotic injury with Pronation-external rotation ankle fractures is higher than the rate with supination-external rotation ankle fractures (8–10).

There are two options for the management of syndesmotic injuries. The syndesmotic injuries, that are isolated without displacement, are not treated surgically. But the syndesmotic injuries with concomitant fractures should be treated surgically (11,12). Two surgical options are primarily used for the management of syndesmotic injuries: (1) direct open reduction with posterior to anterior fixation or (2) indirect reduction with anterior to posterior fixation with lag screws (13). The last one is preferred as the surgeon is familiar with the approach and the supine positioning of the patient (14,15). However, recent studies demonstrated that direct reduction may provide better functional results than indirect reduction due to the fracture alignment accuracy and better compression with posterior to anterior fixation (16).

However, open reduction is associated with damage to adjacent tissue and postsurgical stiffness (17). Syndesmosis screw fixation may cause some problems such as stiffness, breakage, loosening, need for a second operation, and the risk of late diastasis after early removal (18). Tightrope is a relatively new technique for syndesmosis fixation. It comprises a non-absorbable FibreWire held tight between two cortical metal buttons. As the tightrope provides semirigid fixation of the syndesmosis, it obviates the need for routine removal of the implant and allows early weight-bearing (19).

The aim of the study is to assess the outcomes of dynamic fixation by tightrope and static fixation by conventional 3.5 mm cortical screw in patients with acute syndesmosis injuries.

Methods

We performed this clinical study on patients suffering from acute syndesmosis injuries from January 2018 to September 2020. We included forty patients suffering from acute syndesmosis injuries and divided them into two groups according to the type of treatment. the first group was treated with a conventional 3.5 mm cortical screw (Group A) and the other group was treated by ORIF using an Arthrex tightrope (group B).

Eligibility Criteria

Our inclusion criteria were: (1) the age of the patients range from twenty to sixty years, (2) patients who suffered from closed fracture, and (3) patients who are fit for surgery. On the other hand, our exclusion criteria were: (1) patients who had open fractures, (2) vascular injuries, (3) uncontrolled diabetes mellitus, (4) non-united and mal-united fractures, or (5) rheumatoid patients.

Pre-operative management protocol

First, we did a clinical evaluation of the included patients by taking a brief history including the personal data, name, age, sex, occupation, address, telephone number, special habits of medical importance, mode of trauma, time of trauma, any history of co-morbidities as diabetes, hypertension, cardiac problems, renal impairment, any allergies. After taking the history we did a general examination (ABCDE) and local examination of the injured limb. Second, we did some investigations such as x-ray and routine preoperative labs.

Preoperative preparations

All patients were immobilized in a below-knee slab to decrease pain and soft tissue injury. Multidisciplinary consultations were done and anesthesia consultations and all patients consented about the surgery, possible risks, complications, and follow-up protocol.

Surgical technique

In nine cases, we used the direct lateral approach to the distal fibula which is a longitudinal incision in line with the fibula. We used a combined direct lateral approach and direct medial approach to medial malleolus in 29 cases. In one case, we used a small incision as they had isolated syndesmosis injury. In another case, we used both a direct lateral approach and a small incision. The direct medial approach is a 10 cm longitudinal incision over the medial malleolus with good protection of the saphenous nerve and vein. We localized the site of insertion at the central fibula under the fluoroscopy for the isolated injury and we incised the skin vertically to expose the bony surface of the fibula.

The lateral malleolus fracture is reduced anatomically with the insertion of a 3.5 mm cortical screw as a lag screw in some cases and a fibular locked plate was used for the fixation as shown in figure 1. The medial malleolus fracture was reduced anatomically with two malleolar screws or tension band and wiring for

the fixation. After fixation of the ankle fracture, the fibula was pulled laterally by a bone clamp or bone hook to test the syndesmosis, then the reduction clamp was used for the reduction of the syndesmosis.

Figure 1: lag screw 3.5 mm insertion by drilling near cortex with 3.5 mm drill bit and far cortex with drill bit 2.5 mm.

Syndesmosis fixation

In group A, a 3.5 mm cortical screw was inserted quadricortical or tricortical through a 2.5 mm hole that was drilled in the lateral cortex of the fibula. In group B, two centimeters above the inferior tibiofibular joint and parallel to the tibial plafond a k-wire (guide wire) was inserted then over-drilled with a 4 mm cannulated drill. The TightRope device was inserted, and the long needle was brought through the skin on the medial side without a skin incision. We flipped the button under the skin by fiber wire sutures attached to the medial button and we pulled down the lateral button 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 as shown in figure 2.

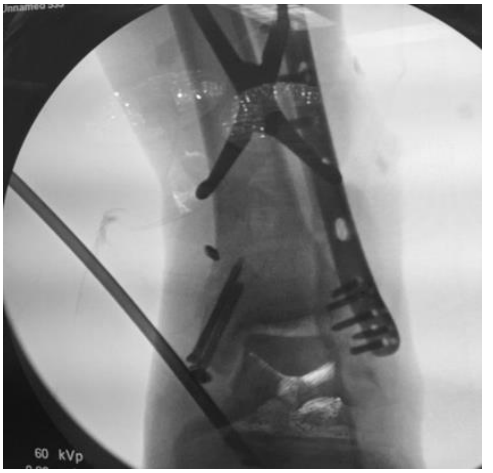

Figure 2: fluoroscopy image showing inserted tightrope through tibia and fibula.

Postoperative management

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

Follow up program

After two weeks, we removed the stitches, discontinued the oral antibiotics, and did superficial and deep infection assessment, and complex regional pain syndrome assessment. At six weeks, we did a new x-ray, and a range of motion assessment removed the screw and the slab, and physiotherapy started. At twelve weeks, all patients were instructed to start full weight-bearing on the affected ankle and were assessed by AOFAS hindfoot functional score. At 24 weeks, all patients were assessed by AOFAS hindfoot functional score (20).

Results

From January 2018 to September 2020, this study was conducted on 40 patients with acute syndesmosis injuries. 20 patients were treated by conventional 3.5 mm cortical screw (Group A) and other 20 patients were treated by ORIF using arthrex tightrope (Group B). The average age of the included patients was 26.8±4.67 in Group A and 28.2±6.3 in Group B. we included 32 males and 8 females distributed in both groups. 85% of patients included in the study had no co-morbidities (Table 2)

Table 1: Illustrates demographic characteristics of the included patients

Socio-demographic	Classes of Variables	Group A (N= 20)	Group B (N= 20)
Age	20-30 Y	13 (65%)	15 (75%)
	30-40 Y	5 (25%)	2 (10%)
	40-50 Y	2 (10%)	3 (15%)
Gender	Male	15 (75%)	17 (85%)
	Female	5 (25%)	3 (15%)
Occupation	Office	7 (35%)	8 (40%)
	Manual worker	10 (50%)	10 (50%)
	Housewife	3 (15%)	2 (10%)
Co-morbidities	No Comorbidities	15 (75%)	19 (95%)
	HTN	2 (10%)	0
	HTN & DM	2 (10%)	0
	DM	0	1 (5%)
	Epilepsy	1 (5%)	0

We included 21 patients with bi-malleolar fractures and according to Lauge-Hansen classification, thirty-two cases came under the category of external rotation injuries. 29 patients had mild foot swelling while nine cases had severe swelling (Table 2). Additionally, 25 patients were operated on within 24 hours and 11 patients were operated on after 1 week.

Table 2: shows trauma characteristics among study groups and pre-operative assessment data

Group B (N= 20)	Group A (N= 20)	Classes of Variables	
8 (40%)	6 (30%)	Lateral malleolus fracture	Anatomical/descriptive
10 (50%)	11 (55%)	Bi-malleolus fracture	
0	1 (5%)	Tri-malleolus fracture	
1 (5%)	1 (5%)	Fracture / Dislocation	
1 (5%)	1 (5%)	Isolated syndesmosis injury	
10 (50%)	11 (55%)	Supination external rotation	Lauge-Hansen classification of ankle injuries
6 (30%)	5 (25%)	Pronation external rotation	
3 (15%)	3 (15%)	Pronation abduction	
15 (75%)	14 (70%)	Mild	Foot swelling
1 (5%)	1 (5%)	Moderate	
4 (20%)	5 (25%)	Severe	

Data are presented as n (%), N= number

The American Orthopedic Foot-and-Ankle Society (AOFAS) rating system is considered the most important used foot and ankle scoring system by orthopedic surgeons and medical researchers. It assesses the foot and ankle condition through the following three scales, pain, function, and alignment. The combined score from the three scales ranges from 0 to 100. Healthy full-functioning ankles without pain receive 100 points (21,22). We found that AOFAS scores of pain,

function, and alignment after 12 weeks were 24, 25.1, and 9.90, respectively among patients in Group A while that of Group B were 25, 30.5, and 9.9 respectively among patients in Group B. After 24 weeks the AOFAS scores of pain, function, and alignment of patients in Group A were 34.5, 42.6, and 9.8, respectively. While the patients' scores in Group B were 38.5, 45.25, and 9.9, respectively. The overall AOFAS score was significantly higher in patients in Group B than patients in Group A after 3 months of follow-up (64.75±10.9 versus 58.5±12.9, respectively) P=0.05 and at 24 weeks follow-up (94.15±5.35 versus 86.95±11.45, respectively) P=0.005 as shown in Table 3 and Figure 1

Table 3: AOFAS score after 12 and 24 weeks in both studied groups

WEEK	GROUP		Pain	Function	Alignment	Total	p-value
AOFAS score 12 weeks after surgery	Group A (screw)	Mean	24	25.1	9.90	58.5	*0.05
		Standard Deviation	5.026	10.09	0.447	12.9	
	Group B (Tightrope)	Mean	25	30.55	9.9	64.75	
		Standard Deviation	5.11	9.05	0.447	10.9	
AOFAS score 24 weeks after surgery	Group A (Screw)	Mean	34.5	42.65	9.8	86.95	**0.005
		Standard Deviation	6.04	6.20	0.61	11.45	
	Group B (Tightrope)	Mean	38.5	45.25	9.9	94.15	
		Standard Deviation	3.66	4.11	0.44	5.35	

P-value ≤0.05 is statistically significant,*p-value between group A and group B at 12 weeks, **p-value between group A and group B at 24 weeks.

Postoperative Complications

Regarding patients in Group A, five patients (25%) had joint stiffness, two patients (10%) had a hardware failure, two patients (10%) had Complex Regional Pain Syndrome (CRPS), one patient (5%) had a superficial infection, three patient (15%) needed hardware removal, and no patient had an implant irritation. Concerning patients in Group B, four patients (20%) had joint stiffness, one patient (5%) had a hardware failure, one patient (5%) had CRPS, and one patient (5%) had implant irritation. No patients had a superficial infection or needed hardware removal (Table 4)

Table 4: shows post-operative complications

p-value	Group B		Group A		
0.0421	%	N	%	N	
	20%	4	25%	5	Joint Stiffness

	5%	1	10%	2	Hardware failure/mal-reduction
	5%	1	10%	2	CRPS
	0%	0	5%	1	Superficial infection
	5%	1	0%	0	Implant irritation
	0%	0	15%	3	Hardware removal

CRPS= Complex Regional Pain Syndrome, N= number.

Discussion

In our trial, we used the AOFAS rating system to assess the foot and ankle condition. The pooled analysis showed that the AOFAS score was significantly higher in patients in Group B than patients in Group A after 3 months and 24 weeks of follow-up. Regarding the complications, Group B was associated with fewer complications such as joint stiffness, hardware failure, CRPS, superficial infection, and need for hardware removal.

Bava et al (23) studied the available modalities for syndesmosis fixation and management. There is a great controversy regarding the number of devices that should be used, the number of cortices the screws should engage, and when the screws should be removed. They found that the most common method of fixation was one or two 3.5-mm screws engaging 4 cortices. Besides, the screws were removed in the operating theatre three months after the surgery.

A randomized prospective trial compared the Arthrex tightrope and syndesmotic screw fixation in terms of accuracy and maintenance of syndesmotic reduction using bilateral computed tomography (CT) for assessment of these outcomes. They showed that both techniques were associated with a low incidence of malrotation and accurate reduction. They also reported that intraoperative CT was misleading when assessing the Arthrex tightrope due to its dynamic nature and might lead to false-positive results. Therefore, they suggested open exploration to confirm accurate reduction, especially with TightRope fixation. After more than two years of follow-up, the incidence of malrotation was slightly higher in the screw fixation. However, the incidence of ankle joint osteoarthritis and the functional outcomes were similar in the two groups. The principle that supported the suture button fixation was that; it was associated with physiological movement of the syndesmosis, anatomic healing, the ability to commence earlier rehabilitation, and typically avoiding implant removal.

Other previous studies reported the incidence of malreduction with syndesmotic screw fixation was 6% to 38% when assessed by CT or 3D fluoroscopy (24,25). However, in all of these studies, only the injured side was scanned without side-to-side comparison. Bilateral imaging is essential to pick up any remarkable individual variation in the measurement of syndesmosis width (26–29). The high rate of false-positive findings of the suture button device may be due to its flexible feature. Fibula may mildly slide posteriorly when the lower limb is in a free position and may rotate externally in the plantar flexion position. Laflamme et al (30) performed a prospective multicenter trial to compare the functional outcomes of patients with acute ankle syndesmosis injury treated surgically with a static or dynamic device. They found that dynamic fixation was associated with better radiographic and clinical outcomes. However, the static implant provided more

stabilization without malreduction. Besides, the rate of reoperation was significantly lower in the static fixation. The findings of this trial were consistent with our results regarding the AOFAS, especially at three months. The better results in the dynamic group may be explained by the restoration of the physiological movements of the syndesmosis with the Tightrope led to rapid healing (31,32). Several studies reported the advantage of dynamic fixation and its role in the restoration of movements mainly in the sagittal plane (33,34).

Seyhan et al (35) conducted a study on 32 patients with syndesmosis injury 17 of them were treated with a 4.5 mm cortical screw and 15 patients were treated with a tightrope. He found no statistically significant difference between the AOFAS scores in both groups. However, they reported that elastic fixation was superior to screw fixation regarding the range of motion and had a more physiological nature. Additionally, the elastic fixation did not need a second surgical intervention to remove the fixation material. The limitations of this study were the small sample size, lack of randomization, and retrospective analysis.

A retrospective analysis by Thornes et al (36) studied the safety and efficacy of suture-button syndesmosis fixation. The patients in the suture-button fixation group showed significantly better AOFAS scores at 3 months and 12 months postoperatively and earlier return to work than the screw fixation group. 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.

Kocadal et al (37) included 52 patients in the retrospective study the incidence of complications was as follows; In the suture-button fixation group one patient suffered from low-grade infection, three patients developed joint stiffness and one patient with local irritation. In the screw fixation group; one patient developed reflex sympathetic dystrophy and ten patients needed implant removal. Local irritation, hardware removal, and failure were also reported in our study and were higher in the screw group. In this prospective trial, we compare the safety and efficacy of TightRope versus syndesmosis screw in patients with an acute syndesmosis injury. However, the main limitations facing as were the small sample size and the lack of randomization.

Conclusion

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.

Conflict of interest:
The authors declare no conflicts of interest.

Data availability statement:
Data will be available to any researcher who contact the corresponding author.

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