Functional and Radiological Outcome after Syndesmotic Screw Fixation and Removal

Mohamed Elsadek Atia, Elsayed El Etwey Soudy,
Ahmed Mohamed Abodief Elsayed*, Ehab Mohamed Shehata
Department of Orthopedic Surgery, Faculty of Medicine, Zagazig University, Zagazig, Egypt
***Corresponding author:** Ahmed Mohamed Abodief Elsayed, **Mobile:** (+20)1286172144,
E-mail: ahmedabodief999@gmail.com

ABSTRACT
Background: There is a wide debate about the necessity and timing for syndesmotic screw and removal.
Objective: The aim of the current work was to assess the improvement in functional and radiological outcome after syndesmotic screw fixation and removal.
Materials and Methods: This prospective cohort study included a total of 18 patients who underwent ankle fracture surgery with syndesmotic fixation, attending at Department of Orthopedic, Zagazig University Hospitals and Sharq El-Madina Hospital. Patients were divided into two groups: Group (I): included 9 patients who underwent ankle fracture ORIF with syndesmotic fixation followed by subsequent syndesmotic screw removal (SSR). Group (II): included 9 patients, who underwent ankle fracture ORIF with syndesmotic fixation without subsequent SSR.
Result: Clinical and x-rays results were similar in both groups at follow-up. There were no significant differences between both groups regarding to clinical data, clinical outcomes, radiological outcomes, and complications.
Conclusions: It could be concluded that syndesmotic screw removal is not necessary. Removal's timing of the device must guarantee the complete healing of the injured syndesmotic soft tissues.
Keywords: Ankle, Fracture, Syndesmosis, Screw, Fixation.

INTRODUCTION
Ankle fractures remain one of the most common fracture types, representing up to 50% of all lower extremity fractures [(1)]. The mechanism of injury is mainly a traumatic event in external rotation with the foot supinated (SER) or pronated (PER), as described by Lauge Hansen [(2)]. The consequence is often a Denis-Weber Type B or C lesion associated to syndesmotic injury occurring in up to 40% of all Type B injuries, and up to 80% of all Type C [(3)].

Syndesmotic injuries occur frequently with 30%–39% of bimalleolar ankle fractures having concomitant syndesmotic disruption [(4)]. Syndesmotic injuries involve rupture of one or more of the ligamentous structures between the distal fibula and tibia, just proximal to the ankle joint. These ligaments play a critical role in stabilizing the distal tibiofibular anatomy and enable physiological motion of the ankle joint [(5)].

The distal tibiofibular syndesmosis stabilizes the ankle joint and transmits loads during weight-bearing [(6)]. Anatomical restoration and stabilization of the disrupted distal tibiofibular syndesmosis are essential in order to prevent changes in contact load and posttraumatic osteoarthritis, and to improve functional outcome [(7)].

The presence of these injuries has been reported to have a significant negative impact on functional ankle fractures' functional outcomes, whether treated operatively or non-operatively [(8)]. Despite the high prevalence of ankle fractures and high incidence of associated syndesmotic injuries, a standard protocol of syndesmotic injury management is yet to be established. Intra-operative syndesmotic fixation traditionally involves placing a positional syndesmotic screw through the fibula onto the tibia to maintain reduction as the ligaments heal. Extensive clinical and bio mechanical research has been done regarding various aspects of this screw like number, diameter, level of placement and number of cortices to be engaged [(9, 10)].

However, screw fixation is the gold-standard in treatment of syndesmotic injury, some important issues should be considered, such as screw loosening, breakage, discomfort, reoperation, loss of reduction due to early implant removal [(11, 12)].

Two recent studies examined patients before and after screw removal. Moore et al examined 120 patients to compare 3- versus 4-cortex fixation. They found that in both groups, there were no differences clinically if screws were left in place [(13)]. In the second study, patients with syndesmotic screw fixation were divided into 2 groups: those allowed weight bearing before screw removal and those who had screws removed before bearing weight. They found no difference in functional outcomes or range of motion between these groups but recommended screw removal to avoid screw breakage once weight bearing commenced [(9)].

The aim of the present study was to assess the improvement in functional and radiological outcome after syndesmotic screw fixation and removal.

PATIENTS AND METHODS
This prospective cohort study included a total of 18 patients who underwent ankle fracture surgery with syndesmotic fixation, attending at Department of Orthopedic, Zagazig University Hospitals and Sharq El-Madina Hospital. This study was conducted between January 2022 to June 2022.

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Patients were divided into two groups:
Group (I): included 9 patients who underwent ankle fracture ORIF with syndesmotic fixation followed by subsequent syndesmotic screw removal (SSR). **Group (II):** included 9 patients, who underwent ankle fracture ORIF with syndesmotic fixation without subsequent SSR.

Patient aged between 20-50 years, with isolated syndesmotic injury, combined ankle fractures and syndesmotic injury. They underwent syndesmotic Screw fixation.

Exclusion criteria:
Patient unfit for surgery, with syndesmotic injury and neuromuscular insult, syndesmotic injury and charcot foot, syndesmotic injury and open ankle fractures, development of postoperative infection and hardware failure and the need of additional surgery due to complications were excluded.

Patients were subjected to full history taking, name, age, sex, address, occupation, history of chronic illness, mechanism of injury and characteristics of fractures (affected side and fracture type). Laboratory investigations: including CBC, liver function tests (LFT), kidney function tests (KFT), random blood sugar, HCV-Ab, HBS-Ag, PT, PTT and IRN. Clinical assessment: including edema, limitation of movement and associated injuries. Radiological assessment: including ankle joint plain X-ray AP view, lateral view, mortise view, stress external rotation view. All patients had syndesmotic fixation with 1 or 2 3.5mm screws with a tricortical placement. Intraoperative fluoroscopy for the ORIF with syndesmotic fixation was used to assess the anatomic reduction of the syndesmosis and fracture.

Postoperatively, all patients were immobilized for 4 weeks without weight-bearing. After this period rehabilitation started and progressive loading was allowed. Postoperative radiographs after 6 months using anteroposterior, lateral and mortise views were followed for evaluation of fracture healing and maintenance of reduction by the treating surgeon. Tibiofibular clear space (the horizontal distance between the lateral margin of the posterior tibial malleolus and the medial border of the fibula) was recorded in patients of both groups as well as fracture's consolidation. The choice to retain or remove the syndesmotic screw was based on consultant preference. A functional evaluation was performed 1 year after surgery through 2 validated scoring systems: OMAS and AOFAS [14]. In group I after SSR, radiographs were compared with prescrew removal radiographs showing no loss of syndesmotic reduction.

Outcome measures

1. **The American Orthopedic Foot and Ankle Society Ankle-Hindfoot Scale (AOFAS)**: In 1994, the American Orthopedic Foot and Ankle Society designed a rating scale to establish standards for the clinical assessment of the foot and ankle surgery. Four rating systems corresponding to anatomic regions of foot and ankle quantified subjective and objective factors on a numerical scale to describe function, alignment, pain and range of motion [15].
2. **Olerud-Molander Ankle Score**: The Olerud-Molander Ankle Score (OMAS) is a self-administered patient questionnaire. The scale is a functional rating scale from 0 (totally impaired) to 100 (completely unimpaired) and is based on nine different items: pain, stiffness, swelling, stair climbing, running, jumping, squatting, supports and activities of daily living. OMAS has been frequently used to evaluate subjectively scored function after ankle fracture. The score measures: Subjective recovery, range of motion in loaded dorsal extension, presence of osteoarthritis, and presence of dislocations on radiographs, and it has been found to correlate well with these four parameters [16].

Ethical consent:
An approval of the study was obtained from Zagazig University Academic and Ethical Committee. Every patient signed an informed written consent for acceptance of participation in the study. This work has been carried out in accordance with the Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical analysis
Data were analyzed using Statistical Package for the Social Sciences (SPSS) software version 20 (IBM, USA). The parametric data expressed as mean ± SD (Range) or number (%) for categorical data. Comparisons for parametric data were carried out using independent student t test or Fischer exact test and Chi square test for categorical data. Quantitative data were expressed as mean ± SD (Standard deviation). Independent samples t-test was used to compare between two independent groups of normally distributed variables (parametric data). P value < 0.05 was considered significant.

RESULTS
Table 1 shows that there was no significant difference between both groups regarding to demographic data.

Table (1): Comparison between both groups regarding to demographic data.

	Screw removal (N=9)	No screw removal (N=9)	X^2 / t	P Value
Age (years)	42.6 ± 12.9 (22-65)	43.4 ± 16.1 (26-75)	t= -0.11	0.91
Gender				
Male	6 (67%)	5 (56%)	X^2 = 0.23	0.62
Female	3 (33%)	4 (44%)		

Data are represented as mean ± SD or number (%). Data are analyzed using independent student t test or chi square test.

Table 2 shows that there were no significant differences between both groups regarding to comorbidities.

Table (2): Comparison between both groups regarding to comorbidities.

	Screw removal (N=9)	No screw removal (N=9)	X^2 / t	P Value
Co-morbidities				
Yes	4 (44%)	5 (56%)	X^2 = 0.22	0.63
No	5 (56%)	4 (44%)		

Data are represented as mean ± SD or number (%). Data are analyzed using independent student t test or chi square test.

Table 3 shows that there were no significant differences between both groups regarding to clinical data.

Table (3): Comparison between both groups regarding to clinical data.

	Screw removal (N=9)	No screw removal (N=9)	X^2 / t	P Value
Side of fracture				
Right	4 (44%)	3 (33%)	X^2 = 0.23	0.62
Left	5 (56%)	6 (67%)		
Type of fracture				
Denis-Weber B type fractures	3 (33%)	4 (44%)	X^2 = 0.23	0.62
Denis-Weber C type fractures	6 (67%)	5 (56%)		
SER injuries			X^2 = 0.4	0.52
Yes	2 (22%)	1 (11%)		
No	7 (78%)	8 (89%)		
PER injuries			X^2 = 0.4	0.52
Yes	7 (78%)	8 (89%)		
No	2 (22%)	1 (11%)		

Data are represented as mean ± SD or number (%). Data are analyzed using independent student t test or chi square test.

Table 4 shows that there were no significant differences between both groups regarding to clinical outcomes.

Table (4): Comparison between both groups regarding to clinical outcomes.

	Screw removal (N=9)	No screw removal (N=9)	X^2 / t	P Value
OMAS 6 months after surgery	93.1 ± 2.02 (90-96)	97.2 ± 1.64 (95-99)	t= 1.16	0.26
AOFAS 6 months after surgery	94.8 ± 1.05 (93-96)	92 ± 1.73 (90-95)	t= 0.3	0.76

Data are represented as mean ± SD or number (%). Data are analyzed using independent student t test or chi square test.

Table 5 shows that there were no significant differences between both groups regarding to radiological outcomes.

Table (5): Comparison between both groups regarding to radiological outcomes.

	Screw removal (N=9)	No screw removal (N=9)	X^2 / t	P Value
Tibiofibular Clear Space POSTOPERATIVE	5 ± 0 (5-5)	4.5 ± 0.52 (4-5)	t= 0.99	0.33
Tibiofibular Clear Space at Follow Up	5 ± 0 (5-5)	5 ± 0 (5-5)	t= 0	1
Time of Healed Fractures/ month	3.7 ± 0.83 (3-5)	3.7 ± 0.66 (3-5)	t= 0	1

Data are represented as mean ± SD or number (%). Data are analyzed using independent student t test or chi square test or Fischer exact test

Table 6 shows that there were no significant differences between both groups regarding to complications.

Table (6): Comparison between both groups regarding to complications.

	Screw removal (N=9)	No screw removal (N=9)	X^2 / t	P Value
Wound Infection				
Yes	2 (22%)	1 (11%)	$X^2 = 0.4$	0.52
No	7 (78%)	8 (89%)		
Metal Prominence				
Yes	1 (11%)	0 (0%)	Fischer exact test	1
No	8 (89%)	9 (100%)		
Nonunion				
Yes	0 (0%)	0 (0%)	-	-
No	9 (100%)	9 (100%)		
Delayed Union				
Yes	1 (11%)	1 (11%)	$X^2 = 0$	1
No	8 (89%)	8 (89%)		

Data are represented as mean ± SD or number (%). Data are analyzed using independent student t test or chi square test or Fischer exact test.

DISCUSSION

Ankle fracture is among the most prevalent of the joint and bone fractures in worldwide, with an occurrence of 174 patients per 100,000 individuals annually. This fracture can induce serious complications and morbidities in short, moderate, and long terms [17]**.**Syndesmosis injuries are common with rotational ankle injuries and are usually associated with ankle fractures. The prevalence of syndesmotic injury, which is also referred to as distal tibiofibular instability, is up to 40% in ankle fractures [18]**.** Anatomic reduction and stabilization of the syndesmosis after injury is essential for prevention of post-traumatic arthritis and improved patient outcomes [19]**.** Inadequate reduction of syndesmosis can lead to late arthrosis and instability that is correlated with poor subjective and objective outcomes [20]**.** Transsyndesmotic fixation with either screws or a suture-type construct is well supported in the literature [21]**.**

Syndesmotic fixation provides a stable environment to allow for the ligamentous disruption between the distal tibia and fibula to heal. Screw fixation has been shown to inhibit physiologic motion through the syndesmosis, disproportionally affecting ankle dorsiflexion [22]**.**

Stabilization of the disrupted ankle syndesmosis maintains reduction as healing of the distal tibiofibular ligaments occurs. Syndesmosis screws may contribute to ankle dysfunction by restricting the normal motion between the tibia and fibula**.** Screw removal, breakage, or loosening may restore motion but can permit loss of reduction if these occur before complete ligamentous healing**.** As a result, although some well-established principles exist for reduction and surgical treatment of syndesmotic injuries, there remains controversy regarding whether routine syndesmosis screw removal is desirable [23]**.**

So, we aimed in this study to assess the improvement in functional and radiological outcome after syndesmotic screw fixation and removal.

In the current study, there were no significant differences between both groups regarding to demographic data.

In agreement with our study, **Kripalani *et al.*** [24] demonstrated that mean age of the patients in group A (removed screw) and group B (retained screw) were 41.2 years and 46.78 years respectively. There was no difference in the age distribution between the two groups (p=0.35). Male predominance was seen in their study with, 33 males (76.74%) to 10 (23.25%) females**.**

In the current study, there were no significant differences between both groups regarding to clinical data.

This came in agreement with **Moon *et al.*** [25] who found that there were no significant differences between both groups regarding to clinical data.

In the present study, there were no significant differences between both groups regarding to clinical outcomes.

In agreement with our study, **Khurana *et al.*** [26] showed that six articles were identified that used the AOFAS score. One hundred seventy patients were found in Screw removal group and 181 patients in Screw retention group. Pooled analysis showed non-significant difference in AOFAS score in the two groups (MD = − 1.84; 95% CI: − 4.33 to 0.66; P = 0.150).

In addition, **Francesco *et al.*** [27] demonstrated that there were no statistically significant differences in these results between the two groups ($p < 0.05$) regarding clinical outcomes for OMAS and AOFAS scores. In a literature review, in which seven clinical studies were analyzed, there were no differences in outcomes of patients who maintained or removed this device. Its rupture occurs in 29% of cases [28], but numerous studies do not report significant differences in outcomes of patients with intact, broken or removed screw [29-31, 32]. Indeed, more recent studies showed that patients with rupture of the screw report a better outcome than the group of patients with intact one [31, 33]. Another report demonstrated that the functional evaluation in patients with retained or removed screw was not statistically different, although the group of patients with intact screw had a worse ankle function [30]. Authors hypothesized that the cause was the decrease of the physiological movement of the fibula in relation to the tibia, which limited ankle's movement [33]. To confirm this, surgeons who are usual to remove the screw state that its removal guarantees a recovery of the biomechanical physiology of the ankle [9, 34] with better long-term outcomes [30].

Opponents instead stress that an increased risk of distal tibiofibular diastasis exist after removal [35], as well as an increased risk of infections [31].

Clinical results observed in our study are similar to those described in the literature. In fact, data registered 6 months after surgery were not statistically different between both groups. One of the main problems after ankle ORIF is the management of the postoperative period in which an aggressive rehabilitation and an early weight bearing may induce the rupture of the syndesmotic screw and an early removal may favor distal tibiofibular diastasis. In many cases, the patient struggles to accept the idea of being able to load on the ankle with retained screw, which is essential to avoid the evolution towards a rigid joint. Likewise, the patient does not accept the idea of maintaining a screw that has broken although this does not entail any risk [31,32]. In any case, authors believe that, whatever the treatment performed, the postoperative management has to be the same with an initial period of cast immobilization for at least 4 weeks, thus facilitating the healing of the disrupted soft-tissues structures.

In the present study, there were no significant differences between both groups regarding to radiological outcomes.

In agreement with our study, **Francesco *et al.*** [27] demonstrated that the tibiofibular clear space (normal 0-5 mm), measured immediately after surgery and 1 year later, was similar in removal group and retained screw group ($p < 0.05$). All fractures healed after a mean period of 3.5 months (range 3-5).

In the current study, there were no significant differences between both groups regarding to complications.

In agreement with our study, **Kripalani *et al.*** [24] demonstrated that there were no cases of intra operative complications in both the groups. In group A (removed screw) post-operative complications were noted to be 3 cases (15%) had superficial skin infections and 2 cases (10%) had Ankle stiffness. In Group B (retained screw), 3 cases (13%) had superficial skin infections, 3 cases (13%) had Ankle stiffness and in 1 patient (4.3%) screw breakage was noted. The difference in the incidence of complications in both groups was not significant ($p>0.05$).

While in the study of **Khurana *et al.*** [26] the results showed that complications were reported in 167 (out of 306) patients in the screw retention group and 52 (out of 347) patients in the screw removal group. Complications like loss of reduction were included for screw retention group, while wound infection, delayed wound healing, and recurrent diastasis were included for screw removal group. Pooled analysis revealed that 14.9% (95% CI: 8.11–23.32) complications/adverse events were recorded for screw removal group and 13.1% (95%CI: 1.75–32.58) complications for screw retention group.

CONCLUSION

It could be concluded that syndesmotic screw removal is not necessary. Removal's timing of the device must guarantee the complete healing of the injured syndesmotic soft tissues.

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