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# Lag versus Positional Syndesmotic Screw in the Treatment of Distal Tibiofibular Syndesmotic Injuries Concomitant with Ankle Fracture: Early Functional and Radiological Outcomes

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**Original Article**

## ABSTRACT

*Syndesmosis is important for ankle stability and load transmission and is commonly injured in association with ankle sprains and fractures. Failure to recognize and appropriately treat syndesmotic disruption can portend poor functional outcomes for patients, Surgical treatment aims to providing anatomic reduction of any deformities or fractures, care of soft-tissue damage, repair of associated injuries, rehabili¬tation, and treatment of any complications that may arise. This study aimed to evaluate the early functional and radiological outcomes of operative treatment for syndesmotic injuries concomitant with ankle fractures using lag screw fashion technique versus the standard (positional) screw fixation method.*

***Keywords:*** *Syndesmotic Injuries , Tibiofibular , Ankle Fracture Syndesmotic Screw, Lag, Positional,*

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## 1. INTRODUCTION

Syndesmosis is important for ankle stability and load transmission and is commonly injured in association with ankle sprains and fractures. Syndesmotic injuries are difficult to diagnose, and even when identified and treated, a slightly malreduced syndesmosis can lead to joint destruction and poor functional outcomes and frank osteoarthritis may ensue (1-3). Failure to recognize and appropriately treat syndesmotic disruption can portend poor functional outcomes for patients. Therefore, early recognition and appropriate treatment are critical (1). Historically, the first case of syndesmotic injury was described by "Quenu" in 1907 as a tibioperoneal diastasis after a ligamentous disruption and thereafter began to be studied in more depth (3)

Syndesmotic injury is not common. The incidence is 2.09 per 100,000(7,8).Syndesmotic disruption is associated with between 5 and 10% of ankle sprains and 11–20% of operative ankle fractures (1) and 17-74% of all sport injuries to the ankle(4). Purely ligamentous injuries are typically referred to as high ankle sprains. While complete ligamentous disruption can occur, these more commonly occur in association with an ankle fracture, specifically a distal fibular Weber B or C or a proximal fibular fracture (Maisonneuve injury). Conversely, syndesmotic injuries that require stabilization have been shown to accompany ankle fractures 10% to 20% of the time. Concomitant syndesmotic injuries have also been shown to occur in 17.8% of lateral ankle sprains (5).

Regarding the mechanism of injury, trauma to the distal tibiofibular syndesmosis commonly result from high-energy ankle injuries. They can occur as isolated ligamentous injuries, as seen in contact sports, or associated with ankle fractures due to other traumatic events (e.g. falls, twisting weight bearing injuries, and motor vehicle accidents( 6,7).

Pronation-External Rotation fractures (PER or Weber type C), Supination-External Rotation fractures (SER or Weber type B), and proximal fibular fractures with associated syndesmotic injury (Maisonneuve fractures). (8) .

External rotation and excessive dorsiflexion of the foot on the leg have been reported as the most common mechanisms of injury (6). Stable and precise articulation of the distal tibiofibular syndesmosis is essential for normal motion of the ankle joint. Complete disruption of syndesmosis with a disruption of the deltoid ligament causes a 40% decrease in the tibiotalar contact area and a 36% increase in the tibiotalar contact pressures. Injury to the syndesmosis occurs through rupture or bony avulsion of the syndesmotic ligament complex (9).

Syndesmosis injuries have been classified both chronologically and radiographically (2). On the other hand, the classification systems based either on radiographic criteria (Massobrio, Porte and MRI classification of Sikka), or clinical criteria (Edwards& DELee, Gerber, porter) (10). However, Edwards and DE Lee classification seems to be more useful for the application in clinical practice.

Diagnosis of syndesmosis based on clinical evaluation , careful history, physical examination, special clinical tests and imaging radiological evaluation (4-6) .

Surgical treatment aims to providing anatomic reduction of any deformities or fractures, care of soft-tissue damage, repair of associated injuries, rehabilitation, and treatment of any complications that may arise. The general principle is to restore the ankle joint congruency and maintain the distal tibiofibular syndesmosis stability, re-establishing the correct tibia–fibula interval, fibula length, and proper align¬ment of the fibula in the tibial incisura (11). Syndesmotic screw fixation considered the gold standard, nonetheless, a diastasis screw is recommended only for fractures of the fibula > 3.5 cm above the ankle joint if the deltoid ligament is ruptured, and 15 cm above if there is a concomitant fracture of the medial malleolus that has been rigidly repaired (12). Hence, it has been suggested that almost 15% to 60% of syndesmotic fixations are performed unnecessarily(13). From other point of view, early reports described the use of syndesmotic screws in 40% of Weber B fractures and up to 80% of Weber C fractures, but the frequency significantly decreased in recent years (12, 14). According to AO recommendation, syndesmosis screws are kept in place for 6–8 weeks with the patient restricted to 15 kg partial weight-bearing in a below knee cast or special boot. The screw(s) should not be removed before 3 months or in symptomatic patients only. Postoperative rehabilitation program included four phases, and the postoperative rehabilitation protocol lasts from 2 to 6 months and includes progressive steps toward full recovery (11).

Complications include general complications such as infection and wound-related complication, stiffness, loss of fixation, posttraumatic arthritis, heterotopic ossification, nonunion/mal-union, mal-reduction, anterior impingement syndrome of the talocrural joint (8,15,16). Complications related to syndesmotic screws are hardware failure, infection&

recurrent diastasis, loosening of the screw and Osteolysis around the implant (8,13,17)

Prognosis Rapid and accurate identification of the injury can reduce the risk of poor outcomes and life-long morbidity associated with chronic syndesmosis injuries (11). Syndesmotic disruption usually takes longer to heal than common lateral ligamentous injury of the ankle, while 40% of patients still have ankle instability symptoms 6 months after the injury. In some patients, the ligament complex failed to heal completely and resulted in a prolonged disability (9). The single most important predictor of good functional outcome is accurate reduction of the syndesmosis. The worst results are observed in ankles dislocated at the time of injury, those associated with a fracture of the medial malleolus, and a > 1.5 cm increase in the width of the syndesmosis (13).

Outcome measurement in this study, ankle function & syndesmotic ligaments stability were evaluated with AOFAS score (18), which measures Pain, function and alignment on scale of 100 points ; 40 for pain, 50 for function and 10 for alignment.

## 2. PATIENTS and METHODS

This was a comparative, prospective study comparing the early functional and radiological outcomes of patients treated with lag screw fixation of the distal tibiofibular syndesmotic injury versus the standard (positional) screw in Al-Imamain Al-Kadhimain medical city, department of Trauma and Orthopedics Surgery from March 2017 to October 2018.).The study conducted on 40 patients (22 males, 18 females) presented with clinical and radiological evidence of syndesmotic injury concomitant with ankle fracture (Weber B "SER & PA" and Weber C "PER"), randomized into two groups.

**Inclusion Criteria**

1. Patients age between 20-55 years old
2. Acute distal tibiofibular syndesmotic injury (within 6 weeks from presentation) with concomitant closed ankle fracture (Weber type B and Weber type C).

**Exclusion Criteria**

1. Patients age less than 20 years and more than 55 years old.
2. Multiply injured patients.
3. Compound ankle fractures.
4. Patients with pathological fractures.

5. Syndesmotic injury concomitant with proximal fibula fracture (Maisonneuve fracture).
6. Previous ankle fracture.

**Sampling and Data Collection**

The sample size was 45 patients from both genders; 5 patients refused to participate in the study. The data were collected from patients who attended the orthopedic department of the hospital. All patients evaluated clinically and radiologically (anteroposterior, mortise and lateral views) for injured ankles and contralateral limb. Temporary below knee plaster cast was applied. Complete work up was done preoperatively. The surgery was accomplished, for all patients after 6-7 days on elective operative list. All patients were followed up in the orthopedic consultation clinic of the hospital in the perioperative period. Data collected using a pre-constructed data collection form (case-sheet) for each patient with a serial number. Collected data included demographic, clinical and follow up findings. Patients assigned into two groups according to the mode of treatment with 20 patients in each group;

Group 1: treated by syndesmotic fixation with the standard positional (Diastasis) screw and Group 2 treated with syndesmotic fixation with lag screw.

Radiological findings were assessed preoperatively, postoperatively, and 12 weeks after surgery, prior to screw removal. Functional outcome of patients was evaluated with AOFAS score at 12 weeks post operatively before removal of the syndesmosis screw and 6 months after surgery after removal of screws and the patients achieved full weight bearing.

*Surgical Technique*

Preoperatively, patients sent for routine investigations and prepared for surgery. Both groups of patients operated on through the same approach and technique for open reduction and internal fixation (ORIF) of the ankle fractures and syndesmotic fixation through the standard lateral approach by the same surgeon; but through different fixation methods.

Prophylactic intravenous antibiotics were administered 30 minutes prior to skin incision . Surgery was done under general or spinal anesthesia according to anesthetist decision.

The anatomical site of the syndesmotic screw determined under fluoroscopic guidance.

Patients in group1, large reduction clamp applied from the lateral surface of the distal fibula to the medial border of the distal tibia, tensioned and position checked under image intensifier. Patients in group 2,with the foot in neutral position, some cases in plantar-flexion and manual reduction of the fibula into the tibial incisura, without using reduction clamp, cortical (partially threaded or fully threaded screw) introduced in lag fashion technique, engaged 3 or 4 cortices. (Figures 1 & 2). For both groups, stability of the syndesmosis assessed by "Hook test"; performed by applying bone hook, pulling the fibula laterally in the coronal plane to assess the integrity of the syndesmosis after reduction under fluoroscopic guidance. Postoperative care during the first 24 hours; close monitoring of the limb status and the patient condition as a whole with special attention paid to assess capillary refilling and any signs of compartment syndrome., in-hospital (Day 1), the patients encouraged to perform active movement of the toes with continued elevation of the limb. All the patients discharged to home after 24 hours( some after 48 hours),continued on antibiotics and analgesics as required, instructed on non-weight bearing, continued elevation with active movement of the toes; to be seen in the next visit (14 days after surgery).

All patients were followed for 6 months. During follow-up, five patients (2 in group 1 and 3 patients in group 2) identified that their syndesmotic screws were break but with maintained reduction and good ankle range of motion (Screws were left in situ and not removed according to the patients' request). In the last follow up visit (6 months after surgery), no diastasis were seen radiologically, stable ankle joints with no limitation in the range of motion.

***Statistical analysis***

Discrete variables presented using there number and percentage, chi square test used to analyze the discrete variable. Two samples "t test" used to analyze the differences in means between two groups (if both follow normal distribution with no significant outlier), while "paired t test" used to assess the difference between 3 and 6 months. SPSS 22.0.0 (Chicago, IL), Graph Pad Prism version 8.0.0 for Windows, Graph Pad Software, San Diego, California USA, software package used to make the statistical analysis, p value considered when appropriate to be significant if less than 0.05.

Figure 1. Determining syndesmotic screw position on fluoroscopy

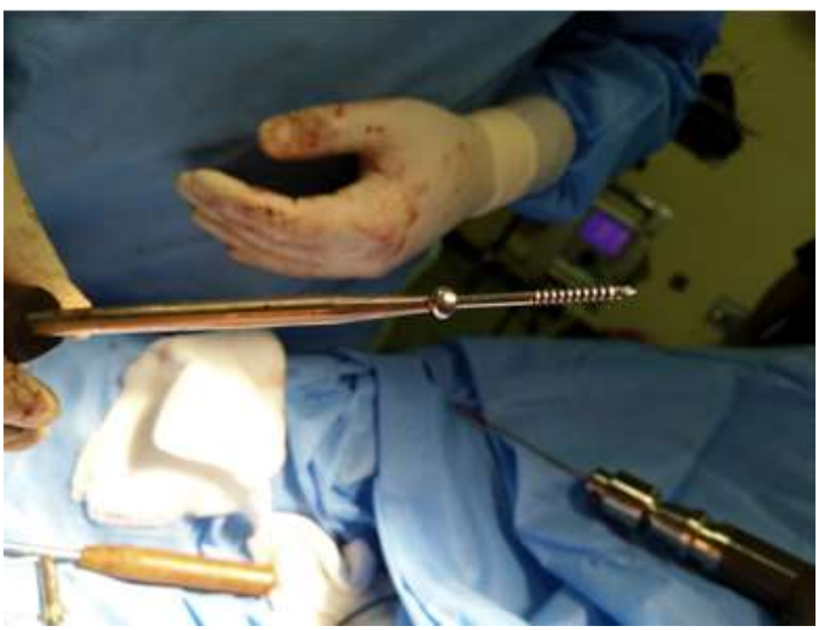

Figure 2. partially threaded cortical screw for syndesmotic fixation by lag technique

## 3. RESULTS

In the current study, there was no significant difference in the age of patients according to the surgical procedure. However, the frequency of male was significantly higher in Lag syndesmotic screw treated (Group 2) compared to positional syndesmotic screw treated patients (Group 1). (**Table 1**). There was no significant difference in injured side, mechanism of injury, broken syndesmotic screw, and superficial infection in relation to the surgical procedure. (**Table 2**). In Group 1(Positional screw), the mean AOFAS ankle-hind foot score (At 12 weeks after surgery) was 82.9±9.4 points (range, 62-100) were: 1 patient with a total score of 100, 4 patients (90-99), 10 patients (80-98), and 2patients (71-79), and 3 patients with a total score of (62-70) point. At last follow up endpoint (6months after surgery), the mean AOFAS ankle-hind foot score was 92.5±3.0 point (range, 87-95) were: 17 patients had a total score of (90-95) and 3 patients of 87. Activity limitation and maximum walking distance changes were significantly higher in "Lag syndesmotic screw" treated group compared to "Positional syndesmotic screw" treated patients,12 weeks after surgery(Prior to screw removal).While the rest of components in the score and the total score were not significantly different between the two surgical procedures. (**Table3**).

For group 2 (Lag syndesmotic screw), 12 weeks after surgery, the mean AOFAS score was 84.2±3.9 points (range, 79-90) were: 3 patients with a score of 90, and 17 patient (79-89).

At the last follow up end point (6 months after surgery), the mean score was 92.9±7.3 (range, 90-95). There was no significant difference in the total score and its components according between the two surgical procedures, 6 months after surgery (in which the Syndesmotic screws were removed apart from the broken ones; which left in situ). (**Table 4**). In patients with positional syndesmotic screw fixation (Group 1), there was an increment in total score from 3 months to 6 months. (**Figure** 3). In patients with Lag syndesmotic screw fixation (Group 2), there was an increment in total score from 3 months to 6 months. (**Figure** 4).

At preoperative., and immediately post-op. period, there was no significant difference in "Medial clear space" measurement between the two surgical procedures. But after 12 weeks, patients treated with lag screw syndesmotic fixation show significantly higher "Medial clear space". (**Table 5**)

In the pre-op., and immediately post-op. period, there was significant difference in "Tibiofibular clear space" measured on A.P. view between different surgical procedures. But after 12 weeks, there was no significant difference between the two surgical procedures. In the pre-op. period, there was significant difference in "Tibiofibular clear space" measured on mortise view between different surgical procedures. But immediately in the post-op period and after 12 weeks, there was no significant difference between the surgical procedures. (**Table 6**). In the preoperative., immediate post-op period and after 12 weeks, there was no significant difference in "Tibiofibular overlap" measured on AP view between the surgical procedures. In the preoperative. period, there was significant difference in "Tibiofibular overlap" measurement on mortise view between different surgical procedures. But immediate post-op. and 12 weeks after surgery, there was no significant difference between the surgical procedures(**Table 7**).

***Table 1. Assessment of demographic data***

| Variables | | Positional syndesmotic screw (n = 20) | Lag syndesmotic screw (n = 20) | P. value |
|---|---|---|---|---|
| Age (years), mean ± SD | | 39.4 ± 11.7 | 34.6 ± 9.4 | 0.161 |
| Gender, n (%) | Female | 13 (65.0%) | 5 (25.0%) | 0.011 [s] |
| | Male | 7 (35.0%) | 15 (75.0%) | |
| SD: standard deviation, n: number | | | | |

***Table 2. Assessment of patient's characteristics***

| Variable | | Positional syndesmotic screw (n = 20) | Lag syndesmotic screw (n = 20) | P. value |
|---|---|---|---|---|
| Injured side, n (%) | Left | 10 (50.0%) | 11 (55.0%) | 0.752 |
| | Right | 10 (50.0%) | 9 (45.0%) | |
| Mechanism of injury, n (%) | Low energy trauma | 16 (80.0%) | 17 (85.0%) | 1.000 |
| | High energy trauma | 4 (20.0%) | 3 (15.0%) | |
| Syndesmotic screw breakage | Yes | 2 (10.0%) | 3 (15.0%) | 1.000 |
| | No | 18 (90.0%) | 17 (85.0%) | |
| Superficial infection | Yes | 2 (10.0%) | 3 (15.0%) | 1.000 |
| | No | 18 (90.0%) | 17 (85.0%) | |

***Table 3. Assessment of the AOFAS score after 12 weeks***

| Item | Positional syndesmotic screw (n = 20) | Lag syndesmotic screw (n = 20) | P. value |
|---|---|---|---|
| Pain | 29.0 ± 4.5 | 30.0 ± 0.0 | 0.324 |
| Activity limitation | 6.3 ± 1.3 | 7.2 ± 0.7 | 0.012 [S] |
| Maximum walking distance | 4.7 ± 0.5 | 5.0 ± 0.0 | 0.010 [S] |
| Walking surface | 3.0 ± 1.3 | 3.0 ± 0.0 | 1 |
| Gait abnormality | 7.0 ± 1.8 | 6.6 ± 2.0 | 0.503 |
| Sagittal motion | 5.6 ± 2.0 | 4.8 ± 1.6 | 0.176 |
| Hindfoot motion | 4.4 ± 1.5 | 4.7 ± 1.5 | 0.539 |
| Ankle-hindfoot stability | 8.0 ± 0.0 | 8.0 ± 0.0 | 1 |
| Alignment | 15.0 ± 0.0 | 15.0 ± 0.0 | 1 |
| Total | 82.9 ± 9.4 | 84.2 ± 3.9 | 0.572 |
| Data presented as mean ± SD | | | |

***Table 4. Assessment of the AOFAS score after 6 months***

| Item | Positional syndesmotic screw (n = 20) | Lag syndesmotic screw (n = 20) | P. value |
|---|---|---|---|
| Pain | 30.0 ± 0.0 | 30.0 ± 0.0 | 1.000 |
| Activity limitation | 8.7 ± 1.5 | 8.8 ± 1.5 | 0.757 |
| Maximum Walking distance | 5.0 ± 0.0 | 5.0 ± 0.0 | 1.000 |
| Walking Surface | 4.2 ± 1.3 | 4.1 ± 1.0 | 0.896 |
| Gait abnormality | 8.0 ± 0.0 | 8.0 ± 0.0 | 1.000 |
| Sagittal Motion | 8.0 ± 0.0 | 8.0 ± 0.0 | 1.000 |
| Hindfoot motion | 5.7 ± 0.9 | 6.0 ± 0.0 | 0.163 |
| Ankle-hindfoot stability | 8.0 ± 0.0 | 8.0 ± 0.0 | 1.000 |
| Alignment | 15.0 ± 0.0 | 15.0 ± 0.0 | 1.000 |
| Total | 92.5 ± 3.0 | 92.9 ± 2.3 | 0.642 |
| Data presented as mean ± SD | | | |

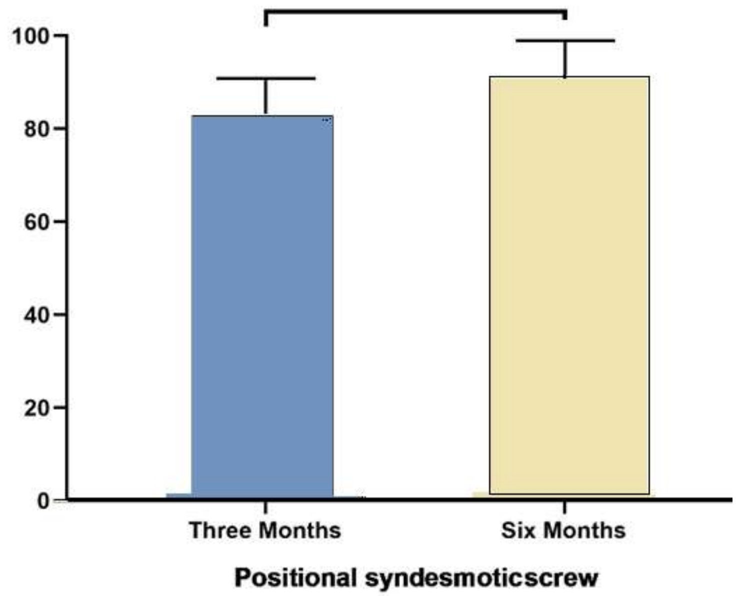


***Figure 3. Total score changes in patients treated with positional syndesmotic screw***

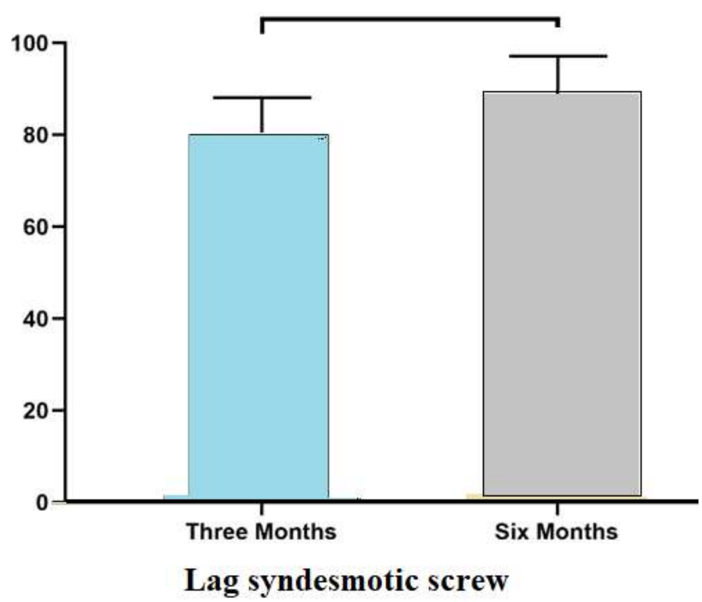


***Figure 4. Total score changes in patients treated with Lag syndesmotic screw***

***Table 5. Rradiological changes in Medial clear space, Antero-posterior view***

| Variable | Positional syndesmotic screw (n = 20) | Lag syndesmotic screw (n = 20) | P. value |
|---|---|---|---|
| Preoperative | 6.9±0.9 | 6.9±3.5 | 0.999 |
| Immediate post-operative | 3.1±0.7 | 3.4±0.6 | 0.154 |
| 12 weeks post-operative | 3.0±0.3 | 3.6±0.8 | 0.003 |
| Data presented as mean ± SD | | | |

***Table 6. Radiological changes in tibiofibular clear space (AP and Mortise view)***

| Variable | Positional syndesmotic screw (n = 20) | Lag syndesmotic screw (n = 20) | P. value |
|---|---|---|---|
| **Antero-posterior view** | | | |
| Pre-Op | 6.3±1.1 | 7.8±0.4 | <0.001 |
| Immediate post-op | 4.7±1.1 | 3.9±1.1 | 0.027 |
| 12 weeks post-op | 4.3±0.8 | 4.3±0.4 | 0.999 |
| **Mortise view** | | | |
| Pre-Op | 4.3±1.2 | 7.8±0.4 | <0.001 |
| Immediate post-op | 4.4±1.0 | 3.9±1.1 | 0.141 |
| 12 weeks post-op | 4.3±0.9 | 4.3±0.4 | 0.999 |
| Data presented as mean ± SD | | | |

***Table 7. Radiological changes in Tibiofibular overlap (AP and Mortise view)***

| Variable | Positional syndesmotic screw (n = 20) | Lag syndesmotic screw (n = 20) | P. value |
|---|---|---|---|
| **Antero-posterior view** | | | |
| Preoperative | 5.1±0.4 | 4.7±1.1 | 0.135 |
| Immediate post-op | 7.7±2.1 | 8.4±2.1 | 0.299 |
| 12 weeks post-op | 7.9±1.9 | 6.5±2.9 | 0.079 |
| **Mortise view** | | | |
| Preoperative | 1.9±0.9 | 0.9±0.3 | <0.001 |
| Immediate post-op | 3.2±1.6 | 3.2±0.3 | 0.999 |
| 12 weeks post-op | 3.5±1.7 | 3.9±0.8 | 0.347 |
| Data presented as mean ± SD | | | |

## DISCUSSION

Syndesmotic injuries are most commonly associated with "Weber C" and less often with "Weber B" ankle fractures. However, they can also occur in isolation after traumatic supination. Patients who required syndesmotic stabilization in addition to malleolar fracture fixation had poorer outcomes than patients who only required malleolar fracture fixation. Physical examination and radiographic measurements, such as the location of the fibular fracture (the height of the fibular fracture in Weber C fractures), and amount of tibiofibular overlap, tibiofibular clear space, and medial (between talus and medial malleolus) and superior (between talus and tibial plafond) clear space, are of little value in detecting syndesmotic stability. Even additional quantitative measurement of all syndesmotic parameters with repeated radiographs of the ankle have been of little value .The most sensitive indicator of syndesmotic injuries are the intraoperative stress tests(“hook” test or external rotation stress test),performed under fluoroscopic control to assess syndesmotic stability. Treatment of these injuries must address the restoration of stability to the distal tibiofibular joint and ankle joint congruency(19).It's a matter of debate whether the syndesmotic screw should be routinely removed(20).

In the current study, the incidences of syndesmotic injuries were more in males (55%) in comparison to females (45%), in a ratio of 1.2:1. Sixteen patients had "Weber B" ankle fracture (9males, 7females) and 24 patients had "Weber C" (13male, 11female).Two surgical stabilization methods were performed for syndesmosis fixation in this study and the patients were prospectively followed where their radiological and functional outcomes recorded and compared. No previously published literature compared the outcome between such surgical procedures. Most of the literatures (comparative studies, systematic reviews, and others) discuss the technical aspects of the standard (position) syndesmotic screw and their effect on the functional outcome regarding the number and diameter of the screws, timing and necessity of retaining or removal of the screw(s) and discussing complications of syndesmotic screw stabilization.

In the present study, the age of the patients had no significant impact on the outcome of patients according to the surgical procedure (P. =0.161) which was similar to the findings of Vlijmen et al. (2015) (21) were retrospective cohort study conducted on 43 patients with ankle fracture with associated syndesmotic disruptions, followed for 5 years, investigated long term patient reported, radiographic and functional outcomes of syndesmotic injuries treated with screw fixation and subsequent timed screw removal on injury& patients satisfaction with the functional outcome (No significant correlations were found between the age& functional and radiological outcome, P. >0.05).

There was no significant difference regarding the injured side (P. =0.752), mechanism of injury (P. =1.0) on the outcome of patients of both groups which was not mentioned in the published literatures.

In this study, only one syndesmotic screw was used in distal tibiofibular joint stabilization, sized 3.5 or 4.5 mm according to the size of the bone, and purchased 3 or 4 cortices with the same final functional outcome. These findings coincide with Høiness&Strømsøe (2004)(22) in which they conducted a prospective, comparative randomized clinical trial in a period of 20 months on 64 patients with ankle fracture in which trans-syndesmotic screw was indicated, aimed to assess short term functional results in two types of syndesmotic fixation(rigid quadricortical syndesmotic screw fixation with a more dynamic tricortical screw fixation),end with conclusion that after 1 year, there were no significant differences between the 2 groups in functional score, pain, and dorsiflexion and finding of Markolf et al.(2013) (23) in their biomechanical study, concluded that screw size and the number of engaged tibial cortices had no significant effect on mechanical stability of the distal fibula during their experimental testing and application of external foot torque(internal tibial torque) to a weight-bearing ankle produced the greater bending displacements of the screws and should be avoided during rehabilitation to reduce the possibility of screw breakage.

In the present study, the complications encountered were screw breakage and infection were 2 patients (10.0%) from group 1(positional screw treated group) and 3 patients from group 2 (lag screw treated group).

For group 1, there were middle aged male patients, obese (BMI>38.4), started early unprotected weight-bearing without support. For group 2 (more rigid fixation),1 patient was young aged male started unprotected weight-bearing before recommended period and sustained an occupational injury during work to his operated ankle.others,33 years old female&43 years old male, they were obese (BMI=37.8 for male,36.8 for female),unequaled weight bearing even with crutches. These results were not significant statistically in relation to the surgical method (P. =1.0) and were relative with Mendelsohn et al. (2013)(24) in their retrospective, comparative cohort study on 213 patients with operative syndesmotic injury. Patients grouped into 2 cohorts (102 obese their BMI≥30,111 non-obese their BMI<30) and found that 15% of patients of the obese cohort sustained failure of syndesmotic fixation compared to 1.8% in non-obese cohort (P.:0.0005) and established strong association between obesity and loss of reduction following syndesmotic screw fixation and obese patients 12 times more likely to suffer loss of reduction compared with non-obese patient (P. =0.02).

Two patients in group 1(10%) and 3 patients in group2 (15%) identified with superficial infection. All of them were patients with fairly controlled diabetes mellitus (mean HbA1c was 6.9±0.4) and smokers; which agreed that these had adverse effects on wound healing and cause for their wounds breakdown.

For patients in group 1, radiological medial clear space measurement on antero-posterior significantly reduced in the immediate postoperative measurement (6.9±0.9mm pre op. to 3.1±0.7mm post op., 3.0±0.3mm 12 weeks post operatively).

Tibiofibular clear space measured (in mm): 6.3±1.1 pre-operatively, 4.7±1.1 in the immediate post-operative period and, 4.3±0.8 (12weeks post operatively) assessed on anteroposterior radiographs. On mortise view, the measures was (in mm) 4.3±1.2 pre-op., 4.4

±1.0 immediately postop. , and 4.3±0.9 (12 weeks post op.).

Tibiofibular overlap measurements on anteroposterior view were (in mm):5.4±0.4 pre-op., 7.7±2.1 immediately post-op. and 7.9±1.9 (12 weeks post op.).

On mortise view, 1.9±0.9 pre-op., 3.2±1.6 immediately postop. , and 3.5±1.7 (12 weeks post op.) (mm).

There were significant reduction in medial clear space and tibiofibular clear space post-operatively from the preoperative level and still maintained till next assessment visit (12 weeks postoperatively) and increment of tibiofibular overlap were features of adequate syndesmosis reduction& good scar tissue formation. The result of the current study were in contradiction with Vlijmen et al.(21) (reported 51%loss of tibiofibular overlap&33% widening of medial clear space measured 2cm above the tibial plafond as complications for retained syndesmotic screw).In this study, these measures were obtained before removal of the syndesmotic screw and not assessed after its removal.

The results of the following studies are relative to our findings:

Jasqui Remba et al.(2015)(25):conducted a retrospective cohort study on 58 patients (30 female, 28male) to determine the effect of syndesmotic screw removal on changes in the tibiofibular clear space and tibiofibular overlap(increase of both tibiofibular clear space& tibiofibular overlap with slight widening of the syndesmosis; changes considered not significant).In our study group,20 patients assessed, patients with "Weber B" and "Weber C "were evaluated for changes in radiological indexes(TFCS decreased ,TFO increased, and MCS was decreased post operatively and still reduced till time of screw removal.(

S.Sipahioglu et al. (2017)(26) in their retrospective study on 23 patients with supra-syndesmotic (Weber C) in which they fixed the syndesmosis only through mini lateral open incision. They documented decreased tibiofibular clear space and lateral fibular distance with no changes in medial clear space (all statistically not significant).In this study group, patients with "Weber B" and "Weber C "were assessed for radiographic changes but lateral fibular distance not evaluated.

The following studies coincided with this study:

Sipahioglu, et al. (2018)(27): prospective, comparative study on 21patients (15male, 6 females) underwent syndesmotic stabilization with single, 4.0m.m stainless steel malleolar screw with tri-cortical purchase following the AO/ASIF principles of syndesmosis fixation.

Radiological indexes (TFCS, TFO, and lateral fibular distance) were significantly decreased from pre-to postoperative period (P. <0.05).

In 'Weber B" group, statistically significant decrease in TFCS found (P<0.05), changes in lateral fibular distance and MCS were not significant (P>0.05).In "Weber C" group, postoperative changes in TFCS and lateral fibular distance were significant (P<0.05), postoperative MCS change was not significant (P. >0.05).

Gennis et al. (2015)(20): retrospective cohort study on 166 patients ( 94 male,72female) underwent syndesmotic screw stabilization. Radiological measures (TFCS, TFO and MCS) were assessed on 3 occasions: pre-&immediate postoperative, and at follow up when weight bearing started and syndesmosis screw removed. Slightly increased tibiofibular clear space and decreased tibiofibular overlap after elective screw removal ≥3months after surgery, assessed on mortise view were statistically not significant. Pre-&postoperative changes in changes in medial clear space were not significant. In patients with loosened, broken or still intact screws, there were no significant changes from postoperative to final follow up periods.

Manjoo et al. (2010)(28): retrospective, radiological review of 76patients aimed to determine the effect of syndesmosis screw removal on the functional& radiological outcome of patients. Mean follow up duration was 23.2±12.5months (range, 12-32months).Radiological indices (TFCS, TFO, MCS, LCS, and talar tilt) measured on the final follow up radiographs. Tibiofibular clear space was greater in patients with broken, loosened or removed compared to intact screws (P=.005).For patients with intact, loosened, broken, or removed screws, no changes in medial clear space and tibiofibular overlap were identified (P=.09 for MCS, 0.69 for TFO respectively).

In the current study, the effect of fate of syndesmotic screw fate was not discussed.

Baek et al. (2017)(29):prospective, prognostic study on 29 patients(20male,9females),aimed to determine the effect of syndesmotic screw removal on the syndesmosis integrity on plain radiography and CT scan. There were no statistical difference were identified at pre-screw removal (P=0.761) and post screw removal (P=0.628).In the present study, radiological indices were assessed on plain radiography only; CT scan not routinely requested.

For Group 2 (Lag screw), there were no significant changes from pre-&postoperative period in regard to medial clear space& tibiofibular clear space measurement; indicated adequate reduction of the ankle mortise, were slightly increased after12 weeks when patients started to bear weight on the operated ankle(with rigid screw fixation, especially when partially threaded screws used, the screw would loosen from the tibial cortex(cortices) as weight bearing increased gradually, given rise to increase in the measurement of the above listed indices.Tibiofibular overlap was significantly reduced in the immediate postoperative period, slightly decreased when weight bearing started (assessed on A.P. & mortise view).

In this study group, the fate, status of the screws (broken, loosen) were not assessed as they routinely removed after 12 weeks from surgery.

One published study has similar finding with this study where Lee et al. (2018)(30) conducted a prospective, comparative study on 58 patients (45male,13female) treated with a partially threaded 5.0mm cannulated screw for syndesmosis fixation. Radiological indices (TFCS,TFO,MCS and fibular position on lateral radiographs) measured on 3 occasions: pre-&Postoperative and at final follow up end point (14.4 months after surgery).Significant different changes identified between injured and intact ankles(regarding MCS,TFCS and TFO; P. <0.001 for each, fibular position on lateral radiographs, P. =0.026). Medial clear space was significantly wider between injured and intact ankles; became significantly narrower on immediate postoperative radiographs (P<0.001).No significant difference was found between injured and intact ankles on final follow up examination (P. =0.522).

The clinical and functional outcome for lag screw treated patients, there were significant changes in two subdomains of the score (Activity limitation, P=0.012, walking distance, P. =0.010), 3 months after surgery where the screws still in place. This probably attributed to the rigid form of fixation that limits the normal physiological micro motion within the syndesmosis ligaments which was significantly improved at last follow up end point (6months after surgery) in both electively removed and those with broken screws (activity limitation, P=0.757, walking distance, P=1.0) with increment of the total score (84.2±3.9 at 12 weeks to 92.9±2.3 after 6 months).

These findings coincides with results of K.Y.Kwaduu et al.(2015)(31) in their study(clinical experience) conducted on 31 patients treated with lagged syndesmotic trans fixation and were available for short and intermediate term follow up, their functional outcome evaluated with AOFAS ankle-hind foot score. The mean score was 88.38 points (range, 42-100) at a mean follow up interval of 34.87 months (range, 12-52 months).

*Studies discussed the lag syndesmotic screw effect on the ankle motion;*

Tornetta et al. (2001)(32): cadaveric study measured maximal dorsiflexion through an applied dorsiflexion force(No restriction in motion occurred regardless of ankle joint position at time of screw; the syndesmosis may be fixed by allowing the foot and ankle in the resting position.

S.Kukreti et al. (2005)(33): retrospective cohort study on 36 patients, mean follow up period was 35.4 months (range,9-106 months),compared the functional outcome in patients treated with trans-syndesmotic and supra-syndesmotic screw fixation(no significant difference in their clinical outcome, (P. =1.0)

Hamid et al. (2009)(34): retrospective study on 52 patients compared the fate of the syndesmotic screws (intact, broken, and removed screws), one year after surgery. Functional outcome evaluation with AOFAS score was (intact screws 83.07±13.95) (broken screws, 92.40±2.69), and (removed screws 85.80±11.33) (P=0.0466).No difference in the clinical outcome of patients with intact or removed screws, Patients with broken screws had the best functional outcome.

Manjoo et al. (2010)(28): retrospective radiographic study on 76 patients, mean follow up was23±13 months (range, 17-32 month), their functional outcome evaluated with LEM score and OM ankle score. The fate of the syndesmotic screw documented (intact, broken, loosen, or electively removed).LEM scores(intact screws:70±6,broken,loosen or removed screw:85±3) (P. =0.01), OMAS(intact screws:47±8.0,broken,loosen or removed screws:64±4) (P.=0.04).Improved functional outcome(with no difference) in patients with fractured, loosened, or removed screws in comparison with those with intact screws.

Schepers et al. (2011)(17): comprehensive literature review on seven studies, theorized no difference in the functional outcome between retained or removed screws and patients with broken or loosened screws had similar or improved outcome compared to removed screws patients.

Darwish et al. (2012)(35): cadaveric study on seven fresh-frozen lower extremities subjected to 100N. medial and lateral tibial loads with the talus restrained. Three screw fixation method were evaluated in each specimen: (3.5mm screw, ticortical purchase with clamp to achieve syndesmosis reduction),(3.5mm lag screw with quadricortical purchase),and (4.5mm lag screw with quadricortical purchase)reduction in the medial clear space achieved, from

3.2mm to 1.36 (3.5mm tricortical),1.22mm (3.5 lag screw),and 1.19mm (4.5mm lag screw).No difference between the two lag screw sizes and all screws configurations reduced the medial clear space, syndesmosis reduction was more effective by lag screws than tricortical screws inserted with clamp reduction to maintain syndesmosis reduction in vivo.

Schepers et al. (2013)(36): retrospective study on 93 patients, followed for 51 months, their clinical outcome evaluated with AOFAS score, OM ankle score and single question VAS for patient satisfaction with the clinical outcome. Clinical was good for all patients; mainly influenced by patient and fracture characteristics, most different aspect off screw placement had no effect on the outcome apart from screws placed 41mm above the tibial plafond were negatively influenced the outcome.

A.Tucker et al. (2013)(37): retrospective review of 63 patients, mean follow up duration was 31 months (range, 10-43 month). The clinical outcome evaluated for patients with retained and removed screws by "Olerud-Molander" ankle score. Mean OMAS score (retained screw group: 81.5±19.3, removed screw group: 75±12.9) (P. =0.0107).Retained screws did not significantly impair the functional outcome with additional cost effectiveness.

M.J.Boyle et al. (2014)(38): prospective, randomized controlled trial conducted on 51 patients (36 male, 15 female),compared the functional outcome in patients with retained syndesmotic screws with those electively removed three months postoperatively, followed for one year, their clinical outcome evaluated with AOFAS score, OMAS,AAOS foot and ankle score, and VAS.

.Seyhan et al. (2015)(39): comparative study, syndesmotic screw fixation with elastic fixation method. No statistical difference in the AOFAS score of both groups (P>0.05).

Kwaduu et al. (2015)(31) :unrestricted motion compared with the uninjured limb was used as the end points(no restriction of ankle motion, refuting the assumption that lagged trans syndesmotic fixation resulted in more restriction of the ankle motion than positional syndesmotic screw).

Kaftandziev et al. (2015)(40): retrospective study on 82 patients, compared the functional outcome in patients with retained screws and those, their screws removed by AOFAS score and VAS for general patient satisfaction. Mean AOFAS score was (fractured screws group: 83, broken screws: 92.5, and removed screws: 85.5).No statistical difference in the clinical outcome between broken, loosened, or removed screws and broken screws patients had the best functional outcome.

Mahapatra et al. (2017)(41): reported a case of 26 years old female with weber C ankle fracture with transfixing, 3.5mm cortical syndesmotic screw in lag fashion. Postoperative CT scan (well aligned fibula in the peroneal notch), mortise view (anteromedial subluxation of the talus, reduced within the ankle mortise when syndesmotic fixation revised and screw relaxed with restoration of the previously debilitated medial clear space and where electively removed twelve weeks postoperatively(Advise lag syndesmotic fixation, but with caution, rendered the possibility to over compress the syndesmosis and resulting in iatrogenic subluxation of the tibiotalar articulation.

Gonzalaez et al. (2017)(42):cadaveric study, introduced malreduction as a purposeful error; determined its effect on ankle motion following fixation and tested the maximal dorsiflexion with compression syndesmosis screw to create malreduction (No significant reduction in maximal dorsiflexion occurred, malreduction of the fibula, while not an ideal scenario, allowed for a greater space within ankle mortise to allow motion of the talus).

Pallis et al. (2018)(43):cadaveric study on twenty leg specimens, assessed the effect of ankle position during syndesmosis fixation where the amount of maximum dorsiflexion being recorded following hand tight lag screw fixation(Ankle position during distal tibiofibular syndesmosis fixation did not limit dorsiflexion of the ankle joint).

For patients treated with positional syndesmotic screw (Group1), The AOFAS ankle-hind foot score al last follow up end point was 92.5±3.01 (range, 87-95) where in similarity with:

MSipahioglu,et al.(2018)(27): prospective study on 21 patients, functional outcome evaluated with Hannover scoring system(100 points score). Functional outcome of patients treated with syndesmotic fixation by single, 4.0mm stainless steel malleolar screw, tricortical purchase according to AO/ASIF principles, removed 6 weeks postoperatively, their functional outcome at last follow up visit was in a mean of 83.8.5 points (range, 62-91point) where designated as good results.

One year post operatively, there was no significant difference in the mean scores:

AOFAS ankle-hind foot score (retained screws 88.7vs removed screws 90.1, p. =0.688), OMAS (84.2vs 86.7, p. =0.367), AAOS foot and ankle score (96.3vs94.0, p. =0.250), and VAS (1.0vs 0.7, p. =0.237).Thus, removal of the syndesmotic screws had no significant effect on the functional outcome of patients.

In the above listed studies, the duration of follow up, in all, was more than one year(contradicted with the current study where the follow up end point was 6 months) and the number of patients were larger the total population in the current study (n=20). Despite being comparative, prospective study, the present study had several limitations which considered as weak points: small sample size, short duration of follow up, lacks any evidence of malreduction; mostly iatrogenic with placement of the syndesmotic screw where should be assessed by immediate postoperative and follow up CT scan, after weight bearing started and not requested routinely in this study, intermediate to long term sequelae not assessed and the radiological indices measured in the 2 occasions only(immediate postoperative and prior to screw removal),not measured when the patients started to bear weight on the operated ankles

## 5. CONCLUSIONS

According to the results obtained in this study, no significant differences in the radiological outcome were found between the two involved patient populations in this study at their end points of follow up (12 weeks after surgery).The functional outcome of both groups at their end point of follow up (6 months after surgery) not favoring the lag syndesmotic screw fixation over the standard positional screw method. However, further studies and randomized trials are recommended with larger sample size and longer duration of follow up to aid in the assessment of late squeals of lag screw fixation method and if it's possible to be considered an alternative method of fixation.

## Ethical Clearance

Ethical clearance and approval of the study are ascertained by the authors. All ethical issues and data collection were in accordance with the World Medical Association Declaration of Helsinki 2013 for ethical issues of researches involving humans, verbal and signed informed consent obtained from all patients. Data and privacy of patients were kept confidentially. .

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