



## FUNCTIONAL OUTCOMES FOLLOWING SYNDESMOTIC SCREW FIXATION- A COMPARISON OF SCREW REMOVAL VERSUS RETENTION.

<b>Dr. Rahul Thampi</b>	MS Ortho, Amrita Institute Of Medical Sciences, Kochi.
<b>Dr. Balu C Babu*</b>	MS Ortho, DNB, Assistant Professor, Amrita Institute Of Medical Sciences, Kochi. *Corresponding Author
<b>Dr. Melvin J George</b>	DNB, MNAMS, MCh[Ortho], Amrita Institute Of Medical Sciences, Kochi.
<b>Dr. Druvan Shaji</b>	MS Ortho, Associate Professor, Amrita Institute Of Medical Sciences, Kochi.
<b>Dr. V K Bhaskaran</b>	MS Ortho, Professor, Amrita Institute Of Medical Sciences, Kochi.
<b>Dr. Chandrababu K K</b>	D Ortho, MS Ortho, Professor, Amrita Institute Of Medical Sciences, Kochi.

### ABSTRACT

**BACKGROUND:** The incidence of distal tibiofibular syndesmotic injury in ankle fractures is about 13%. The integrity of syndesmosis is a critical factor which stabilizes ankle mortise during weight-bearing besides load transmission. The primary purpose of the study was to assess the functional outcome in patients with Weber B and C fractures and to decide whether the syndesmotic screws are to be removed or not before weight-bearing. **MATERIALS AND METHODS:** This was a prospective observational study involving patients (>18 years of age) who had undergone open reduction and internal fixation of an ankle fracture belonging to Weber B or C classification who had screw stabilization of a disrupted syndesmosis. The study period was three years commencing from August 2014. They were divided into two groups based on the syndesmotic screw retention or removal before weight-bearing. The patients were then regularly followed up with American Orthopaedic Foot and Ankle Society (AOFAS) ankle/hindfoot score and Visual Analogue Score-Foot and Ankle (VAS-FA) score were used to assess the functional outcome. Clinical and radiographic evaluations were done with each follow-up at 4,6,9,12 months. **RESULTS:** We identified 32 fractures in 32 patients. Treatment undertaken was open reduction and internal fixation for the malleoli and syndesmotic screw fixation in all patients, and syndesmotic screws were removed in 17 and retained in 15. None of the patients were managed conservatively. We lost a patient to long-term follow-up. The AOFAS score was seen to be progressively increasing (92.3 – 96.75) and higher in the removed group as compared to retained. The VAS-FA score was also seen to be increasing besides being higher in the removed group (160.17 to 187). None of the patients failed the operative stabilization. Also, none of the patients had long-term complications like non-union, mal-union or screw back out excepting one patient who had persistent pain in the retained group. **CONCLUSION:** It is safe and better to remove the syndesmotic screw prior to weight bearing, when compared to retaining them insitu. Level of evidence IV-prognostic

### KEYWORDS : Syndesmotic Injury, Screw Removal, Screw Retention

#### INTRODUCTION

Syndesmotic injuries are commonly associated with ankle fractures, particularly Weber B [Supination-external rotation (SER)]<sup>1</sup> and Weber C [Pronation-external rotation (PER) or Pronation abduction (PAB)]<sup>2,3</sup> classifications. Syndesmotic injury either occurs in isolation or external rotation trauma or after traumatic supination<sup>3,24</sup>. Aetiology can be either twisting of ankle or road traffic accident (RTA). The infrequency of these injuries associated with ankle fractures restricts this study in a large population. Majority of the present literature is comprised of various small studies.

The main classification systems proposed for ankle fractures are the Danis-Weber and the Lauge-Hansen classifications<sup>2,3,24</sup>. Although the Lauge-Hansen classification describes the mechanism of injury and helps assess the mode of management, the location of injury and level of syndesmosis can be clearly elucidated in the Weber classification. Surgical treatment involves fixation of the medial and lateral malleoli and introduction of a syndesmotic screw to fix the syndesmosis. However, recent studies have drawn to the fact that the syndesmotic screw can be retained and removal prior to weight-bearing can be avoided<sup>4</sup>. Their conclusion was based on patients in whom the functional outcome bettered in the retained group. Controversy also exists regarding the number of screws introduced, type of metal (stainless steel vs titanium), diameter and the position of the screws, type of fixation (screw vs suture button)<sup>5-7</sup>.

The purpose of our study was to evaluate the functional outcome in patients divided into two groups-screws removed vs. screws retained. The assessment began three months post-operatively and thereafter continued every three months in the first and second year and then once in six months thereafter. Patients were assessed clinically and radiographically on every follow-up visit.

We hypothesized that syndesmotic screws could be retained and required no removal before weight-bearing as propounded in recent studies<sup>4,8</sup>. Although involving a small set of subjects, this study includes meticulous follow-up and assessment of the functional outcome in the same group of patients prospectively with no loss of follow-up excepting one.

#### MATERIALS AND METHODS

For conducting this study, institutional review board approval was obtained. A prospective study was conducted at a single academic trauma centre between August 2014 and July 2017. The patients were meticulously followed up thereafter. Inclusion criteria included patients who were diagnosed with ankle fractures belonging to Weber B and C classification, associated with syndesmotic injury and fixation done with screws. Exclusion criteria included patients with age less than eighteen years, usage of bio-absorbable implants, patients with non-acute or pathologic fractures or an improper radiological evaluation.

We had a uniform protocol for patients presenting to the Emergency Department (ED) with ankle fractures. If there was an ankle dislocation, the reduction was done emergently in the ED and if unsuccessful, in the operating room by an open reduction. Until the swelling subsided, the injured limb was elevated. Intra-operatively, the lateral malleolar fracture was initially fixed with a 1/3rd tubular plate followed by medial malleolar fracture with a cancellous screw. Then, a hook test is done to assess the syndesmotic injury. Lateral fibular movement >2 mm indicates positivity. The syndesmotic screws are then placed through three cortices.

Radiographic assessment for loss of fixation, reduction of syndesmosis and failure of implants were done in each visit. Tibiofibular overlap and clear space on anteroposterior radiograph and medial clear space

and tibiofibular overlap were looked for in mortise radiograph. On each follow-up, clinical evaluation included range of motion, healing, tenderness, swelling and gait, which were compared with normal contralateral ankle joint. Patients were interviewed using AOFAS and VAS-FA scores.

A total of 32 patients were identified. They were divided into two groups:- screw removed and retained. The average age was 49 (ranging from 24-72) in the retained group and 45 in the removed group (ranging from 22-70). Screws were retained in 15 patients and removed in 17 patients (Table 1).

**Table 1 Patient groups**

Sex	Implant				p Value
	Retained		Removed		
	n=15	%	n=17	%	
Male (18)	10	62.5	2	33.3	0.348
Female (14)	6	37.5	4	66.7	

To compare the mean difference of VAS-FA and AOFAS between retained and removed groups, Mann Whitney U test was applied. Repeated ANOVA was applied for numerical data and Friedman's Two way ANOVA was applied for non-parametric data. Since it was found to be significant, multiple comparison tests were applied.

## RESULTS

The study shows that it is better to remove the syndesmotomic screw at the stipulated time of three months in comparison to retaining them.

VAS-FA and AOFAS scores assessed at different time periods among removed and retained groups using Mann Whitney U test is seen to be higher in the removed group compared to the retained group. Statistical significance was noted in the improvement of VAS-FA (table 2) and AOFAS scores (table 3) as the follow-up progressed.

Of all 32 fractures which were treated with ORIF and syndesmotomic screw fixation, all excepting two had uncomplicated outcomes. One patient had a superficial wound infection. He required a return trip to the Operating Room for debridement of the wound. Deep infections were detected in none. The other patient in the retained group had persistent pain in the ankle.

**Table 2 Comparison of VAS-FA score at different time periods among retained and removed groups using Mann Whitney U test**

Follow up	Syndesmotomic Screw	N	Mean	SD	p Value
VAS-FA score at 4 months	Retained	15	140.81	30.01	0.268
	Removed	17	160.17	14.36	
VAS-FA score at 6 months	Retained	15	153.86	30.32	0.458
	Removed	17	167.17	12.86	
VAS-FA score at 9 months	Retained	15	162.79	28.71	0.116
	Removed	17	184.00	8.49	
VAS-FA score at 12 months	Retained	15	170.86	26.59	0.182
	Removed	17	187.00	14.65	

**Table 3. Comparison of AOFAS score at different time periods among retained and removed groups using Mann Whitney U test**

Follow up	Syndesmotomic Screw	N	Mean	SD	p Value
AOFAS score at 4 months	Retained	15	81.44	11.39	0.020
	Removed	17	92.33	4.80	
AOFAS score at 6 months	Retained	15	86.71	13.05	0.089
	Removed	17	94.83	3.54	
AOFAS score at 9 months	Retained	15	91.29	11.08	0.170
	Removed	17	97.33	2.88	
AOFAS score at 12 months	Retained	15	90.86	12.68	0.552
	Removed	16	96.75	5.25	

## DISCUSSION

The syndesmosis in the ankle joint is a dynamic articulation. When dorsiflexion of the ankle joint happens, widening of distal tibiofibular joint space occurs so that the talus bone's wider portion is accommodated. During normal ankle range of motion and weight bearing, the ankle mortise requires this relative motion between the bones. Static articulation is provided at the distal tibiofibular syndesmosis after injury by fixation of this syndesmosis. The healing of the ligaments and maintenance of reduction are attained by this static stabilization<sup>9</sup>. Transsyndesmotomic fixation has plenty of recommendations in the literature, meanwhile still remaining as the

standard treatment of these injuries<sup>10</sup>. However, doubt still exists as to whether to remove or retain the screws prior to weight-bearing, which was the prime purpose of this study.

Nair A.V. et al. showed in their study that VAS-FA and AOFAS scores have a similar pattern of extracting scores and hence are efficient tools in the assessment of ankle scores in Indian patients. In our study, AOFAS and VAS-FA scores are the primary tools in determining the functional outcome.

Although the sex distribution was not of much significance, we found that males predominated over females in our study.

Physiological micromovement had been shown to occur when the distal tibiofibular joint was fixed by a screw, as by Beumer, Valstar and Garlinge<sup>11</sup>. Abnormal ankle movement and 'micromovement' may finally result in fatigue fracture of the screw or loosening. A retained screw may cause further complications including excess syndesmosis widening, inferior tibiofibular synostosis and osteolysis seen generally around the screw<sup>12</sup>. They, therefore, support removal of the screw at the end of three months.

The trio of de Souza, Gustilo and Meyer<sup>12</sup> proved in their study that the clinical outcome is not seriously affected if weight-bearing happens prior to removal of the screw. Patients who retained screw were followed up to approximately four years after insertion. Radiological follow-up showed no backed out or broken screws although a few remained loose. Similar findings were confirmed in another study by Heim and Regazzoni which found loosening in 91% of the patients with a retained tricortical screw indicating that micromovement of these screws makes them more likely to loosen rather than to break in the end. This supports the view of loosening by Beumer et al. Retaining screw does not affect the ankle range of movement<sup>13</sup>. Moreover, they also argued against removing the screw since it involves a second surgery with the incision being made into a healing wound, which may result in a higher rate of infection noted with metallic implants.

Hampering of dorsiflexion and affection of the tibiofibular movement by retaining the screw are the findings brought out by another group of researchers<sup>13,14</sup>. Breakage of the screw may also happen by leaving it in place<sup>14</sup>. Some of the major orthopaedic reference books<sup>15</sup> advocate removal prior to weight-bearing around 6-8 weeks influencing the existing practice<sup>17</sup>. This concept has been in dispute since the late 1950s and 1960s<sup>18,19</sup>. One of the prominent article is by de Souza et al.<sup>20</sup> which showed in a study of 30 patients, 12 had screws left in place. At an average follow-up of 36 months, no difference could be detected in pain, outcome and motion between removed and retained screws. An extra surgery for removal of the screw can also be avoided in the process.

Screw removal has its own risks, Schepers et al. showed a 22.4% complication rate after removal of the screws, infection in 9.2% and recurrent diastasis in 6.6%<sup>21</sup>. However, removal of the broken fragments if the syndesmotomic screw is broken is extremely difficult.

Neglected treatment or improperly treated syndesmotomic injuries shall result in chronic instability, latent diastasis, chronic pain, arthritic changes detected in radiographs and osteochondral lesions<sup>22</sup>. Based on Olerud-Molander and Short Form Musculoskeletal Assessment, Segi et al through two years of follow-up in a study compared correlation between functional outcome and syndesmosis malreduction and concluded that malreduction has worse functional outcomes. Open reduction of syndesmosis can result in lower malreduction rate<sup>16</sup>. Hence, it is crucial to check syndesmosis stability and confirming reduction.

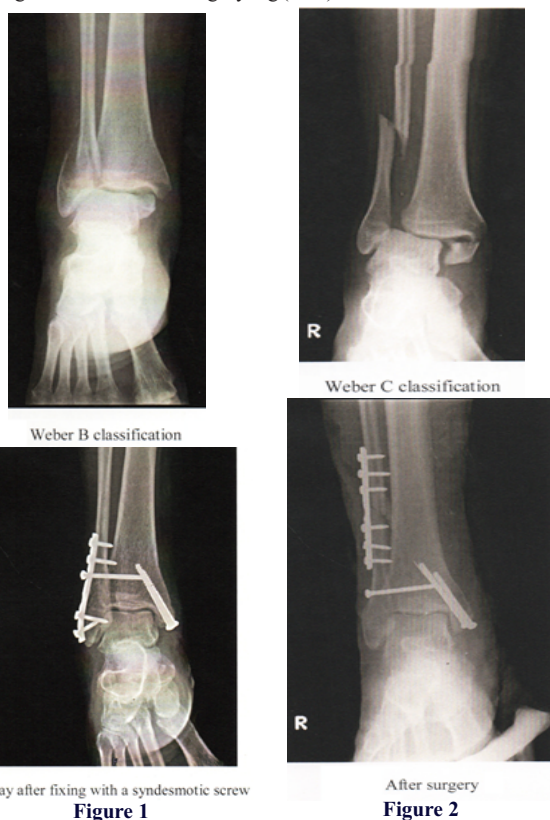
In a cadaveric study, Needleman et al<sup>22</sup> showed that a 4.5 mm screw fixed across four cortices reduced anterior and posterior talar translation and tibiotalar exorotation. Their conclusion was that since full weight-bearing and activity can cause fatigue fracture of the syndesmotomic screws, they should be removed prior to weight-bearing. Moore et al., in their study, did not remove screws routinely regardless of engagement of either three or four cortices. 8% hardware failure was detected in the group with three cortices of fixation and 7% in four cortices group. No screws were removed as all remained asymptomatic. Even with mechanical failure, retention of the screws will not pose clinical problems. Perhaps, with the thought that a second surgery would be required for removal and also that normal tibiofibular joint mechanics could be altered with the metallic syndesmotomic screws.

We generally had tricortical purchase with the syndesmotomic screw for all our patients. Mechanical failure was not noted within the course of study.

During daily activities, the distal tibial and fibular bony structures sustain large three-dimensional loads<sup>24</sup>. Non-anatomically reduced syndesmosis may result in disability, including osteoarthritis. In order to prevent a recurrence, restriction of daily activity for at least three months is a must. When screws are removed at six weeks, breakage is prevented, but the risk of recurrence is increased<sup>23,25</sup>.

We in our study have always tried to fix the fracture along with the syndesmotomic injury as early as possible provided the local skin condition, as well as the general condition of the patient, allowed us to do so.

In accordance to the published literature, Hickey, Ghaffar and Rice have proved in their study that Weber type C fractures constitute the main etiological fracture for syndesmosis injury. In our study, we have noted that 18 patients fell under the Weber B category, while 14 belonged to the Weber C category Fig (1&2)



**Figure 1**

**Figure 2**

No difference in outcome was noted between removed or retained screws in a few studies<sup>26,27</sup>. Ironically, in a landmark study by Hamid et al.<sup>4</sup>, they included a third group comprising broken screws and found that patients with such broken screws had the best functional outcome. They found that patients with retained screws had mean AOFAS score (and standard deviation) of 92.40 +/-12.69 compared to 83.07 +/-13.59 with syndesmotomic injuries and who had open reduction and fixation. Functional scores improved at the two-week mark following removal of the syndesmotomic screw but then plateaued with no further improvement at the twelve-week follow-up.

Manjoo et al.<sup>8</sup> proved less favourable outcome in intact screws that were retained but loosened, or broken screws had the same outcome as compared to removed screws. They recommend removal after six months if still intact, although they feel it prudent to remove them earlier.

Recent literature does not support routine removal<sup>28-30</sup>, as the outcome is found similar in both removed and retained syndesmotomic screws.

In the above studies, broken screws had no bad outcome, but in contrary had a similar or improved outcome over intact syndesmotomic

screws as emphasized by Hamid et al.<sup>29,30</sup>. It is a plea for avoiding routine removal. This point is stressed in three surveys with increased numbers of retained screws from 8% in 2004, 14% in 2008 and 35% in 2010<sup>31-33</sup>. The main limitation of these studies were their retrospective design.

The main advantage of our study is that it is a prospective study design. Patients were seen initially from the time of the accident and regularly followed up pre-operatively and post-operatively. We had no incidence of broken screws in the retained group.

Approximately, 7%-29% screws break in the retained group during follow-up irrespective of tricortical or quadricortical purchase. Synostosis can occur as seen by Karparinar, Kalenderer and Altay<sup>34</sup>. Heim et al showed that tricortical purchase screws, when left in place, showed loosening in 91% of patients. Early removal was more appropriate when no loosening happened, or dorsiflexion was limited<sup>2</sup>. Hoiness et al<sup>30</sup> removed quadricortically placed screws routinely, but tricortical screws were removed only when hardware complications originated. In this study, about 93% of patients required no hardware removal with tricortical screws. This points to the fact that when placed tricortically, a second surgery for removal of the screw can be avoided in about 90% of subjects.

The expectation of a less favourable outcome, if screws are left in situ, is seemingly unsupported. The need for removal is approximately 10% if inserted tricortically. Biomechanical stability or outcome are not affected in three cortical vs. four cortical screw placement. We preferred tricortical purchase for all our patients<sup>35,36</sup>. During placement of the screw, the position of the foot is said not to influence the outcome or range of motion according to studies<sup>28,37</sup>.

None of the patients showed radiographic loss of reduction in their fracture pattern or at the syndesmosis during their final follow-up visit. None of the patients excepting one had any wound complication or infection after the screw removal procedure. The one patient had persistent discharge which was debrided, washed and treated with antibiotics. In the retained group, one patient had chronic ankle pain on weight-bearing and the screw had to be removed subsequently.

VAS-FA score showed a steady increase as time progressed in both screw retained and removed groups. However, the increase was more noted in the removed group. AOFAS score too showed a similar trend. There were also significant mean increases in different time periods that too noted more in the removed groups. The AOFAS and VAS-FA scores almost approached their near maximum in the last follow-up, showing good functional outcome. Hence from these scores, we came to the conclusion that it is prudent to remove the syndesmosis screws at the end of three months after the surgery prior to weight-bearing on that particular limb.

Although the patients had a uniform opinion not favouring a second surgery for removal of the screw, the concept of screw removal for better functional movement and alignment had widespread acceptance among them. The main limitation of the study was its reduced sample size. In spite of the reduced sample size, there was statistical significance noted in some comparisons. Even if a few were found to be statistically not significant, there was a trend for an increase in the scores as time progressed.

## CONCLUSION

Our study points to the conclusion that it is safe and better to remove the syndesmotomic screw prior to weight-bearing when compared to retaining them.

## Compliance with ethical standards

**Conflict of interest:** There are no conflicts of interest; in the preparation of the manuscript, no extra- or intra- mural funding has been utilized. The authors and their affiliated research centres have not received any financial benefits or payments from any commercial entity with regard to subject of this manuscript

**Ethical standards:** The 1964 Helsinki Declaration and its amendments have been strictly obliged to. Approval had been obtained from the Institutional Review Board and the Ethical Committee

**Patient consent:** Informed consent was obtained from all patients for the study both for surgery and regular follow-up evaluation



**Funding:** There was no funding obtained or required for the study

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