

# **Technical aspects of the syndesmotic screw and their effect on functional outcome following acute distal tibiofibular syndesmosis injury**

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## **Abstract**

**Introduction** Much of the currently available data on the technical aspects of syndesmotic screw placement are based upon biomechanical studies, using cadaveric legs with different testing protocols, and on surgeon preference. The primary aim of this study was to investigate the effect of the level of syndesmotic screw insertion on functional outcome. Secondly, the effects of number of cortices engaged, the diameter of the screw, use of a second syndesmotic screw, and the timing of removal on functional outcome were tested.

**Material and method** All consecutive patients treated for an ankle fracture with concomitant acute distal tibiofibular syndesmotic injury that had a metallic syndesmotic screw placed, between January 1, 2004 and December 31, 2010, were included. Patient characteristics (*i.e.*, age at injury and gender), fracture characteristics (*i.e.*, affected side, trauma mechanism, Weber fracture type, and number of fractured malleoli), and surgical characteristics (*i.e.*, level of screw placement, screw diameter, tri- or quadricortical placement, number of syndesmotic screws used, and the timing of screw removal) were recorded. Outcome was measured using validated questionnaires, which were sent by post, and consisted of the American Orthopaedic Foot and Ankle Society ankle-hindfoot score (AOFAS), the Olerud–Molander Ankle Score (OMAS), and a single question Visual Analog Scale (VAS) for patient satisfaction with outcome.

**Results** During the seven year study period 122 patients were treated for syndesmotic injury. A total of 93 patients (76%) returned the questionnaire. The median follow-up was 51 months. The outcome scoring systems showed an overall score for the entire group of 92 points for the AOFAS, 77 for the OMAS, and 8.2 for the VAS. Outcome was statistically significantly influenced by the number of fractured malleoli, age, trauma mechanism, and the level of screw insertion.

**Conclusion** Overall, the functional outcome of acute syndesmotic injuries treated with a syndesmotic screw was good and mainly influenced by patient and fracture characteristics. Most different technical aspects of placement appeared not to influence these results. Only screw placement above 41mm negatively influenced outcome.

**Keywords** Syndesmotomic screw; distal tibiofibular joint; acute injury; surgery, outcome

## Introduction

The distal tibiofibular syndesmosis stabilizes the ankle joint, which as a dynamic system allows motion of the fibula in relation to the tibia in all directions. The syndesmosis consists of the anterior inferior tibiofibular, the interosseous ligament and membrane, the posterior inferior tibiofibular, and the inferior transverse ligament. Each of these ligaments contributes to the stability between 9 and 35%.<sup>1-2</sup> Rupture of two or more of these ligaments may lead to instability.

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The most recent biomechanical analysis of fibular motion with an intact syndesmosis showed an anterior/posterior translation of 1.5mm, a cranial movement of 0.5mm, and a lateral movement of 2mm during each plantar to dorsiflexion of the ankle. When looking at rotation the most pronounced motion is a 4 degree rotation around the fibular axis.<sup>4</sup>

It is estimated that 10% of all ankle fractures and 20% of the surgically treated fractures have a concomitant syndesmotic injury. In Weber C-type fractures (Lauge-Hansen Pronation ExoRotation (PER)) a syndesmotic disruption should be assumed.<sup>5-8</sup> In Weber B-type (Lauge-Hansen Supination-ExoRotation (SER) and pronation-abduction (PA)) the percentages of syndesmotic involvement range widely between 19 and 85 percent.<sup>9-13</sup>

Upon diagnosis proper treatment is warranted for favorable outcome. However, much of the data currently available on the technical aspects are based upon biomechanical studies using cadaveric legs with different testing protocols, and on expert opinions. Even though treatment is partially influenced by type of fracture and level of fracture, a large proportion of the management is based on surgeon preference. The primary aim of this study was to investigate the influence of the level of syndesmotic screw insertion on functional outcome. Secondly, the effect of the number of cortices engaged, the diameter of the screw, use a second syndesmotic screw and timing of removal were tested.

## Material and Method

All consecutive patients treated for an ankle fracture with concomitant acute distal tibiofibular syndesmotom injury that had a metallic syndesmotom screw placed, between January 1, 2004 and December 31, 2010, were included. Patients were treated at a single large level-2 trauma center. Patients in whom a bioresorbable screw was used (n = 4), had died (n=1), or had severe mental impairment (n=2) were excluded from participation.

Syndesmotom screws were placed upon stress testing using the hook-test or external-rotation stress test. The screw was placed either through the plate in Weber-B fractures or below the plate or individually in higher Weber-C fractures. Two syndesmotom screws were placed in Maisonneuve fractures, or when deemed necessary by the attending surgeon to increase the construct stability. The screw was angled at 30 degrees with the foot in 90 degrees or in a more neutral position. The screw diameter, level of placement, number of engaged cortices, and timing of removal were at the discretion of the surgeon (Figure 1). According to hospital protocol, patients received a postoperative non-weightbearing splint for two weeks, followed by a wound check and depending on fracture-type a weightbearing (in case of unilateral injuries) or non-weightbearing (in case of bi- or trimalleolar fractures) short leg cast for four weeks. After screw removal patients were allowed full weightbearing. Removal of syndesmotom screws between six to eight weeks was standard practice, as propagated by the *Arbeitsgemeinschaft für Osteosynthesefragen*. Patient characteristics (*i.e.*, age at injury and gender), fracture characteristics (*i.e.*, affected side, Weber fracture type, trauma mechanism, and number of fractured malleoli), and surgical characteristics (*i.e.*, level of screw placement, screw diameter, tri- or quadricortical placement, number of syndesmotom screws used, and the timing of screw removal) were recorded from the patient files and the picture archiving and communication system (PACS Kodak Carestream, Rochester, NY). The trauma mechanism was classified as low energy trauma (*i.e.*, sporting injury and sprain-like (supination) injury) or high energy trauma (*i.e.*, fall from height and traffic injury).

Level of screw placement was measured from the tibial pilon (joint line) to the center core of the screw. In case of placement of two screws the lowest screw was measured. Measurements were made in two consecutive radiographs (direct post-op and at first appointment at the outpatient department), these two values were averaged to correct for slight differences in radiographic projection. The level of the syndesmotic screw was then classified into three groups according to the AO-recommendations: 1) 0-20.99 mm above the tibia joint line or transsyndesmotic, 2) 21-40.99 mm, and 3) 41-60 mm. Timing of removal was divided into three groups according to findings of previous studies on syndesmotic screw removal: 1) <8 weeks, 2) ≥8 weeks, 3) still in place at follow-up. <sup>14-15</sup>

### *Outcome measurement*

Outcome was measured using validated questionnaires, which were sent by post in April 2012 after a minimum follow-up of 18 months, and consisted of the American Orthopaedic Foot and Ankle Society ankle-hindfoot score (AOFAS), the Olerud–Molander Ankle Score (OMAS), and a single question Visual Analog Scale (VAS) for patient satisfaction with outcome. A reminder was sent to patients that had not responded after four weeks. The OMAS is a self-administered patient questionnaire with a score of zero (totally impaired) to 100 (completely unimpaired) and is based on nine different items: pain, stiffness, swelling, stair climbing, running, jumping, squatting, sports, and work/activities of daily living. <sup>16</sup> The AOFAS ankle hindfoot score includes nine questions related to three components: pain (one question; 40 points), function (seven questions; 50 points), and alignment (one question; 10 points) leading to a total possible score of 100 points. The question related to alignment and range of motion was completed by a physician based upon patient files and radiographs; the other questions were completed by the patient. A Visual Analog Scale was used to measure overall satisfaction of patients with outcome (range 0–10).

### *Data analysis*

The statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 20.0 (SPSS, Chicago, IL). Normality of the continuous data was tested using the Kolmogorov-Smirnov test and by inspecting the histograms (Q-Q plots). The Levene's test was applied in order to assess homogeneity of variance between groups. A Student's T-test with or without assuming equal variance as applicable (numeric data), or Chi square analysis (categorical data) was performed in order to assess statistical significance between groups. When more than two groups were compared, a one-way Analysis of Variance (ANOVA) was performed, followed by a post-hoc pairwise comparison (Student's T-test) if the ANOVA p-value reached statistical significance. Numeric data are expressed as median with percentiles; categorical data are shown as numbers with percentages. Multivariable linear regression analysis was performed in order to model the relationship between different covariates (age, gender, Weber fracture type, number of fractured malleoli, trauma mechanism, and surgical variables) and the outcome scores (dependent variable). A p value  $<0.05$  was taken as level of statistical significance in all statistical tests.

## Results

During the seven year study period 122 patients were treated for an ankle fracture with a concomitant syndesmotic injury. A total of 93 patients (76%) return the questionnaire. The non-responders (n=29) were statistically significantly older than the responders (mean 52 (SD19) versus 43 (SD17) years;  $p=0.019$ ). For all other patient, fracture, and surgical characteristics these two groups were comparable. The mean follow-up was 54 months (SD 24).

Of all included patients 51 (55%) were male and in 56 (60%) the right side was injured. The trauma mechanism was a low energy trauma in 62 patients (sports injury in 39 and sprain-like injury in 23) and a high energy trauma in 28 patients (fall from height in 15, and traffic accident in 13). The mean delay to surgery was 5 (SD 5) days. The numbers of uni-, bi-, and trimalleolar fractures were 48 (52%), 33 (35%), and 12 (13%), respectively. Weber B fractures were seen in 37 (40%) patients and Weber C in 56 (60%).

Six patients developed a wound complication following surgery, and one male patient aged 54 with a trimalleolar Weber-B developed a chronic pain syndrome (CRPS); his outcome scores for the AOFAS, OMAS, and VAS were 19, 10, and 7 points, respectively, with a single screw at 36.6mm.

### *Statistical analysis*

The mean outcome scoring systems showed an overall score for the entire group of 92 points for the AOFAS, 77 for the OMAS, and 8.2 for the VAS. In the univariable analysis the following findings were of interest (Table 1). Patients with a trimalleolar fracture had significantly lower outcome scores than patients with a unimalleolar fractures (AOFAS 77 vs 95 points,  $p=0.034$ ; OMAS 60 vs 83,  $p=0.001$ ; VAS 7.1 vs 8.6,  $p=0.001$ ) and bimalleolar (VAS 7.1 vs 8.6,  $p=0.045$ ). Unimalleolar versus bimalleolar fractures showed no significant difference in outcome. Bi- and



trimalleolar fractures occurred significantly more frequently in women (29 of 45), and unimalleolar fractures predominated in men (35 of 48) ( $p=0.001$ ).

In the univariable analysis, when dividing the level of the syndesmotic screw into three groups, a difference in outcome as measured on the VAS was detected with higher placement (41-60mm) showing a worse outcome than placement between 21-40.99mm (7.5 vs 8.5 points,  $p=0.024$ ). In bimalleolar fractures the level of insertion was lower than with uni- and trimalleolar fractures (25.7mm vs 31.2mm and 32.5mm,  $p=0.033$ ). A statistically significant difference was found in the OMAS in favor of two screws compared with single screw placement (85 vs 75 points,  $p=0.043$ ).

Outcome, as measured on the AOFAS, OMAS and VAS, was not influenced by the number of engaged cortices, and diameter of the screw. Two screws were significantly more often placed in unimalleolar (13 of 48; 27%) versus bi- and trimalleolar (3 of 45; 7%) ( $p=0.033$ ) and Weber C-type versus B-type (24% vs 5%,  $p=0.007$ ) fractures. Patients where the screw was not removed or removed after eight weeks reported significantly more often stiffness on the subdomain of the Olerud-Molander Ankle Score (34 of 57 patients if not or delayed removed (60%) compared with the group with screw removal within 8 weeks (10 of 34 patients; 29%,  $p=0.017$ ), without a statistical significant effect on overall outcome.

In the multivariable analysis (Table 2), the AOFAS, OMAS, and VAS consistently showed a statistically significant decrease with increasing age and number of fractured malleoli. In addition, the AOFAS and VAS showed a decrease with a higher placement of the syndesmotic screw, and the AOFAS was influenced by trauma mechanism with low energy trauma resulting in a higher score than a high energy trauma.

## Discussion

The treatment of acute syndesmotic injuries has been and still is surrounded by many expert opinions. The primary aim of this study was to investigate the influence of the level of syndesmotic screw insertion on functional outcome. Secondly, the effect of the number of cortices engaged, the diameter of the screw, use a second syndesmotic screw and timing of removal were tested. The functional outcome as measured on the AOFAS and VAS score decreased with placement higher than 41mm. Moreover, none of the other technical aspects of syndesmotic screw insertion had a significant influence on the patient reported outcome.

The current study confirms findings of other studies with increasing age negatively affecting outcome<sup>17-18</sup> and the number of fracture malleoli as predictor of worse results.<sup>19</sup> No radiographic analysis was performed at follow-up to look at the accuracy of syndesmotic reduction, as pre-operative and postoperative conventional radiographs are not predictive of malreduction.<sup>11, 20-22</sup> Whether or not possible malreduction in this series attributed to a poorer outcome, as suggested by other studies could therefore not be assessed.<sup>22-23</sup>

Below a comparison is made of the results of the current study between the effect of technical aspects of the syndesmotic screw on functional outcome following acute distal tibiofibular syndesmosis injury and the existing literature.

### *Level of syndesmotic screw*

There is controversy in the literature considering the level of screw insertion ranging from two to five cm.<sup>3, 24-29</sup> The AO recommends placement just above the syndesmosis or at approximately 4 cm proximal to the joint and biomechanical studies frequently use the level of 2.5 cm.<sup>3, 26-27, 29</sup> Unfortunately, these biomechanical studies either use different protocols or report contradicting findings.<sup>28-30</sup> In the Netherlands, the level of placement was between 0 and 2.0 cm in 5.3%,

between 2.1 and 4.0 cm in 76.3% and between 4.1 and 6.0 cm in 16.4%.<sup>31</sup> An other study showed a placement of 57% at 2 cm and 25% at 4 cm. <sup>32</sup>

Theoretically, the level of screw insertion is dictated by the level of the fracture, type of implant, and surgeon's preferences. Besides these, one should take the vascular anatomy into consideration, as the perforating branch of the peroneal artery, which is one of the most important vessels of the syndesmotomous ligaments, penetrates the interosseous membrane at about 3 cm from the tibia pylon. <sup>33-34</sup> Up to date, one clinical study looked at the difference in outcome between transsyndesmotomous (< 2 cm from tibia pylon; 17 patients) and suprasyndesmotomous (> 2 cm from tibia pylon; 19 patients) screw insertion and found no difference in various items (i.e. pain, ADL restriction, range of motion, arthritis, and synostosis) at an average follow-up of approximately three years. <sup>35</sup> No patient-reported functional outcome score was used. The current study confirmed this finding in a larger series of patients with syndesmotomous injuries. There appears to be no difference in outcome in supra- or transsyndesmotomous placement of the syndesmotomous screw and the level should be chosen to obtain the most stable construct per individual fracture type. However, caution should be made not to place the syndesmotomous screw too high, as placement above 41mm resulted in a lower outcome. This might be attributed to less stability of the syndesmotomous screw at this level or by slight inward bending of the fibula at the fracture site with subsequent widening at the ankle mortise.

### *Number of cortices*

Considering the preferred number of engaged cortices biomechanical studies report contradicting findings. <sup>26, 29</sup> Clinically three studies have been performed. <sup>36-39</sup> These studies either show no benefit of four over three cortices <sup>38</sup>, or a clinical advantage at 3 months and a nonsignificant difference of 7 points on the OMAS in favor of the tricortical group at one year. <sup>37</sup> At an average follow-up of 8.4 years this difference completely disappeared. <sup>36</sup> One study reported a

significantly higher rate of synostosis with four-cortical screws but without any difference in outcome.<sup>39</sup> There were only twelve four-cortical screws in the current study, so a solid statement that the number of cortices did not influence outcome could not be made.

#### *One versus two syndesmotic screws*

Placement of a second syndesmotic screw is reported infrequently, and is suggested in cases where a more stable construct is needed. Examples are high Weber C-type fractures (Maisonneuve), comminuted fractures, higher BMI, or osteoporotic bone. On the contrary, there is a strong association with increasing BMI and loss of syndesmotic reduction irrespectively of the number of screws, diameter and number of engaged cortices.<sup>40</sup> Secondly, high Weber C fractures are frequently treated using a single screw, without reporting higher failure rates.<sup>25, 41-43</sup> Again, the biomechanical studies (partially) contradict each other.<sup>3, 29</sup> In the current study the number of screws did not influence outcome in the multivariable analysis.

#### *Screw type and diameter*

There appears to be no biomechanical advantage of a 4.5 mm screw over a 3.5 mm screw considering displacement, stiffness, and failure in exorotation.<sup>27, 44</sup> Clinically, outcome does not differ between one quadricortical 4.5mm screw removed at 8 weeks and two tricortical 3.5mm screws removed on indication.<sup>37</sup> The screw failure rate was non-significantly higher in one study (18/178 in 3.5 screws versus 0/18 following 4.5 screws) without clinical consequences.<sup>40</sup> Two locking screws through a plate give minimal displacement at the syndesmosis during axial loading, not significantly different as two 4.5mm quadricortical screws in a Maisonneuve model. However, they provide twice as much resistance to external stress testing.<sup>45</sup>

### *Timing of screw removal*

In the current study no difference in outcome scores between early, late, and no removal of the syndesmotic screw could be found. However, when looking at the subdomain stiffness from the OMAS, more patients reported stiffness after 4.3 years in the late removal and retained group. Arguments against removal would be costs and risks of secondary surgery, low benefit considering functional outcome, infectious complications, and recurrent syndesmotic diastasis.<sup>14-15, 46-48</sup> In case of three-cortical placement the screw is expected to behave more physiologically and removal was considered unnecessary in up to 90% of cases.<sup>9, 37-38</sup> On the other hand, routine removal of the syndesmotic screw might be beneficial in quadricortical and locking screws.<sup>37, 49</sup> Intact syndesmotic screws without loosening with complaints of stiffness after three months might benefit from removal as well.<sup>46-47, 49</sup> A second indication for removal might be a malreduced syndesmosis. It is known that malreduction of the fibula in the incisura of the tibia occurs in a high number of cases<sup>20-22, 50</sup> and is associated with a reduced outcome.<sup>22</sup> Mild malreductions might spontaneously reduce on an axial CT-scan following screw removal<sup>51</sup>; effect on outcome was not reported in this abstract. Removal of the syndesmotic screw on indication after 3 months in case of three cortical placement and proper reduction might be advised from a literature point of view.

Even though the current study is limited by its retrospective design and in some of the comparisons the number of patients was quite small to draw firm conclusions, the main strength of this study lies in the fact that it is one of the largest series of acute syndesmotic injuries with outcome reporting. Overall the functional outcome of acute syndesmotic injuries treated with a syndesmotic screw was good and the different technical aspects of placement apparently did not influence these results. There may be, however, some bias in the fact that age negatively influenced outcome and the responders (76%) were significantly younger than the non

responders. Per 10-years increase in age the AOFAS decreased with two points, and the OMAS with seven points.

The level of screw should be chosen based upon the level of the fracture and should not be too high (>4cm). In light of the current findings and the literature one or two 3.5mm tricortical screws should be placed below 4 cm of the tibial pilon, and removal after eight to twelve weeks in case of residual complaints of stiffness or in case of syndesmotic malreduction.

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**Table 1.** Outcome following acute syndesmotic injury for different fracture and surgical characteristics

		<b>N (%)</b>	<b>AOFAS</b>	<b>OMAS</b>	<b>VAS</b>
<b>Overall</b>		93 (100)	92 (14)	77 (24)	8.2 (1.5)
<b>Number of malleoli</b>	<b>Unimalleolar</b>	48 (52)	95 (10)	83 (19)	8.6 (1.4)
	<b>Bimalleolar</b>	33 (35)	92 (11)	73 (29)	8.1 (1.6)
	<b>Trimalleolar</b>	12 (13)	77 (23) a	60 (22) a	7.1 (1.2) a,b
<b>Trauma mechanism</b>	<b>Low energy trauma</b>	62 (69%)	94 (9)	79 (22)	8.3 (1.5)
	<b>High energy trauma</b>	28 (31%)	87 (19)	71 (28)	8.0 (1.6)
<b>Weber type</b>	<b>Weber-B</b>	37 (40)	88 (18)	72 (27)	8.0 (1.6)
	<b>Weber-C</b>	56 (60)	93 (10)	79 (22)	8.3 (1.5)
<b>Level of insertion</b>	<b>0-20.99mm</b>	24 (26)	93 (10)	74 (24)	8.3 (1.3)
	<b>21-40.99mm</b>	49 (53)	92 (14)	81 (23)	8.5 (1.5)
	<b>41-60mm</b>	19 (21)	88 (15)	71 (26)	7.5 (1.6) c
<b>Number of screws</b>	<b>1 screw</b>	77 (83)	91 (14)	75 (25)	8.1 (1.5)
	<b>2 screws</b>	16 (17)	93 (11)	85 (16) d	8.6 (1.4)
<b>Number of cortices</b>	<b>Tricortical</b>	81 (87)	91 (14)	77 (24)	8.3 (1.5)
	<b>Quadricortical</b>	12 (13)	92 (12)	74 (26)	7.9 (1.4)
<b>Diameter of screw</b>	<b>3.5mm</b>	84 (90)	92 (14)	76 (26)	8.2 (1.5)
	<b>4.5mm</b>	9 (10)	91 (10)	80 (21)	8.6 (1.6)
<b>Timing of removal</b>	<b>&lt; 8 weeks</b>	37 (40)	94 (4.6)	82 (20)	8.4 (1.4)
	<b>&gt;= 8 weeks</b>	44 (47)	90 (17)	73 (27)	8.1 (1.6)

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<b>Left in place</b>	12 (13)	92 (10)	73 (20)	8.2 (1.7)
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Outcome scores are expressed as mean with SD within brackets. AOFAS, American Orthopaedic Foot Ankle Society hindfoot score; OMAS, Olerud-Molander Ankle Score; VAS, Visual Analog Scale

a Statistically significant difference for all scores compared with unimalleolar ( $p=0.034$ ;  $p=0.001$ ;  $p=0.001$ )

b Statistically significant difference compared with bimalleolar ( $p= 0.045$ )

c Statistically significant difference compared with placement between 21-40.99mm ( $p=0.024$ )

d Statistically significant difference compared with single screw placement ( $p=0.043$ )

**Table 2.** Items influencing outcome in the multivariate regression analysis

<b>Outcome score</b>	<b>Covariate</b>	<b>Beta</b>	<b>95% Confidence Interval</b>
AOFAS (0-100)	Number of fractured malleoli	-7.6	(-11,3 ; -3,8)
	Level of screw placement	-4.5	(-8,1 ; -0,8)
	Trauma mechanism*	3.2	(0,7 ; 5,7)
	Age (year)	-0.2	(-0,4 ; -0,05)
OMAS (0-100)	Number of fractured malleoli	-7.6	(-1.0 ; -0.5)
	Age (year)	-0.7	(-14,1 ; -1,1)
VAS (0-10)	Level of screw placement	-0.5	(-0,9 ; -0,1)
	Number of fractured malleoli	-0.5	(-0,9 ; -0,1)
	Age (year)	-0.03	(-0,1 ; -0,02)

AOFAS, American Orthopaedic Foot Ankle Society hindfoot score; OMAS, Olerud-Molander Ankle Score; VAS, Visual Analog Scale

\* see Material and method section for classification of trauma mechanism

Figure 1. Three examples of the different syndesmotomic screw placement strategies

a. A 4.5 screw placed above 40.99mm quadricortically

b Two 3.5 screws with most distal one placed below 21mm tricortically

c. Single 3.5 screw placed between 21 and 40.99mm tricortically

