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Syndesmotic Fixation in Supination-External Rotation Ankle Fractures: A Prospective Randomized Study

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Abstract

Background: This study compared mid-term functional and radiologic results of syndesmotic transfixation with no fixation in supination external rotation (SER) ankle fractures with intraoperatively confirmed syndesmosis disruption. Our hypothesis was that early-stage good functional results would remain and unfixed syndesmosis disruption in SER IV ankle fractures would not lead to an increased incidence of osteoarthritis.

Methods: A prospective study of 140 operatively treated patients with Lauge-Hansen SER IV (Weber B) ankle fractures was performed. After bony fixation, the 7.5-Nm standardized external rotation stress test for both ankles was performed under fluoroscopy. A positive stress examination was defined as a difference of more than 2 mm side-to-side in the tibiotalar or tibiofibular clear spaces on mortise radiographs. The patients were randomized to either syndesmotic screw fixation (13 patients) or no syndesmotic fixation (11 patients). After a minimum of 4 years of follow-up (mean, 58 months), ankle function and pain (Olerud-Molander, a 100-mm visual analogue scale [VAS] for ankle function and pain) and quality of life (RAND-36) of all 24 patients were assessed. Ankle joint congruity and osteoarthritis were assessed using mortise and lateral projection plain weight-bearing radiographs and magnetic resonance imaging (MRI; 3T) scans.

Results: Improvement in Olerud-Molander score, VAS, and RAND-36 showed no significant difference between groups during the follow-up. In the syndesmotic transfixation group, improvements in all functional parameters and pain measurements were not significant, whereas in the group without syndesmotic fixation, the Olerud-Molander score improved from 84 to 93 (P = .007) and the pain (VAS) score improved from 11 to 4 (P = .038) from 1 year to last follow-up. X-ray or MRI imaging showed no difference between groups at the last follow-up visit.

Conclusion: With the numbers available, no significant difference in functional outcome or radiologic findings could be detected between syndesmosis transfixation and no-fixation patients with SER IV ankle fracture after a minimum of 4 years of follow-up.

Level of Evidence: Level II, prospective comparative study.

Keywords: syndesmosis, stress test, ankle fracture, supination-eversion, Weber B, fixation

Ankle fractures are the most common injuries treated operatively by orthopedic surgeons,[28,51] and Lauge-Hansen[21] supination external rotation (SER), Weber B[31] type of fracture is the most common of all indirect fibular fractures.[26,28,39] Syndesmosis injury may occur with more than 30% of Lauge-Hansen SE-type ankle fractures,[15,32,36,43,46] but the clinical relevance of syndesmotic disruption and repair in this fracture pattern is not well understood.[2,6,9,22,30,37,41,51]

Ankle fractures with instability of the distal tibiofibular syndesmosis result in poor function, pain, and early osteoarthritis.[10,22,23,38] Therefore, several studies recommend

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syndesmosis transfixation if intraoperative external rotation test or hook test suggests an unstable syndesmosis after malleolar fixation.[2,9,15,30,41,43,51] However, Kennedy et al,[19] in their prospective randomized study, found no difference in patients treated with or without a syndesmosis screw in low Weber C–type ankle fractures (within 5 cm of the talocrural [TC] joint) with associated syndesmosis injury.

A previous randomized controlled trial by Pakarinen et al[37] compared syndesmotic transfixation with no syndesmotic transfixation in SER IV fractures with syndesmotic disruption and found similar functional result at 1-year follow-up. However, short follow-up time may not reveal osteoarthritis-related changes from radiographs[10,23,28] and their impact on ankle function. Osteoarthritis has been reported to occur within 2 years after the initial trauma.[10,23,28] Patients developing arthritis following initial trauma may experience degradation of their initially good early functional results. In SER IV (Weber B) ankle fractures, the incidence of posttraumatic osteoarthritis Kellgren-Lawrence (K-L)[18] class III-V or equivalent has been reported to vary from 12% to 31%.[3,8,23,25] However, very little data are available on mid- or long-term functional results and the incidence of posttraumatic arthritis in SER-type ankle fractures.[3,8,23,25,52]

We are not aware of any published clinical studies with medium- or long-term follow-up reporting radiographic or functional outcomes comparing syndesmotic transfixation to no syndesmotic fixation in SER IV ankle fractures. The aim of this study was to compare mid-term functional and radiologic results of syndesmotic transfixation with no fixation in SER IV (Weber B)–type ankle fractures with intraoperatively confirmed syndesmosis disruption. We hypothesized that good functional results at an early stage would remain and that unfixed syndesmosis disruption in SER IV ankle fractures would not lead to an increased incidence of osteoarthritis.

Methods

This study was approved by the local ethics review board, and informed consent was obtained from each patient for study participation.

A previous study by Pakarinen et al[37] identified 24 patients with an unstable syndesmosis after malleolar fixation from a group of 140 operatively treated patients with Lauge-Hansen SER IV (Weber B) ankle fractures. After bony fixation, the 7.5-Nm standardized external rotation stress test, as described by Jenkison et al[15] and Pakarinen et al,[36,37] for both ankles was performed under fluoroscopy. A positive stress examination was defined as a difference of more than 2 mm side-to-side in the tibiotalar or tibiofibular clear spaces on mortise radiographs. The patients were randomized to either syndesmotic screw fixation (13 patients) or no syndesmotic fixation (11 patients). In this study, 20 patients had deltoid ligament rupture or avulsion on the medial side, and 4 patients had a medial malleolar fracture; 2 medial malleolar fractures were fragmentary, and 2 were fractures of the anterior colliculus.[37] Baseline characteristics of the patients showed no significant difference in any parameter (Table 1).

Table 1. Patients' Characteristics at Baseline.

	Syndesmotic Transfixation	No Syndesmotic Fixation	*P* Value
n	13	11	
Age, y	42.5 (SD, 11.6)	44.9 (SD, 14.2)	.4
Male/female	8/5	7/4	.4
Lauge-Hansen SE-4,[a] n/N	13/13	11/11	
Anatomy, n			.38
Fibula	9	6	
Fibula + medial malleolar	1	2	
Fibula + posterior malleolar	1	3	
Trimalleolar	2	0	
Open fracture	0	0	
Comorbidity,[b] n	4	1	.33

[a]SE-4, Lauge-Hansen supination external rotation type-4.
[b]Diabetes, Arteriosclerosis obliterans (ASO), and alcoholism.

All patients had similar postoperative treatment protocols. The ankles were immobilized in a below-the-knee cast for 4 weeks, and weight bearing was allowed as tolerated. The patients had follow-up visits at the outpatient clinic 2, 4, and 12 weeks and a minimum of 4 years after initial trauma. During the visits, the ankle was examined and mortise and lateral plain radiographs were taken. The range of motion of the injured ankle was also measured. Physiotherapists gave rehabilitation instructions at the 4- and 12-week visits. At a minimum of 1 and 4 years of follow-up, the questionnaires for pain and function were collected. Results of the 1-year follow-up of this prospective, randomized, controlled trial have been published earlier, and no difference in functional scores between groups was detected.[37]

After a minimum of 4 years of follow-up (mean ± standard deviation [SD], 58 ± 5 months in the syndesmotic transfixation group and 59 ± 6 months in the no syndesmotic fixation group; range, 48-66 months), we contacted all 24 patients by telephone in April 2013. Questionnaires to assess ankle function and pain (Olerud-Molander),[33,35] a 100-mm visual analogue scale (VAS) for ankle function and pain,[40] and quality-of-life (RAND 36-Item Health Survey)[1] questionnaires were sent to the patients by postal mail. Patients returned the completed questionnaires when they came for a follow-up visit at our outpatient clinic between April 26 and July 20, 2013. Patients were interviewed,

possible additional operations on the injured ankle were recorded, and the medical files were reviewed. An orthopedic resident who had completed hospital trauma training and who was blinded to the initial treatment of the patients conducted the clinical examination.

Range of motion of the injured ankle was measured using a goniometer. Maximum dorsiflexion was measured with the patient standing with his or her injured ankle on a 30-cm-high investigation table, and the patient leaned forward as far as possible with his or her heel remaining on the table. Plantar flexion was measured as the patient sat on an examination plane and was asked to plantarflex his or her injured ankle. The angles were then measured between the fifth metatarsal and fibula.

One patient in the no syndesmotic fixation group was unable to attend the clinical examination visit or to have the magnetic resonance imaging (MRI) or x-ray imaging, but he returned the completed questionnaires. One patient from the syndesmotic transfixation group had a prosthesis in her inner ear and was unable to have the MRI scan. One patient in the no syndesmosis fixation group did not have plain radiographs available.

Radiologic Assessment

Mortise and lateral projection plain standing radiographs and MRI (3T) scans from the injured ankle were taken. Tibiofibular joint congruity was assessed from plain radiographs by measuring the tibiotalar clear space (TTCS) and tibiofibular clear space (TFCS), and the results were compared with previous data from the 12-week follow-up visit. Measurements were done from the digital radiographs using a diagnostic workstation. The measurements were calibrated intraoperatively using the dimensions of the small fragment fixation screw (3.5 mm; Synthes, Valencia, CA) and arm of the F-tool as references. At the follow-up visits, a 30-mm calibration disc and dimensions of the small fragment fixation screw (3.5 mm; Synthes) were used. Measurements were made within 1-mm accuracy. The TFCS was measured at the level of the physeal scar approximately 1 cm proximal to the tibial plafond,[11,22,36,37,53] and the TTCS was measured as the distance between the lateral border of the medial malleolus and the medial border of the talus at the level of the talar dome.[15,16,36,37] An experienced musculoskeletal radiologist, blinded to clinical outcome, assessed and graded the severity of osteoarthritis from plain radiographs according to K-L classification[18] (grade 0, normal joint; grade 1, minute osteophytes of doubtful significance; grade 2, definite osteophytes; grade 3, moderate diminution of joint space; grade 4, joint space greatly impaired, subchondral sclerosis). In addition, syndesmosis calcification was evaluated from plain radiographs. All patients underwent MRI examinations using a 3.0-T MAGNETOM Skyra (Siemens Healthcare Sector, Erlangen, Germany) MR unit, using a dedicated ankle coil. The patients were placed in a supine position with the extremity neutrally positioned. The MRI sequences consisted of sagittal turbo inversion recovery magnitude (field of view, 24 × 24 cm; TR4700/TE33/TI190 milliseconds; section thickness, 3.0 mm; section gap, 0.6 mm; matrix, 320 × 256/4.00NEX), coronal intermediated weighted (field of view, 14 × 14 cm; TR4500/TE26 milliseconds; section thickness, 3.0 mm; section gap, 0.3 mm; matrix, 512 × 384/2.00NEX), and isotropic intermediate weighted 3-dimensional space (field of view, 14.8 × 13.7 cm; TR1200/TE28 milliseconds; ET43; section thickness, 0.5 mm; matrix, 320 × 296/2.00NEX). Another experienced musculoskeletal radiologist, also blinded to clinical outcome, analyzed the MRI scans. The height of the cartilage in the TC joint was measured in the sagittal plane at the center of the talus in the anterior and posterior sections of the joint and the height of the posterior facet at the center of the joint in the sagittal plane. Possible defects and osteophytes were also assessed.

Statistical Methods

Summary statistics are presented as means with standard deviations (SD) unless otherwise stated. Between-group comparisons were performed with Student t test or Mann-Whitney U test (continuous variables) and with Fisher exact test (categorical variables). A linear mixed model was used to analyze the change in functional scores (Olerud-Molander, VAS, and RAND-36), which were obtained after a minimum of 1 year and 4 years. The same method was used to analyze differences in the range of motion and radiologic parameters that had been measured at 12 weeks and at a minimum of 4 years after surgery. *P* values reported with Linear Mixed Model (LMM) were P_{time} for change between measurement points, P_{group} for average between-group difference, and $P_{time \times group}$ for interaction between time and group. A paired-samples test was used to analyze change from 12 weeks or 1 year to 4 years follow-up within the groups. Two-tailed *P* values are reported. A *P* value <.05 was considered statistically significant. Analyses were done using SPSS (IBM, released 2010, IBM SPSS Statistics for Windows, version 20.0, Armonk, NY) and SAS (version 9.3, SAS Institute Inc, Cary, NC).

Source of Funding

There was no outside source of funding for this study.

Results

Improvement in Olerud-Molander score, VAS (pain and function), and RAND 36-Item Health Survey (physical and pain) showed no significant differences in LMM between

Table 2. Function Parameters at the Follow-up[a].

	1 Year	Follow-up	P_{time}	P_{group}	$P_{time \times group}$
Olerud-Molander, mean (SD)			.083	.116	.209
Syndesmotic transfixation	80 (13)	81 (16)			
No syndesmotic fixation	84 (15)	93 (9)			
VAS function, mm, mean (SD)			.027	.193	.834
Syndesmotic transfixation	23 (25)	12 (15)			
No syndesmotic fixation	15 (15)	6 (8)			
VAS pain, mm, mean (SD)			.014	.056	.350
Syndesmotic transfixation	25 (25)	11 (15)			
No syndesmotic fixation	11 (13)	4 (8)			
RAND-36 physical, mean (SD)			.119	.186	.341
Syndesmotic transfixation	78 (23)	86 (19)			
No syndesmotic fixation	88 (19)	92 (15)			
RAND-36 pain, mean (SD)			.174	.059	.331
Syndesmotic transfixation	63 (33)	78 (22)			
No syndesmotic fixation	84 (14)	89 (12)			
Range of motion,[b] degree, mean			<.0001	.562	.302
Syndesmotic transfixation	62 (12)	75 (10)			
No syndesmotic fixation	58 (12)	75 (11)			

[a]*P* values reported with Linear Mixed Model (LMM) are P_{time} for change between measurement points, P_{group} for average between-group difference, and $P_{time \times group}$ for interaction between time and group.
[b]Twelve weeks and a minimum of 4 years of follow-up.

Table 3. Within-Group Change of Function Parameters From 1 Year to Follow-up.

	Syndesmotic Fixation			No Syndesmotic Fixation		
	Mean Difference	95% CI	*P* Value	Mean Difference	95% CI	*P* Value
Olerud-Molander	2	5 to −10	.77	9	3 to 15	.007
Visual analog scale pain, mm	−15	−32 to 2	.079	−7	−14 to −0.5	.038
Visual analog scale function, mm	−11	−27 to 5	.16	−9	−19 to 0.3	.056
RAND-36 physical	10	−5 to 25	.17	2	−1 to 6	.17
RAND-36 pain	−16	−31 to 0.1	.051	−2	−15 to 11	.71

groups during the follow-up (Table 2). Within the syndesmotic transfixation group, improvements in all functional parameters and pain measurements were insignificant, whereas in the no syndesmotic fixation group, significant improvements were seen in Olerud-Molander score and VAS pain (Table 3). Range of motion of the injured ankle improved in both groups during the follow-up period, but there was no difference between the groups during the follow-up (Table 2).

According to plain radiographs, the ankle mortise remained congruent in all patients, and the measurements showed no differences between groups (Table 4). Osteoarthritis was graded as K-L class I in 1 patient, K-L class II in 12 patients in the syndesmotic transfixation group, and as class II in 7 and class III in 2 patients in the no syndesmotic transfixation group ($P = .101$, Mann-Whitney U test). Syndesmotic calcification was detected in 8 (62%) patients in the syndesmotic transfixation group versus 1 (11%) patient in the no syndesmotic fixation group ($P = .031$, Fischer exact test). One patient's syndesmotic screw was broken and left in place. All syndesmotic screws that were intact and in place showed clear radiologic evidence of screw loosening.

Twelve patients had joint cartilage defects visible in the MRI: 8 (67%) in the syndesmotic fixation group versus 4 (40%) in the no syndesmosis fixation group. There were no between-group differences with regard to joint cartilage findings, TC joint cartilage height (anterior and posterior border), or height of the posterior facet in the MRI results (Table 5).

Reoperations

The syndesmotic screw was removed from 2 patients (both 2 months after fracture fixation) because of the local

Table 4. Congruity of the Ankle Mortise Assessed From Plain Radiographs.

	12 Weeks	>4 Years	P_{time}	P_{group}	$P_{time \times group}$
TTCS, mm, mean (SD)			.006	.62	.17
Syndesmotic transfixation	3.5 (0.8)	2.8 (0.8)			
No syndesmotic fixation	3.2 (0.6)	2.9 (0.8)			
TFCS, mm, mean (SD)			.60	.83	.86
Syndesmotic transfixation	5.4 (2.0)	5.5 (1.3)			
No syndesmotic transfixation	5.5 (1.2)	5.9 (0.9)			

Abbreviations: TFCS, tibiofibular clear space; TTCS, tibiotalar clear space.

Table 5. Magnetic Resonance Imaging (MRI) Parameters at Follow-up.

	Syndesmotic Transfixation	No Syndesmotic Fixation	
MRI Findings	Mean (SD)	Mean (SD)	*P* Value
Height of the TC joint cartilage anteriorly, mm	1.8 (0.5)	1.6 (0.4)	.16
Height of the TC joint cartilage posteriorly, mm	2.1 (0.4)	2.0 (0.3)	.46
Height of the posterior facet cartilage, mm	2.4 (0.4)	2.2 (0.3)	.18
	Number of Patients (%)	Number of Patients (%)	*P* Value
Joint cartilage defects	8 (67)	4 (40)	.39
Medial talus	3 (25)	1 (10)	.23
Lateral talus	0 (0)	1 (10)	.46
Medial tibia	6 (50)	3 (30)	.42
Lateral tibia	2 (17)	3 (30)	.62

irritation.[28,49] Both the screws and plate were removed from 1 patient because of the local irritation (15 months after fracture fixation).

Discussion

With the numbers available, leaving an unstable syndesmosis unfixed resulted in similar functional results and pain compared with syndesmosis transfixation at mid-term follow-up. Ankle mortise congruence had remained unchanged at mid-term follow-up, regardless of syndesmosis transfixation or no fixation of SER type IV (Weber B) ankle fractures. No between-group differences were detected. MRI showed several cartilage lesions in both groups. Posttraumatic osteoarthritis was mild in weight-bearing radiographs or MRI, and an unfixed syndesmosis did not lead to increased incidence of osteoarthritis, confirming our hypothesis.

In contrast to previous studies, we found that intraoperatively defined syndesmosis disruption left without fixation did not lead to worse functional outcomes, misalignment of the ankle mortise, or increased radiographic findings of osteoarthritis compared with syndesmotic transfixation with a screw.[9,22,23,38] Similar to our results, Kennedy et al,[19] in their prospective, randomized controlled trial, found no difference between patients with low Weber C–type ankle fractures (<5 cm proximal from the TC joint) and associated syndesmosis injury, treated with or without syndesmotic screw fixation. However, they used only preoperative plain radiographs to detect syndesmosis injury, and no intraoperative syndesmosis stability testing was performed,[19] which is considered superior to plain radiographs in diagnosing unstable syndesmosis.[5,32] Syndesmosis fixation may also have adverse effects. In particular, syndesmosis fixation with a screw or screws may result in malreduction of the distal tibiofibular joint, with the frequency ranging from 16% up to 52% in previous reports,[12,29,42,51] possibly leading to a poor outcome.[22,42,51] Synostosis or calcification around the tibiofibular joint is another possible adverse effect of syndesmotic screw fixation, and it may lead to impaired ankle function.[17,27,48,52]

Several studies have used casting for at least 6 weeks with no weight bearing after syndesmosis transfixation.[4,9,15,22,43] In contrast with previous studies, our postoperative treatment protocol was 4 weeks' immobilization in a cast, and weight bearing was allowed as tolerated despite intraoperatively confirmed syndesmosis injury.

Earlier published data suggest that the incidence of moderate to severe osteoarthritis (K-L class III-IV or equivalent) in SER type of ankle fractures range from 12% to 31%[3,8,23,25] and that osteoarthritis may can begin as early as 2 years after

the initial trauma.[10,23,28] Therefore, a minimum of 4 years of follow-up in our study would be a reasonably long period to show osteoarthritis-related changes. In our series, mild osteoarthritis was common, but moderate osteoarthritis was detected in only in 9% of the patients. This finding further suggests that syndesmosis transfixation in this fracture pattern may not be necessary to prevent osteoarthritis.

Earlier studies have shown that cartilage injuries, especially in the posterolateral tibia and/or talus, are common in SER-type ankle fractures, being diagnosed during the acute phase from in 58% to 73% using MRI or arthroscopy.[7,14,24,47] Some authors have suggested that chronically unstable syndesmosis may be responsible for similar cartilage defects of the tibia and talus.[13,34,50] Cartilage injuries, whether due to initial injury[14,45] or unstable syndesmosis, have been reported to adversely influence the clinical results.[20,24,44,47] In our study, MRI identified joint cartilage defects in 67% of patients, with similar rates in both groups, and they occurred mainly in the tibia and the medial side of the joint. No differences between groups were detected with regard to the location of the defects. Leaving the syndesmosis unfixed in this fracture pattern may not lead to syndesmosis instability and joint cartilage defects.

To our knowledge, no studies with medium- or long-term follow-up reporting radiographic or functional outcome compared syndesmotic transfixation to no syndesmotic fixation in SER IV ankle fracture patients with intraoperatively detected syndesmosis injury, exist. This randomized study was based on a prospectively collected patient series, and the instability of the syndesmosis after fixation of the bony defects was assessed by a reproducible and standardized method.[15,37] Instead of using a 1-mm difference,[15] we used a more than 2-mm side-to-side difference in the tibiotalar or tibiofibular clear spaces on mortise radiographs, comparing the results to the uninjured ankle as an indication of syndesmotic disruption.[37] We regarded the 2-mm accuracy in intraoperative circumstances as more reliable and reproducible than 1-mm accuracy. Ankle function and quality of life were assessed using valid questionnaires.

Syndesmosis instability after bony fixation turned out to be a rare event, and therefore we could enroll fewer patients than expected into the study. A small number of patients leaves us with the possibility of type II error in some functional scores and in the incidence of ankle joint osteoarthritis. However, our results showed consistent improvement in functional results in the no syndesmotic fixation group over time. Our study suggests that it would be safe to conduct a multicenter study in a larger patient population to gain enough statistical power to rule out type II error.

Conclusion

With the numbers available, syndesmosis transfixation in SER (Weber B)–type fracture pattern had no influence to functional results or radiologic findings after minimum of 4 years of follow-up compared with no syndesmosis fixation.

Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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