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Predictors of Hardware Removal in Orthopaedic Trauma Patients Undergoing Syndesmotic Ankle Fixation With Screws

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Abstract

Background: Indications for removal of syndesmotic screws are not fully elucidated. This study aimed to determine factors related to elective syndesmotic screw removal.

Methods: Patients who underwent fixation of ankle syndesmotic injuries were included. Screw removal was offered after a minimum of 12 weeks after surgery for pain, stiffness or patient desire to remove painful or broken hardware. Patient demographics, surgical data, distance of the syndesmotic screw from the joint, location of the screw at the physeal scar, and number of syndesmotic screws placed were collected for all patients. Bivariate and multivariate analyses were performed to determine the relationship between patient characteristics and screw removal and independent predictors of hardware removal.

Results: Of 160 patients, 60 patients (38%) with an average age of 36.1 (range: 18-84) years underwent elective syndesmotic screw removal at a mean of 7 (range, 3-47) months after initial fixation. The most common reason for screw removal (50/60 patients) was ankle stiffness and pain (83%). Patients who underwent screw removal were more likely to be younger (36.1 years $\pm$ 13.0 vs 46.6 years $\pm$ 18.2, $P < .001$) and have a lower ASA score (2 ± 0.8 vs 2.1 ± 0.7, $P = .003$) by bivariate analysis. Of patients who underwent screw removal, 21.7% (13/60) had a broken screw at the time of removal. Whether the screw was placed at the physeal scar was not significantly associated with patient decision for hardware removal ($P = .80$).

Conclusion: Younger and healthier patients were more likely to undergo elective removal of syndesmotic hardware. Screw distance from joint and screw placement at the physeal scar were not significantly associated with hardware removal.

Level of Evidence: Level III, retrospective cohort study.

Keywords: ankle fractures, syndesmosis, hardware removal, syndesmotic screws, ankle trauma, foot and ankle

Introduction

The syndesmosis plays a key role in stabilizing the tibiotalar joint, such that disruption of this structure can lead to drastic consequences in regard to weightbearing. Injuries to the syndesmosis are common following ankle fractures, with some studies suggesting syndesmotic injuries are present in 40% of Weber type B fractures.[26,27] Inadequate healing of the syndesmosis can result in early osteoarthritis and poor functional outcomes.[30] As such, fixation of an unstable syndesmosis following an ankle fracture is paramount to patient satisfaction. Traditionally, rigid screw fixation of the syndesmosis was the mainstay of treatment until biomechanical studies determined that rigid screws have a tendency to over-constrain the joint, which can lead

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to perception of stiffness or pain at the screw site.[1,4,7,16,17,29] These factors can lead to patient dissatisfaction following their procedure and lead to requests for hardware removal.

The decision to remove rigid syndesmotic screws remains controversial. Although studies suggest there is no evidence to support routine removal of syndesmotic screws,[5,14,21] some surgeons routinely remove all hardware in all patients. In surgeons who opt for removal of syndesmotic hardware, indications can include pain, stiffness, or patient desire to avoid loose or broken hardware.[3,20] Although the decision to remove hardware remains a topic of debate, there has been evidence that in patients who are symptomatic, physical function scores and ankle range of motion may improve following syndesmotic screw removal.[15]

To date, there has been no prior study investigating the characteristics of patients who opt for elective hardware removal or the relationship of syndesmotic hardware and its distance to the joint as a predictor of removal. Studies investigating hardware removal around the tibia have found that younger patients elect for removal more often, yet this has not been investigated for syndesmotic screws.[8] The aim of this study was to determine factors related to patients desiring elective syndesmotic screw removal. Our hypothesis was that younger patients would opt for removal at a higher rate and that screws placed closer to the tibiotalar joint would undergo a higher rate of removal because of an increase in stiffness about the syndesmosis.

Methods

Study Design

Following institutional review board approval, a retrospective cohort study was performed at an urban level 1 trauma center in the United States. Patients who were aged $\geq$18 years and underwent fixation of ankle syndesmotic injuries with rotational ankle fractures between 2011 and 2020 by a single fellowship-trained trauma surgeon were queried. All syndesmotic injuries were stabilized using 3.5-mm screw(s) placed tetracortically ideally located at the physeal scar. If placed above the scar, it was to avoid the fibular fracture or fibular hardware. Those with syndesmotic injuries with distal tibia or pilon fractures were excluded, as well as patients who underwent fibula fixation with a fibular nail, had diabetic complications, and those with neuropathy as syndesmotic screw removal was not offered for these patients. At our institution, syndesmotic hardware is not routinely removed; however, it is offered to eligible patients at least 12 weeks from surgery for reasons of (1) subjective ankle stiffness or perceived pain with an intact syndesmotic screw or (2) the patient not wanting to risk hardware breakage or loosening. If the syndesmotic screw was broken, removal was offered as long as part of the screw was still in the fibula across the syndesmosis or if the patient desired its removal. Patients were evaluated 2-3 weeks after screw removal to determine if there was relief of symptoms.

Data Collection

Recorded patient characteristics included age, sex, number of patient-reported allergies, American Society of Anesthesiologists (ASA) score, body mass index, race, and smoking status. Data on the number of syndesmotic screws used, number of broken malleoli, distance of the most distal screw from joint, and if the syndesmotic screw was placed at the level of the physeal scar was also collected.

Outcomes of Interest

The primary outcome of interest was patient factors that were associated with patient request for hardware removal. Secondary outcomes of interest included whether screw distance from the tibiotalar joint or location of the screw at the physeal scar was predictive of hardware removal, as well as if there was broken hardware present on follow-up radiographs.

Statistical Analysis

Bivariate analyses using 2-samples t test for continuous variables and Fisher exact test for categorical variables were performed to determine the association between characteristics and syndesmotic screw removal. Multivariable logistic regression modeling was used to determine independent predictors of syndesmotic screw removal. To minimize confounding, all variables with $P<.10$ in the univariable analysis were inserted into multivariable logistic regression models. All statistical analyses were conducted using R Studio Team 2020 (RStudio, PBC, Boston, MA). Statistical significance was defined as P value less than .05.

Results

A total of 160 patients were included in our analysis. The average age of patients was 42.6 (range: 18-84) years. The average ASA score was 2.0 ± 0.8 and the average BMI was 30.6 ± 6.7. Seventy-one patients (45%) only had 1 syndesmotic screw placed whereas 56% of patients (90/160) had more than 1 screw. All patient demographics can be found in Table 1.

The mean follow up time was 12 (range, 1-103) months. Sixty patients (38%) underwent syndesmotic screw removal (Table 2). The most common reason for hardware removal was ankle stiffness and pain (83%) followed by a desire to avoid broken screws (17%). The mean number of days from initial surgery to hardware removal was 7 (range, 3-47)

Table 1. Patient Demographics and Characteristics (N=160)

Parameter	Mean ± SD or n (%)
Age, y	42.7 ± 17.1
Sex	
Female	77 (48.2)
Male	83 (51.8)
No. of patient-reported allergies	0.6 ± 1.3
ASA score	2.0 ± 0.8
BMI	30.6 ± 6.7
Race	
White	107 (66.9)
Black	23 (14.4)
Hispanic	15 (9.4)
Asian	8 (5.0)
Asian Indian	5 (3.1)
(Missing)	2 (1.2)
Smoking status	
Never	94 (58.8)
Current	35 (21.9)
Former	31 (19.4)
No. of syndesmotic screws	
1 screw	70 (43.8)
>1 screw	90 (56.2)
No. of malleoli broke	1.8 ± 0.9
Screw distance from joint (mm)	12.1 ± 5.3
Screw at physeal scar	
Yes	90 (56.3)
No	70 (43.7)

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index.

months. Sixty percent (36/60) of patients had relief of symptoms (perceived stiffness or pain) after removal by the first postoperative visit

Patients who underwent screw removal were more likely to be younger (36.1 years ± 13.0 vs 46.6 years ± 18.2, $P < .001$) and have a lower ASA score (2.0 ± 0.8 vs 2.1 ± 0.7, $P = .002$). After controlling for confounding variables in the multivariable logistic model, age at surgery again was predictive of hardware removal ($P = .010$) whereas ASA score was not ($P = .10$) (Table 3).

A total of 90 patients (56.3%) had their screw placed at the physeal scar. Across all patients, the average distance of the most distal screw from the tibiotalar joint was 12.1 mm. On average, patients who opted for screw removal had their screw 11.7 mm proximal to the tibiotalar joint whereas those who did not opt for removal had a screw placed an average distance of 12.3 mm proximal from the joint ($P = .49$).

Having more than 1 screw placed was not predictive of undergoing screw removal ($P = .12$). Distance of the screw from the tibiotalar joint was not significantly associated with hardware removal with the numbers available. Each increase of 1-mm distance was associated with a 2% lower risk of hardware removal; however, this was not significant with the numbers available (OR = 0.98, 95% CI 0.92, 1.04; ($P = .48$). Similarly, whether the screw was placed at the level of the physeal scar or not was not significantly associated with hardware removal with the numbers available ($P = .80$).

Of the 100 patients who did not undergo screw removal, 49 patients had radiographic follow-up at 6 months, at which time it was noted that 25 patients (51%) had loose or broken screws on radiographs. Thirteen patients had broken screws and 12 patients were noted to have loose screws. Of the screws that were broken, 9 were placed at the physeal scar compared to 3 that were found to be loose ($P = .047$). Screws that were broken were placed on average 11.56 mm from the tibiotalar joint whereas screws that were loose were placed on average 13.97 mm from the joint ($P = .34$).

Discussion

In our study, 38% of patients elected to undergo hardware removal and these patients were more likely to be younger and have a lower ASA class than patients who did not elect to undergo hardware removal. There was no association between the number of screws across the syndesmosis or the position of the screws and the desire to have the hardware removed. On 6-month radiographs, it was noted that 25 (51%) screws were loose or broken in patients who did not elect for screw removal.

To our knowledge, our study is the first of its kind investigating the relationship between the desire to have elective hardware removal and patient characteristics. A study by Fenelon et al[6] in 2021 found that the median age of patients electing to undergo elective removal of hardware was 37.6 years, similar to the findings in our study where the average age of patients electing to undergo removal was 36.1 years. However, in the aforementioned study, there was no comparison made to the group that did not elect for hardware removal. Sanders in a randomized controlled trial looking at routine removal and on demand removal found that 23% of patients most commonly requested hardware removal for pain, limited range of motion, and stiffness; however, there was no information about the demographics of the patients who requested removal.[22]

Previously published literature reports a rate of syndesmotic hardware removal around 20% to 28%.[6,12,22,28] Interestingly in a randomized controlled trial comparing patients who underwent routine removal of syndesmotic hardware with those who underwent on-demand removal, only 23% of patients in the on-demand removal cohort requested syndesmotic screw removal even though patients were told hardware could be removed at any time.[22] A systematic review published in 2021 found no evidence to

Table 2. Characteristics of Study Population by Hardware Removal.[a]

Parameter	All Patients (N = 160)	Hardware Removal		*P* Value
		Yes (n = 60)	No (n = 100)	
Age, y	42.7 ± 17.1	36.1 ± 13.0	46.6 ± 18.2	**<.001***
Sex				.620
Female	77 (48.2)	31 (51.7)	46 (46.0)	
Male	83 (51.8)	29 (48.3)	54 (54.0)	
No. of patient-reported allergies	0.6 ± 1.3	0.5 ± 1.1	0.7 ± 1.4	.273
ASA score	2.0 ± 0.8	**2.0 ± 0.8**	**2.1 ± 0.7**	**.002***
BMI	30.6 ± 6.7	29.9 ± 5.6	31.1 ± 7.1	.243
Race				.853
White	107 (66.9)	43 (71.7)	64 (64.0)	
Black	23 (14.4)	7 (11.7)	16 (16.0)	
Hispanic	15 (9.4)	4 (6.7)	11 (11.0)	
Asian	8 (5.0)	3 (5.0)	5 (5.0)	
Asian Indian	5 (3.1)	2 (3.3)	3 (3.0)	
(Missing)	2 (1.2)	1 (1.6)	1 (1.0)	
Smoking status				.500
Never	94 (58.8)	38 (63.3)	56 (56.0)	
Current	35 (21.9)	13 (21.7)	22 (22.0)	
Former	31 (19.4)	9 (15.0)	22 (22.0)	
No. of syndesmotic screws				.116
1 screw	70 (43.8)	31 (51.7)	39 (39.0)	
>1 screw	90 (56.2)	29 (48.3)	61 (61.0)	
No. of malleoli broke	1.8 ± 0.9	2.0 ± 0.9	1.7 ± 1.0	.143
Screw distance from joint (mm)	12.1 ± 5.3	11.7 ± 4.6	12.3 ± 5.6	.485
Screw at physeal scar				.797
Yes	90 (56.3)	34 (56.7)	56 (56.0)	
No	70 (43.7)	26 (43.3)	44 (44.0)	

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index.
[a]Data are given as mean ± SD or number of patients (percentage).
*Boldface indicates statistical significance ($P < .05$). Categorical variables were tested with Pearson χ^2 or Fisher exact, and continuous variables with 2-sample *t* test.

Table 3. Multivariable Logistic Regression Model to Predict Hardware Removal.

Predictors	Beta coefficient	SE of the estimate	Adjusted OR (95% CI)	*P* Value	Crude OR (95% CI)
Age at surgery	–0.03	0.01	0.97 (0.95, 0.99)	**.01***	0.96 (0.94, 0.98)
ASA score	–0.43	0.26	0.65 (0.39, 1.08)	.10	0.5 (0.31, 0.79)

Abbreviations: ASA, American Society of Anesthesiologists; OR, odds ratio.
*Boldface indicates statistical significance ($P < .05$).

support routine screw removal and that screw removal should only occur with clear indications, which were not clearly specified.[5,14] Yet, other studies seem to suggest that patients who undergo syndesmotic removal fare better than patients who have not elected to undergo hardware removal.[15]

An important consideration to take into account is the associated risk of hardware removal as this is another invasive procedure for the patient. Analyzing a large database, Kellam et al[13] found an overall complication rate of 9.6%, highlighting that hardware removal is not a completely risk-free operation. Others have reported rates of infection of 0% to 9.2% specifically for syndesmotic screw removal.[23] That being said, as highlighted above, for some patients removal of hardware leads to improved outcomes, implying the importance of patient selection and a joint informed decision-making process.[15,23]

Few studies exist that investigate patient characteristics related to other types of implant removal. A study looking at hardware removal after tibia fracture found sex and

litigation were 2 factors that predicted hardware removal whereas age and BMI were not associated with hardware removal.[25] Garner et al[8] found that patients electing to undergo hardware removal following open reduction and internal fixation of tibial plateau fractures were younger than patients who did not opt for removal. Other studies investigating hardware removal include patients who are undergoing nonelective removal for reasons of infection, secondary fracture, or other complications related to their hardware, making it difficult for those study's findings to be compared to the ones presented here.

Most of the patients in our cohort opted for removal of hardware because of pain or stiffness about the syndesmosis. Other studies have also noted a similar trend in that patients opting for removal of hardware do so because of pain, stiffness, or limited range of motion about the ankle joint.[22,24] This is not entirely surprising given that biomechanical studies have determined that screws have a tendency to overconstrain the joint, which can lead to perception of stiffness or pain around the location of the screw.[4,7,16,17] Suture button fixation has been posed as an alternative option to provide more flexibility about the syndesmosis and limit perceived stiffness; however, concerns regarding stability allowing for proper healing are numerous.[16,17,19]

Of the patients who did not elect to undergo hardware removal, 13 patents were found to have broken screws, whereas 12 showed signs of radiolucency on radiographs. Although our sample size is admittedly small, we did find that screws that were loose were more likely to be placed away from the physeal scar, although when analyzing the measured distance from the joint there was no notable difference between screws that were broken and those that were loose. There has been some suggestion in the literature that a majority of syndesmotic screws break or loosen when the patient begins to bear weight.[10,11] However, this does not appear to affect patients' clinical outcomes, and actually studies have suggested that a broken screw results in improved patient outcomes than if the syndesmotic screw remains intact, as it allows for return of the physiological motion between the tibia and the fibula.[2,9,18] Although clinical outcomes for patients seem to improve, there is concern that broken syndesmotic screws can lead to pain, possibly as a result of bony erosion.[2,11] Although we did not obtain outcome measures on the patients in our study or investigate for bony erosion, these should be important considerations when counseling patients and discussing the possibility of removal of syndesmotic hardware.

Limitations

As this is a patient cohort from 1 urban hospital, the results may not be generalizable to the larger population as a whole; however, it does provide a framework for surgeons when counseling patients. Additionally, though we excluded patients with fibular nails and tibial pilon fractures, we did not classify patients based on the type or severity of rotational ankle fracture, which could impact patient's symptomatic state and long-term prognosis. Another limitation to consider is that at our institution patients are offered screw removal at 12 weeks for pain and stiffness; however, this may resolve over time such that the rate of removal may be higher than if screw removal was offered at 6 months or 1 year. Finally, no patient-reported outcome measures were used in this study, and they would be a valuable area of future study.

Conclusion

Younger and healthier patients were more likely to undergo elective removal of syndesmotic hardware. Screw distance from joint and screw placement at the physeal scar were not significantly associated with hardware removal.

Ethical Approval

Ethical approval for this study was obtained from Tufts Medical Center Institutional Review Board (IRB no. 1429).

Declaration of Conflicting Interests

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