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# Factors associated with adverse events after distal tibiofibular syndesmosis fixation ☆

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ABSTRACT

*Purpose and hypothesis:* Factors associated with adverse outcomes following surgery for syndesmotic instability with associated closed fibula fracture are incompletely understood. The purpose of this study was to determine the pathoetiology and incidence of adverse events after stabilization of syndesmotic instability. In addition, we aimed to identify any patient or surgeon related factors that might be associated with unanticipated outcomes.

*Methods:* Between January 2000 and May 2015, a total of 849 adult patients who were surgically treated with either screw or suture button fixation for syndesmotic instability with associated fibula fracture without open wound were identified and retrospectively evaluated. Multivariable logistic regression analyses were used to determine factors associated with any postoperative complication or unplanned reoperation.

*Results:* Within one year after surgery, 10.7% (91 patients) suffered an infectious complication and 22.0% (187 patients) underwent unplanned reoperation. Factors associated with infectious complications were increased duration of hospital admission (OR: 1.08, $p = .014$), use of an external fixator device before ORIF (OR: 5.19 $p < .001$), peripheral vascular disease (OR: 4.33, $p = .008$), and osteoporosis (OR: 2.71, $p = .022$). For unplanned hardware removal specifically, patients' BMI below 30 was an associated risk factor. (OR: 1.50, $p = .010$).

*Conclusion:* Certain patient groups have an increased risk of adverse events following the use of current surgical fixation methods for stabilizing the syndesmosis. Patients undergoing surgery for syndesmotic instability with associated fibula fracture without open wound should be counseled that up to 1 in 10 suffer an infectious complication and that 1 in 5 require unplanned hardware removal.



## Introduction

Syndesmotic instability often requires surgical stabilization to optimize functional outcome [1,2]. Currently, the most common surgical treatments of syndesmotic instability are rigid screw or dynamic suture button fixation. There exists insufficient evidence to demonstrate which surgical treatment method is superior for this type of injury [3]. Functional recovery is crucial following any such surgical reconstruction, however, to maximize early return to daily activity, work, and sports. Unfortunately, wound, implant, or other complications sometimes occur after surgical treatment of the unstable syndesmosis and can result in delayed functional recovery, long- term disability, and considerable associated cost. In order to guide surgeons in their treatment decisions, previous small sample size studies have tried to determine the complication rate and risk factors associated with postoperative complications [4–11]. While complications can be multifactorial in nature, prior reports have failed to adjust for potential confounders.

☆ Level of evidence: III, Therapeutic study.

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**List of abbreviations**

| | |
|---|---|
| ORIF | open reduction and internal fixation |
| ICD9 | international classification of diseases, ninth revision |
| CPT | current procedural terminology |
| RPDR | research patients data register |
| IQR | interquartile range |
| CI | coincidence interval |
| OR | odds ratio |
| VIF | variance inflation factor. |

The purpose of this study was to determine the nature and incidence of adverse events after stabilization of syndesmotic instability. In addition, we wanted to assess which patient related and surgical factors might be associated with such outcomes.

## Materials & methods

### *Study design and participants*

Our Institutional Review Board approved a waiver of consent for this retrospective study. We used International Classification of Diseases, ninth revision (ICD-9) code 84503 (Sprain of distal tibiofibular ligament) and Current Procedural Terminology (CPT) code 27829 (open treatment of distal tibiofibular joint disruption) to identify patients who underwent surgical treatment for isolated (without associated fibula fracture) syndesmotic instability or syndesmotic instability with associated fibula fracture. Any patient who received surgical treatment in one of three affiliated local level 1 trauma centers between January 2000 and May 2015 were eligible for enrollment. Medical record data of patients flagged with at least one of the CPT or ICD9 codes were retrieved through our Research Patients Data register (RPDR). This is a centralized clinical data registry covering patients from a tertiary care referral center. The RPDR provides diagnostic ICD9 codes, CPT codes, operative reports, radiological reports, clinical encounters, demographic information (e.g. gender, race, date of birth, marital status) and pathological reports. There were 1111 patients with ICD-9 code 84503 and 908 patients with CPT code 27829. All patient charts were manually checked to confirm surgical treatment for syndesmotic instability. In total, there were 1118 patients who were surgically treated.

Inclusion criteria were (1) age 18 years or older, (2) patients with single limb injuries without open wound, (3) confirmed diagnosis of syndesmotic instability with associated closed fibula fracture by widening of the syndesmosis on radiographs, (4) patients with first time surgery for syndesmotic instability, (5) surgical treatment for syndesmotic instability, and (6) minimum follow-up of one-year post-operative. Exclusion criteria were (1) below knee trauma of ipsilateral lower extremity apart from syndesmotic injury or related malleolar fracture, (2) history of ankle trauma treated surgically or removal of hardware prior to syndesmotic surgery, (3) syndesmotic instability treated with a combination of screw and suture-button fixation, (4) patients diagnosed with an isolated syndesmotic instability, (5) patients with an open wound fracture or closed fracture with open wound, and (6) patients with planned removal of hardware.

### *Outcome measures and explanatory variables*

Outcome variables were divided in infectious complications, unplanned reoperation for the removal of hardware and remaining complications. Postoperative infectious complications included deep surgical site infections, superficial surgical site infections, and osteomyelitis. Unplanned reoperation was defined as reoperation for unplanned hardware removal due to, infection, revision of ORIF, failure of fixation, loss of reduction, malreduction or symptomatic hardware. Remaining complications were sepsis, mal-reduction/mal-union/non-union of the fractured fibula, recurrent diastases of the syndesmosis, nerve damage of the ipsilateral lower extremity, compartment syndrome, ankle arthropathy, deep vein thrombosis, and pulmonary embolism. Host related explanatory variables were age at the time of surgery, sex, body-mass-index - patients were considered obese if their body mass index exceeded 30 at time of surgery, tobacco use - categorized as no tobacco use, or current smoker/history of tobacco use, diabetes mellitus, alcohol or drug abuses, peripheral vascular disease, osteoporosis, and rheumatoid arthritis. Other explanatory variables were duration of admission in days, surgeon speciality - categorized as trauma surgeon or non-trauma surgeon, surgeons experience in years of independent practise, time between initial injury and surgical treatment, associated fracture type - divided into Weber A, B, or C based on the Danis-Weber classification [12], open or closed fracture, use of an external fixator device before open reduction internal fixation (ORIF), type of operative treatment - syndesmotic screw fixation, suture button fixation, tricortical or quadricortical screw placement, number of used suture buttons or syndesmotic screws to stabilize the syndesmosis, and type of postoperative immobilization strategy divided in non-weight bearing and partial-weight bearing. Outcome and explanatory variables were identified through specific ICD-9 code search in the RPDR data registry and independently confirmed by manual search of the electronic patient database by two of the authors (DL, RS). Surgical characteristics like type of implant, number of implants, and number of cortices pierced by implants were manually retrieved from surgical and radiological reports.

### *Statistical analysis*

Variables were presented with frequencies and percentages for categorical variables and as median with interquartile range (IQR) for non-normal distributed continuous variables. The difference in explanatory variables among the risk factors were assessed using a Chi-square test for dichotomous and categorical variables and a Mann-Whitney U test for non-normal distributed continuous variables. Postoperative overall complication rates, infectious complications, and mechanical complications were determined. Odds ratios (OR) with 95% confidence intervals (CIs) were presented to quantify the association between risk factors and postoperative complication rate without controlling for other explanatory variables. Multivariable logistic regression analyses were used to assess if risk factors separately associate with postoperative complications after accounting for explanatory variables. Risk factors with a $p$ value of 0.1 or lower in bivariate analysis were analysed in a multivariable logistic regression model. Multicollinearity - a phenomenon in which two or more explanatory variables in a multiple regression model are highly correlated - was suspected between (1) diabetes mellitus, peripheral vascular disease, and tobacco use, (2) osteoporosis and rheumatoid arthritis, and (3) open fracture and external fixation before prior to ORIF**.** Therefore, we evaluated each of these variables by estimating how much the variance of a coefficient was inflated because of linear dependence with one of the other predictors. The variance inflation factor (VIF) for these variables was calculated in all three conducted multivariable logistic regression analyses. If the VIF exceeds 10, there may be a correlation between independent variables influencing the outcome [13]. There was no multicollinearity between diabetes mellitus, peripheral vascular disease, and tobacco (VIF score ranging from 1.01 to 2.35). Similarly, we found no multicollinearity between

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**Table 1**
Baseline characteristics comparing screw fixation with suture button fixation.

| Variables | Screw Fixation ($n$ = 810) | | Suture Button Fixation ($n$ = 39) | | $p$ value |
|---|---|---|---|---|---|
| Age (years) | 42 | 30–56 | 36 | 24–48 | **0.02** |
| Male sex | 455 | 56% | 24 | 62% | 0.51 |
| Duration of admission (days) | 3 | 2–4 | 0 | 0–1 | **<0.001** |
| Surgeons specialization | | | | | |
| Trauma | 493 | 61% | 1 | 3% | **<0.001** |
| Non-trauma | 317 | 39% | 38 | 97% | |
| Surgeon experience (years) | 6 | 1–13 | 4 | 2–14 | 0.97 |
| Days between injury and surgery | 2 | 1–9 | 8 | 4–11 | **<0.001** |
| Number of implants | | | | | |
| 1 | 382 | 47% | 23 | 59% | 0.597 |
| 2 or more | 428 | 53% | 16 | 41% | |
| External fixation | 27 | 3% | 0 | 0% | 0.25 |
| Fracture type | | | | | |
| Weber A | 8 | 1% | 0 | 0% | 0.53 |
| Weber B | 226 | 28% | 7 | 18% | 0.17 |
| Weber C | 561 | 69% | 32 | 82% | 0.089 |
| Other* | 15 | 2% | | 82% | 0.089 |
| Tobacco use | 293 | 36% | 7 | 18% | **0.020** |
| Alcohol/ Drug abuse | 79 | 10% | 2 | 5% | 0.34 |
| Obesity (BMI ≥ 30) | 449 | 55% | 19 | 49% | 0.41 |
| Diabetes mellitus | 97 | 12% | 3 | 8% | 0.42 |
| Peripheral vascular disease | 17 | 2% | 1 | 3% | 0.84 |
| Osteoporosis | 35 | 4% | 2 | 5% | 0.81 |
| Rheumatoid Arthritis | 17 | 2% | 0 | 0% | 0.36 |
| Type of postoperative WB | | | | | |
| Non | 391 | 49% | 35 | 90% | **<0.001** |
| Partial | 416 | 51% | 3 | 8% | **<0.001** |
| Unknown | 1 | 0% | 1 | 3% | **<0.002** |

Abbreviations: SD Standard deviation. BMI body mass index.
WB weight bearing.
* Malleolar fracture without fibular fracture.

osteoporosis and rheumatoid arthritis (VIF score ranging from 1.09 to 1.44). However, the VIF score was high between open fracture and external fixation before prior to ORIF (ranging from 9.18 to 9.98), indicating multicollinearity. For this reason, all patients with open fractures, 128 in total, were removed from analysis so that there remained 849 patients for final analysis. All analyses were performed using Stata® 13.0 (Stata Corp LP, College Station, TX, USA) and two-tailed p-values less than 0.05 were considered significant.

## Results

### *Baseline characteristics*

There were 370 (43.6%) woman and 479 (56.4%) men with a median age of 44 years (IQR, 30–57 years) at time of surgery. The median duration of admission was 3 days (IQR, 2–4 days). Three hundred and eighty-two patients were treated using one syndesmotic screw, 428 with two or more syndesmotic screws, 23 with one suture button, and 16 with two suture buttons, and 27 patients received an external fixator device before ORIF due to severe lower limb swelling. Two hundred and ninety patients had their hardware removed, of which 187 were unplanned removal. Compared to suture button fixation, patients treated with screw fixation were on average older of age, more frequently smoker, and were longer hospitalised (Table 1).

### *Overall postoperative complications*

Two-hundred-and-seventy-six (32.5%) patients had *one or more* complications within one year after surgery. One hundred and eighty-seven (22.0%) had an unplanned reoperation for hardware removal and 91 (10.5%) patients were diagnosed with a postoperative infectious complication. Remaining complications were, 8 (1.0%) sepsis, 23 (2.7%) non- or mal union, 74 (8.7%) arthropathy, and 10 (1.2%) patients were diagnosed with a venous thromboembolism (Table 2).

Multivariable logistic regression analysis found that external fixation before ORIF (OR: 4.52, $p$ = <0.001), osteoporosis (OR: 2.84, $p$ = .006), and rheumatoid arthritis (OR: 8.15, $p$ = .001) were independently associated with overall postoperative complications (Table 3).

### *Infectious complications*

Ninety-one (10.7%) patients were diagnosed with a postoperative infectious complication within one year after surgery. Of these 88 patients had a surgical site infection, and 49 patients developed postoperative osteomyelitis. Multivariable logistic regression analysis demonstrated that increased duration of hospital admission (OR: 1.08, $p$ = .014), use of an external fixator device before ORIF (OR: 5.19, $p$ < .001), peripheral vascular disease (OR: 4.33, $p$ = .008), and osteoporosis (OR: 2.71, $p$ = .0.022), were independently associated with a higher infectious complication rate after surgery (Table 4).

### *Reoperation for unplanned hardware removal*

One hundred and eighty-seven (22.0%) had an unplanned reoperation for hardware removal, including 10 (1%) revision of ORIF, 9 (1%) loss of reduction, 6 (1%) malreduction, 39 (5%) infection, 108 (13%) symptomatic hardware, and 15 (1%) due to other reasons. Multivariable logistic regression analysis showed that a BMI below 30 caused more (OR: 1.50, $p$ = .010) reoperations for unplanned hardware removal (Table 5).

## Discussion

To the best of our knowledge, this study represents to date the largest cohort of patients who have received follow up

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**Table 2**
Complications comparing screw fixation with suture button fixation ($n$ = 849).

| Complication type | Screw Fixation ($n$ = 810) | | Suture Button Fixation ($n$ = 39) | | p value |
|---|---|---|---|---|---|
| Total complications | 271 | 33% | 5 | 13% | **0.007** |
| Unplanned reoperation | 183 | 23% | 4 | 10% | **0.05** |
| Infectious complications | 90 | 11% | 1 | 3% | **0.064** |
| Sepsis | 8 | 1% | 0 | 0% | 0.69 |
| Arthropathy | 74 | 9% | 0 | 0% | 0.33 |
| Mal/ Non-union | 23 | 3% | 0 | 0% | **0.03** |
| Venous thromboembolism | 9 | 1% | 1 | 3% | 0.38 |

**Table 3**
Multivariable logistic regression analysis overall complications ($n$ = 276).

| Variables | Odds ratio | 95% CI | | $p$ value |
|---|---|---|---|---|
| Age (years, median with IQR) | 1.00 | 0.99 | 1.01 | 0.914 |
| Duration of admission (days) | 10.40 | 0.99 | 1.10 | 0.072 |
| Type of implant | | | | |
| Screw | reference value | | | |
| Suture-button | 0.59 | 0.22 | 1.62 | 0.306 |
| External fixation | 4.52 | 1.98 | 10.34 | **<0.001** |
| Diabetes mellitus | 1.37 | 0.85 | 2.22 | 0.199 |
| Peripheral vascular disease | 1.62 | 0.58 | 4.61 | 0.361 |
| Osteoporosis | 2.84 | 1.34 | 5.99 | **0.006** |
| Rheumatoid Arthritis | 8.15 | 2.25 | 29.53 | **0.001** |

**Table 4**
Multivariable logistic regression analysis infectious complications ($n$ = 91).

| Variables | Odds ratio | 95% CI | | $p$ value |
|---|---|---|---|---|
| Age (years, median with IQR) | 1.01 | 0.99 | 1.03 | 0.183 |
| Duration of hospital admission (days) | 1.08 | 1.02 | 1.15 | **0.014** |
| Type of implant | | | | |
| Screw | reference value | | | |
| Suture-button | 0.52 | 0.07 | 4.04 | 0.528 |
| External fixation | 5.19 | 2.19 | 12.31 | **<0.001** |
| Cortices pierced by implant | 1.61 | 0.61 | 4.27 | 0.335 |
| Diabetes mellitus | 1.19 | 0.61 | 2.31 | 0.605 |
| Peripheral vascular disease | 4.33 | 1.46 | 12.84 | **0.008** |
| Osteoporosis | 2.71 | 1.16 | 6.36 | **0.022** |
| Tobacco use | 1.51 | 0.95 | 2.44 | 0.084 |

**Table 5**
Multivariable logistic regression analysis unplanned reoperation ($n$ = 187).

| Variables | Odds ratio | 95% CI | | p value |
|---|---|---|---|---|
| Duration of hospital admission (days) | 1.01 | 0.96 | 1.05 | 0.768 |
| Obesity (BMI≤30) | 1.50 | 1.10 | 2.05 | **0.010** |
| Peripheral vascular disease | 2.48 | 0.93 | 6.57 | 0.096 |
| Osteoporosis | 1.58 | 0.76 | 3.25 | 0.218 |

Abbreviations: CI coincidence interval. BMI body mass index.

after the surgical treatment of syndesmotic instability. Postoperative, 91 (10.7%) patients suffered an infectious complication and 187 (22.0%) had an unplanned reoperation for removal of hardware including syndesmotic specific complications like 10 (1%) revision of ORIF, 9 (1%) loss of reduction, 6 (1%) malreduction, 39 (5%) infection, 108 (13%) symptomatic hardware, and 15 (1%) due to other specified reasons. Risk factors associated with overall complications were external fixation before ORIF, osteoporosis, and rheumatoid arthritis. When looking at infectious complications specifically, associated factors included duration of hospital admission, use of an external fixator device before ORIF, peripheral vascular disease, and osteoporosis. A BMI below 30 increased the chance of an unplanned reoperation for hardware removal.

This study has several limitations to consider. First, complications after surgical treatment may be under-represented, as patients—although presumably reasonably uncommon— could have followed up for such problems at a different institution not included in our database. We tried to minimize this limitation by excluding patients who were followed postoperatively less than one year. Second, in our cohort we had no data on postoperative activity level or return to sports, therefore we cannot make any recommendations in regard to which type of implant is more beneficial regarding this subject. Third, changes in surgical technique or trauma care (e.g. fracture and syndesmotic reduction, rehabilitation) and recent changes in the management of syndesmotic injuries (e.g. diagnostic evaluation of instability or more frequent use of a suture button device), may have impacted the complication rate over the 15-year study period.

The complication rate for syndesmosis ORIF documented in previous studies has ranged from 4.8% to 31%, [4,5,7,9–11] with an average follow-up time of 266 days (range 90 to 365 days). The relative high complication rate reported in our current study could be related to a prolonged follow-up of 365 days. If we used a follow up of 266 days, for example, the number of complications captured herein would have been 201 (23.6%). Regarding syndesmotic specific complications, post-operative malreduction of the syndesmosis has been reportedly linked to degenerative changes of the ankle joint and unsatisfying patient reported outcomes [14,15]. Adequate reduction of the unstable syndesmosis can be challenging as proven by previous studies who found malreduction rates between 16 and 52% [16,17]. The study of Davidovitch et al. [17] included symptomatic and asymptomatic patients with malreduction, while the current study only included symptomatic patients, which may explain the relative low rate of malreduction. Moreover, the studies performed by Cosgrove et al. and Davidovitch et al. [16,17] assessed malreduction on radiographic images specifically, while the current study assessed malreduction by reviewing surgical and radiological reports. This may underrepresent the number of malreduction in the current study.

We found that postoperative adverse events developed more frequently in patients being treated with screw fixation compared to patients receiving a suture button device. This is considered most likely related to the heterogeneous patient profiles in which such constructs were applied. Patients treated with screw fixation were frequently older, smokers, had longer hospital stays, and more severe injuries compared to patients treated with suture button fixation (Table 1). In addition, static fixation with a syndesmotic screw may cause discomfort during weight-bearing and may require unplanned hardware removal. Correspondingly, a systematic review performed by Zhang et al. [18] including 196 participates treated with suture button fixation, and 194 patients treated with screw fixation, found that postoperative implant failure evolved more frequently after screw fixation compared to suture button fixation, 31% vs. 0% respectively. The authors, however, did not specify the definition of postoperative implant failure. A recent meta-analysis by Shimozono et al. including 5 randomized controlled trials compared 143 patients treated with suture button fixation with 142 patients treated with syndesmotic screws. They concluded that patients treated with suture button fixation have an improved functional outcome as well as lower rates of broken implant and joint mal- reduction. Based only on the specific findings of this meta-analysis, Shimozono et al. suggested that the suture

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button technique warrants a grade A recommendation by comparison with the syndesmotic screw technique for the treatment of syndesmosis injuries [19].

In the current study, we initially included patients who suffered an open fracture because we were curious about the potential effects of open fracture on the rates of reoperation, infection, arthropathy, and deep venous thrombosis. A study performed by Smeeing et al. [20] found that age, smoking, right side symptomatic, initial external fixation, and open fractures were independent risk factors for wound-healing complications after surgical treatment of ankle fractures. However, it's likely that external fixation and open fractures are variables that are related to each other (collinear), which may have impacted the study results. Assessing collinearity, the current study found a direct relationship between external fixation and open fractures—so we therefore excluded patients with open fractures from the multivariable logistic regression analysis.

Interestingly, we found that a BMI below 30 was associated with an increased risk to unplanned reoperation for hardware removal. In contrast, Mendelsohn et al. concluded that a BMI more than 30 caused a twelve-time higher likeliness of screw breakage or loosening after tricortical and quadricortical screw fixation, resulting in loss of reduction [9]. However, few studies concluded that screw breakage or loosening leads to normal alignment of the distal syndesmosis in the incisura and dynamic stabilization similar to the healthy syndesmosis [21–24]. In the current study, we defined unplanned reoperation as reoperation for unplanned hardware removal due to, infection, revision of ORIF, failure of fixation, loss of reduction, malreduction or symptomatic hardware. We suggest that discomfort during weight-bearing due to rigid screw fixation occurs more frequently in patients with lower BMI because they are in general more frequently physically active [25,26].

Supporters of syndesmotic screw constructs have argued that fixation with suture button devices does not give the amount of syndesmotic stability in the sagittal plane necessary for allowing the syndesmotic ligaments to heal sufficiently [11,27,28]. The current study did not find patients that required re-operation after suture button fixation because of lasting instability complaints. It is expected, however, that subtle residual instability leads to progressive ankle osteoarthritis over time – beyond the 365 days follow-up period of the current study. Future clinical research determining to what degree coronal plane and sagittal plane fibular stability is needed for daily functional activities would be valuable.

## Conclusion

Within one year after surgical treatment for syndesmotic instability with associated closed fracture, 10.7% (91 patients) suffered an infectious complication and 22.0% (187 patients) underwent unplanned reoperation. Our analysis demonstrated that increased duration of hospital admission, use of an external fixator device before ORIF, peripheral vascular disease, osteoporosis, and patients' BMI below 30 are independently associated with the development of postoperative adverse events and need for re-operations. Novel fixation devices that are specifically made for high-risk patient's groups should be developed in order to decrease adverse events and re-operation rate after surgical fixation of the unstable syndesmosis with associated closed fracture.

## Statement of location

All research was executed at the Massachusetts General Hospital, 55 Fruit Street, Boston, Massachusetts, 02114, United States of America

## Institutional Review Board approval

Our institutional Review Board approved this study, and a waiver of consent was granted.

Protocol number: 2015P000464.

## Declaration of Competing Interest

Each author certifies that he or she, or a member of his or her immediate family, has no funding or commercial associations (e.g., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article.

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