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# Dynamic Fixation Versus Static Fixation for Distal Tibiofibular Syndesmosis Injuries: A Meta-Analysis

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Statistical Analysis C  
Data Interpretation D  
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**Background:** Ankle sprains with distal tibiofibular syndesmosis injuries (DTSIs) require anatomic reduction and fixation to restore the normal biomechanics of the ankle joint. In the last decade, dynamic fixation (DF) for DTSIs using a suture-button device has gained popularity because of its advantages over static fixation (SF).


**Material/Methods:** The present meta-analysis was conducted to compare clinical outcomes between DF and SF of DTSIs. PubMed, Cochrane Central Register of Controlled Trials, and Embase were systematically searched. Three randomized controlled studies and 7 cohort studies, with a total of 420 patients, were involved in this study. DTSIs patients treated with DF were assigned to the experimental group, and patients treated with SF were assigned to the control group. Outcomes were evaluated and analyzed by using review-manager software. Mean difference (MD) or risk ratio (RR) with 95% confidence interval (95% CI) was analyzed and calculated by utilizing the random effects models.

**Results:** Analysis revealed no statistically significant differences between DF and SF in American Orthopedic Foot and Ankle Society Ankle-Hindfoot score (MD, 1.90; 95% CI, -0.23-4.03;  $p=0.08$ ;  $I^2=0\%$ ), Olerud-Molander score (MD, 1.92; 95% CI, -7.96-11.81;  $p=0.70$ ;  $I^2=55\%$ ), incidence of syndesmotic malreduction (RR, 0.19; 95% CI, 0.03-1.09;  $p=0.06$ ;  $I^2=0\%$ ), and overall postoperative complication rate (RR, 0.30; 95% CI, 0.09-0.99;  $p=0.05$ ,  $I^2=75\%$ ). The rate of second procedure was significantly lower compared with DF (RR, 0.17; 95% CI, 0.07-0.43;  $p=0.0002$ ,  $I^2=54\%$ ).

**Conclusions:** The dynamic fixation and static fixation methods are equal in clinical outcomes, with dynamic fixation needing fewer second interventions for DTSIs.

**MeSH Keywords:** **Ankle Fractures • Ankle Joint • Bone Screws • Meta-Analysis**

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## Background

The distal tibiofibular syndesmosis complex is critical for maintaining the congruency of the ankle mortise. The complex consists of 4 ligaments, including anterior-inferior tibiofibular ligament, posterior-inferior tibiofibular ligament, inferior transverse tibiofibular ligament, and interosseous ligament [1]. Distal tibiofibular syndesmosis injuries (DTSIs) of sufficient severity can disrupt or damage the normal stability of the ankle joint. Up to 50% of all ankle sprains occur during sports activities, causing damage to the distal tibiofibular syndesmosis in approximately 1% to 18% of cases [2–5]. DTSIs arise when an external rotation force applied to the foot leads within the ankle mortise [4,6], which is thought to occur in 80% of Weber type C fractures [6]. DTSIs also occur in patients with Weber type B fractures. In one study, DTSIs were identified in 17% of supination-external rotation type 4 injuries [7,8]. Such injuries can also occur in the absence of fractures [9]. DTSIs can disrupt or damage normal stability of the ankle joint and lead to the alterations or changes in weight transmission between the tibia or fibula and subsequent traumatic arthritis [7].

Operative stabilization is performed to treat unstable DTSIs [10]. Static fixation (SF) with one or more cortical screws is the reference standard fixation method. However, some significant issues should be considered. Screw loosening, breakage [11], discomfort, the need for a second operation for screw removal, and the risk of late diastasis after early removal are the potential drawbacks of screw fixation [11–16]. An alternative method, dynamic fixation (DF) using an implanted suture-button device (TightRope; Arthrex, Inc., Naples, Florida), offers potential advantages over the syndesmosis screw, including less risk of hardware pain and recurrent syndesmotic diastasis, quicker return to mobility, maintenance of physiologic movement while retaining reduction, earlier rehabilitation, and no need for implant removal [17–19]. However, functional outcomes, rates of syndesmotic malreduction, and complication rates are still uncertain for these 2 techniques. The optimal surgical protocol is still a subject of dispute in the published literature [20,21].

This study aimed to evaluate effects of DF and SF method on the treatment of DTSIs, by comparing the clinical outcomes, incidence of syndesmotic malreduction, postoperative complications, and rate of second procedures. To the best of our knowledge, the present study is the first to comprehensively compare DF with SF for DTSI treatment.

## Material and Methods

For the present meta-analysis, many comprehensive databases were searched to find the clinical trials that compare the DF and SF for DTSIs treatment. The present study was conducted

according to the Preferred Reporting Items for the Systematic Reviews and the Meta-Analyses (PRISMA) guidelines [22].

### Literature and data sources

PubMed, Cochrane Central Register of Controlled Trials, and Embase were searched from the earliest available date through November 2017. The searches were not limited or restricted by the published language. We included the following Medical Subject Headings or keywords in our searches, including “syndesmo\*,” “screw,” “TightRope,” “endobutton,” and “suture button.”

### Study selection

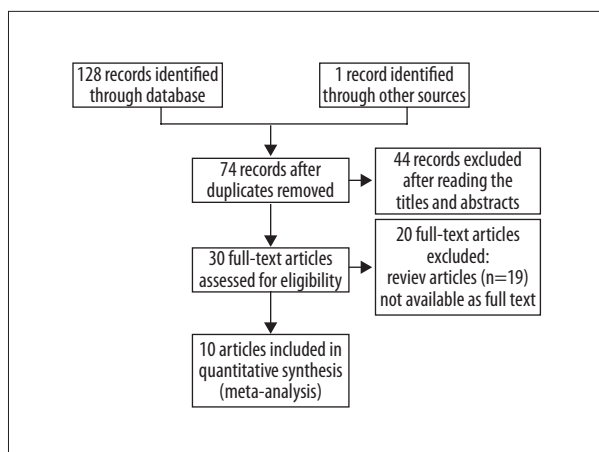
Two authors (Z.K. and H.K.) independently performed the searches to identify studies appropriate for this review. To select studies, the titles or the abstracts in identified researches or studies were firstly screened, and then the full texts or documents were screened. Meanwhile, the lists of selected studies for the other potentially related citations were also reviewed. Studies qualifying for full-text review were subsequently evaluated and either included or excluded on the basis of the established inclusion criteria. Disagreement between the reviewers was resolved by consensus or after review with the senior author. Each of the eligible studies had to be associated with the following listed criteria: (1) Retrospective or prospective comparative study with DF and SF in DTSIs patients; (2) Patients involved in this study must be diagnosed as DTSIs; and (3) Functional score, surgical complications, malreduction of syndesmosis, and second operations were reported. Moreover, duplicate studies were excluded.

### Literatures searching

The literature searches in databases resulted in 129 studies. After removing duplicate entries (55 studies involving duplicate entries), 74 articles remained. Among these, 44 studies were excluded according to their titles and their abstracts (not with DF and SF in DTSIs patients (14 studies) and lack of functional score, surgical complications, malreduction of syndesmosis, or the second operations (16 studies), which indicated that they were not relevant. We evaluated the eligibility of the remaining 30 articles by evaluating the full manuscripts and excluded 20 articles. We thus included 10 studies in our meta-analysis. Figure 1 is a flow diagram of the screening procedure.

### Quality assessment

Two authors (L.L. and S.Y.) independently evaluated qualities of all the included studies. We evaluated 7 studies that were not randomized controlled trials (RCTs) [23–29] by utilizing the Newcastle-Ottawa Quality Assessment Scale (NOS) [30].



**Figure 1.** Flow diagram of study selection.

The NOS is designed and applied to evaluate quality of cohort studies or researches. The contents we evaluated were comparability, outcome, and selection. Meanwhile, for the contents of outcome (3 numbered items) and the selection (4 numbered items), each evaluated study or document could be considered to be a maximum as one-star for every numbered item. However, for the contents of comparability (one numbered item), each evaluated study could be considered to be a maximum as two-stars for every numbered item. The higher the score (represented as stars), the higher the study or document quality. All of the unresolved disagreements or distinguishes among the reviewers were judged and resolved by consensus. Six studies received 9 stars and 1 study received 6 stars (Table 1).

We evaluated risks of bias in each RCT in our study [31-33] by utilizing the Cochrane Risk of Bias Tool [34]. The following domains were also evaluated: 1) the allocation concealment, 2) the blinding of outcome assessment, 3) the sequence generation, 4) the incomplete outcome data, 5) the blinding of participants and personnel, 6) the selective outcome reporting, and 7) the other sources of the bias. The risk of bias was classified into low risk, unclear risk, and high risk for each study. Any unresolved disagreements or distinguishes among the reviewers

were judged and resolved by the consensus. The risks of bias results for the included RCTs are shown in Figures 2 and 3.

**Characteristics of eligible studies**

All 10 studies in the present meta-analysis were mainly published from 2006 to 2016 (Table 2). Seven of these studies were retrospective or prospective cohort studies, and 3 were prospective RCTs. One was a multicenter study, and 9 were single-center studies. A total of 420 patients were finally involved in this meta-analysis.

**Data extraction**

Two authors (H.K. and G.S.) abstracted the data or associated results independently by utilizing the pre-designed spreadsheet (Excel; Microsoft, Redmond, WA, USA). All of the disagreements were judged and resolved by inviting an additional reviewer (G.K.), and finally a consensus was obtained on all of the items.

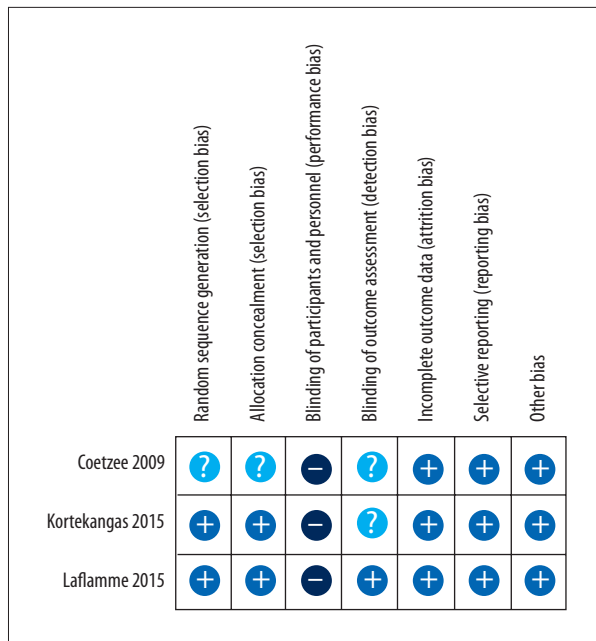
The data in this study extracted mainly included the general or basic information of studies (the publication year, the first author, the patient numbers, the gender and age of patients, the follow-up duration and the study design), the Olerud-Molander (OM) score ( $\geq 12$  months postoperatively), the ankle-hind-foot score of the American Orthopedic Foot and Ankle Society (AOFAS), and the number of syndesmotic malreductions, overall complications, and second procedures. Malreduction of syndesmosis was defined as a difference in syndesmosis width of more than 2 mm compared with the untreated contralateral ankle, as measured on an axial computed tomography scan [35]. Second procedure was defined as another surgical operation conducted after the index operation, and these second procedures included revision surgery and hardware removal.

**Statistical analysis**

We used review-manager software (version: RevMan 5.3; Cochrane Collaboration, London, UK) to analyze the data, extracting values for analyses from published reports. For the

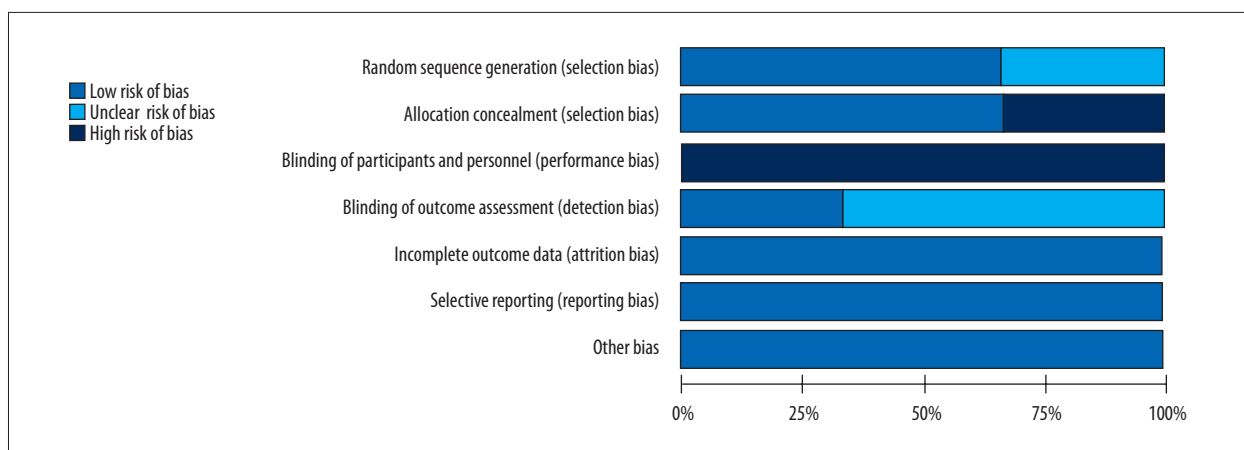
**Table 1.** Newcastle-Ottawa Quality Assessment Scale results for included cohort studies.

| Study               | Selection of study groups | Comparability of groups | Outcome | Total scores |
|---------------------|---------------------------|-------------------------|---------|--------------|
| Maempel et al. [23] | ☆☆☆                       | ☆                       | ☆☆      | 6            |
| Thomes et al. [24]  | ☆☆☆☆                      | ☆☆                      | ☆☆☆     | 9            |
| Cottom et al. [25]  | ☆☆☆☆                      | ☆☆                      | ☆☆☆     | 9            |
| Naqvi et al. [26]   | ☆☆☆☆                      | ☆☆                      | ☆☆☆     | 9            |
| Kim et al. [27]     | ☆☆☆☆                      | ☆☆                      | ☆☆☆     | 9            |
| Kocadal et al. [28] | ☆☆☆☆                      | ☆☆                      | ☆☆☆     | 9            |
| Seyhan et al. [29]  | ☆☆☆☆                      | ☆☆                      | ☆☆☆     | 9            |



**Figure 2.** Risk of bias summary for included randomized controlled trials. ‘+’ – low risk of bias; ‘?’ – unclear risk of bias; ‘-’ – high risk of bias.

dichotomous outcomes, we calculated risk ratios (RRs) with 95% confidence intervals (95% CIs). However, for continuous outcomes, we calculated the mean differences (MDs) with 95% CIs. The treatment effects were assigned as significant if the p value was less than 0.05. We used the random effects model. We explored heterogeneity by utilizing the chi-square ( $\chi^2$ ) test, with significance set at p value less than 0.100. For the quantification, we used the  $I^2$  test, with the significant values of less than 25% indicating low heterogeneity, less than 50% indicating moderate heterogeneity, and greater than 50% indicating substantial heterogeneity.



**Figure 3.** Risk of bias graph for included randomized controlled trials.

## Results

### Functional assessment

Five studies [26–29,32] contributed data for analysis of AOFAS scores. The analysis revealed no remarkable differences for the AOFAS between DF group and the SF group (MD, 1.90; 95% CI, -0.23–4.03;  $p=0.08$ ;  $I^2=0\%$ ) (Figure 4). Two studies [31,32] provided OM scores, which also did not significantly differ between the 2 groups (MD, 1.92; 95% CI, -7.96 to 11.81;  $p=0.70$ ;  $I^2=55\%$ ) (Figure 5).

### Incidence of malreduction of syndesmosis

Two studies that included a total of 86 patients [26,31] reported the number of patients with malreduction of syndesmosis after surgical fixation. The meta-analysis showed no significant differences in syndesmotic malreduction between the DF group and SF group (RR, 0.19; 95% CI, 0.03–1.09;  $p=0.06$ ;  $I^2=0\%$ ) (Figure 6).

### Postoperative complications

Eight studies [23,25,27–29,31–33] reported rates of complications after surgical operations. Complications included wound infections, wound dehiscence, deep infections, local implant irritation, hardware failures (screw loosening and breakage), syndesmosis ossification, nerve injury, subluxation, and reflex sympathetic dystrophy. The meta-analysis revealed no significant differences in incidence of overall complications between the 2 groups. The incidence in the DF group was 17 of 164 patients (10.4%) and 76 of 178 patients in the SF group (42.7%) (RR, 0.30; 95% CI, 0.09–0.99;  $p=0.05$ ;  $I^2=75\%$ ) (Figure 7).

### Second procedure

Numbers of patients who required the second procedure were demonstrated in the 8 studies [23–25,28,29,31–33].

**Table 2.** Characteristics of included studies.

| Study                   | Study type                               | Setting       | Intervention         |                          | Mean age (years) |       | Follow-up (months) |      | Outcomes  |
|-------------------------|--|---------------|----------------------|--------------------------|------------------|-------|--------------------|------|---|
|                         |  |               | DF                   | SF                       | DF               | SF    | DF                 | SF   |   |
| Maempel et al. [23]     | Retrospective cohort study               | Single center | Tight rope (n=12)    | Syndesmotic screw (n=23) | 41.5             | 41    | 14.6               | NR   | Complications<br>Second procedures  |
| Thornes et al. [24]     | Prospective cohort study                 | Single center | Suture button (n=16) | Syndesmotic screw (n=16) | 32               | 31    | 12                 | 12   | AOFAS score, Time not weight bearing, Time to return to work, Patient's overall satisfaction, Second procedures                                     |
| Cottom et al. [25]      | Prospective cohort study                 | Single center | Tight rope (n=25)    | Syndesmotic screw (n=25) | 34.68            | 36.68 | 10.78              | 8.2  | Modified AOFAS score, SF-12 score, Time to full weight bearing, Radiographic outcomes, Complications, second procedures                             |
| Naqvi et al. [26]       | Retrospective cohort study               | Single center | Tight rope (n=23)    | Syndesmotic screw (n=23) | 41.65            | 39.82 | 30.3               | 29   | AOFAS score, FADI score, Time to full weight bearing, Radiographic outcomes, Malreduction   |
| Kortekangas et al. [31] | Prospective randomized, controlled trial | Single center | Tight rope (n=21)    | Syndesmotic screw (n=19) | 46               | 43.5  | 36                 | 39   | OM score, Rand-36 score, FAO score, VAS for pain and function, Complications, malreduction, Second procedure  |
| Laflamme et al. [32]    | Prospective randomized, controlled trial | Multicenter   | Tight rope (n=33)    | Syndesmotic screw (n=32) | 40.1             | 39.3  | 12                 | 12   | OM score, AOFAS score, VAS for pain, ROM, Ankle circumference, Time to full weight bearing, Radiographic outcomes, Complications, second procedures |
| Kim et al. [27]         | Retrospective cohort study               | Single center | Tight rope (n=20)    | Syndesmotic screw (n=24) | 51.3             | 40.5  | 13.4               | 14.6 | Radiographic outcomes, AOFAS score, VAS for pain, Complications   |
| Kocadal et al. [28]     | Retrospective cohort study               | Single center | n=26                 | n=26                     | 43.3             | 44.8  | 16.7†              |      | Radiographic outcomes, AOFAS score, Complications, second procedure   |
| Seyhan et al. [29]      | Retrospective cohort study               | Single center | n=15                 | n=17                     | 43.3             | 44.8  | 14.6†              |      | ROM, AOFAS score, Complications, second procedure   |
| Coetzee et al. [33]     | Prospective randomized, controlled trial | Single center | n=12                 | n=12                     | 35               | 38    | 27                 | 27   | ROM, AOFAS score, AOFAS score, Complications, second procedure  |

AOFAS – American Orthopaedic Foot and Ankle Society; DF – dynamic fixation; FADI – Foot and Ankle Disability Index; FAO – Foot and Ankle Outcome; NR – not reported; OM – Olerud-Molander; ROM – range of motion; SF – static fixation; SF-12 – Short Form-12 Health Survey; VAS – Visual Analogue Scale. The modified AOFAS score is a score system with a maximum of 63 points. The Rand-36 score refers to the Rand 36-Item Health Survey. † Only the mean follow-up for the 2 groups was reported.

The meta-analysis illustrated that risks of a second procedure were significantly greater in the SF group compared to the DF group (RR, 0.17; 95% CI, 0.07–0.43;  $p=0.0002$ ,  $I^2=54%$ ) (Figure 8).

## Discussion

Syndesmotic screws and suture-button devices are accepted surgical fixation options for syndesmotic injuries. Until recently, syndesmotic injuries were treated with static (screw) fixation,

which has been considered the criterion standard treatment. Although this fixation method stabilizes the joint, it eliminates normal motion between the tibia and fibula, according to previous studies [36,37]. DF with a suture-button device has gained increasing interest and popularity over the last decade. Although DF is not as rigid as syndesmotic screw fixation, it can facilitate motion of the distal tibiofibular joint [38].

Debate involving the treatment of superior surgery for the syndesmotic injuries is ongoing [20,21]. However, evidence is

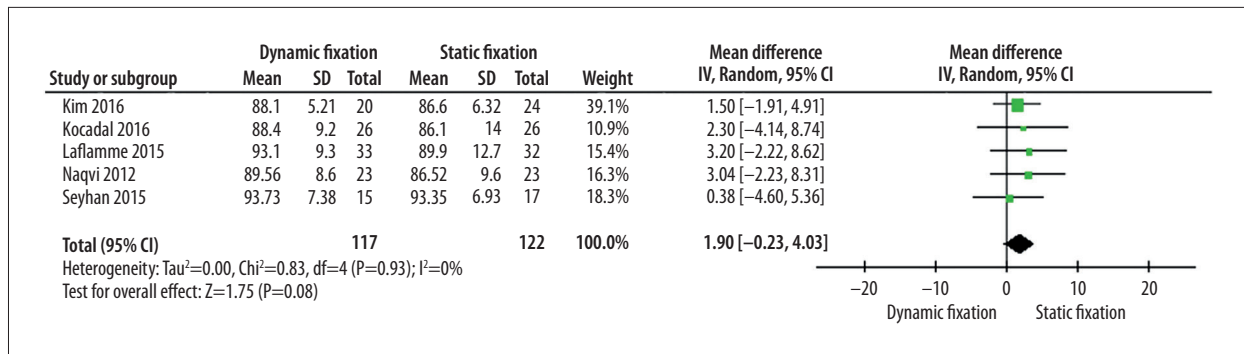


Figure 4. Forest plot of postoperative American Orthopedic Foot and Ankle Society scores.

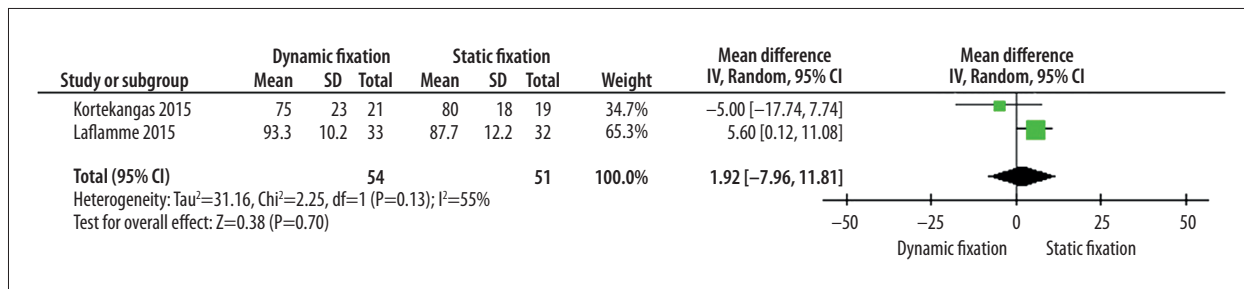


Figure 5. Forest plot of postoperative Olerud-Molander scores.

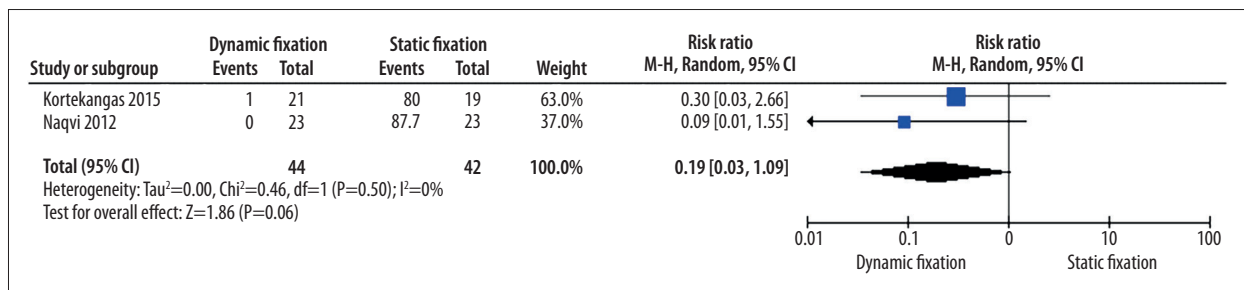


Figure 6. Forest plot of postoperative incidence of syndesmotomal reduction.

insufficient for concluding that one procedure is best. Therefore, a meta-analysis of the clinical comparative researches was conducted to evaluate whether DF or SF was superior in terms of functional scores, incidence of syndesmotomal reduction, and rates of postoperative complications and second procedures.

The results of our meta-analysis revealed that there were no statistically significant differences between the DF and SF group in postoperative functional scores (AOFAS and OM scores). Some previous studies [26–29,31–33] reported no difference between DF and SF in functional scores, whereas other studies [24,32] indicated that the patients receiving DF had better postoperative functional scores compared to those patients receiving SF. Further studies are urgently needed to verify our results involving clinical outcomes of the above procedures due to the limited number of studies we included.

Malreduction of the syndesmosis is the most important independent predictor of long-term functional outcome [39]. We analyzed the incidence of syndesmotomal reduction after DF and SF and found no statistically significant differences between the DF group and SF group. However, in the DF group, 1 in 44 patients experienced a syndesmotomal reduction, as compared with almost 1 in 5 patients in the SF group. We also found no significant difference in overall postoperative complications between the 2 groups; however, nearly 1 in 10 patients in the DF group and nearly 1 in 2 patients in the SF group experienced a complication. It is possible that these differences were not statistically significant because the included studies were underpowered, possibly because of the limited patient numbers or the differences in inclusion criteria regarding fracture type.

Our meta-analysis found that the rates of second procedure were significantly lower in the DF group compared to that in the SF group. The reasons for second procedures among patients

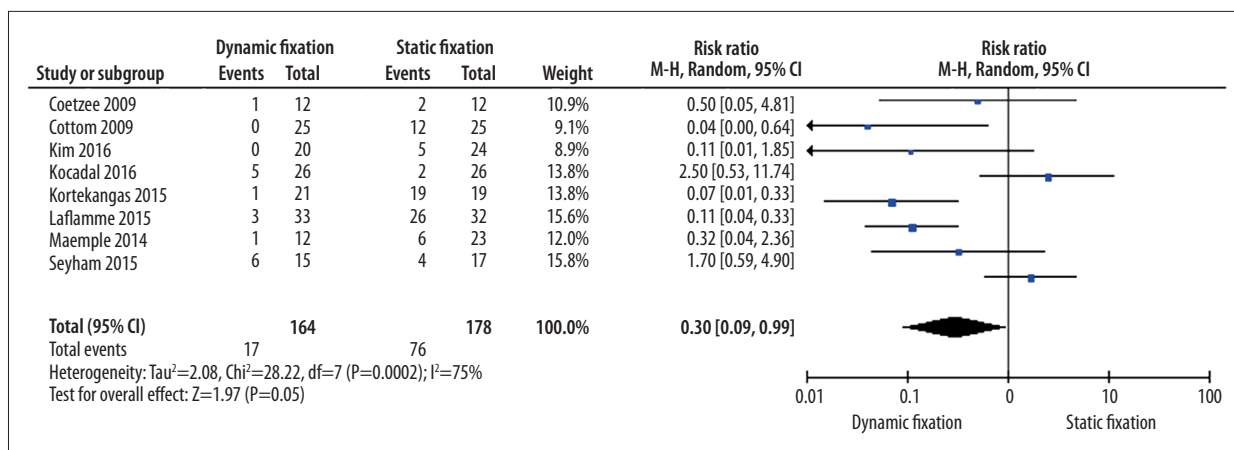


Figure 7. Forest plot of overall postoperative complication rates.

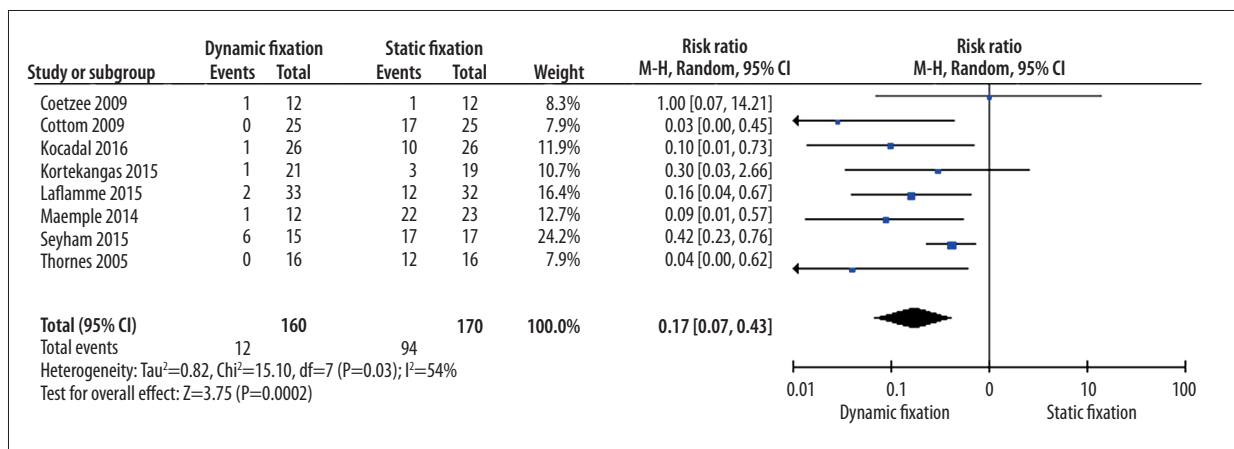


Figure 8. Forest plot of second procedure rates.

in the 2 groups are listed in Table 3, showing that routine removal was the most common reason for a second procedure in the SF group. Syndesmotic screws were typically removed in the 7<sup>th</sup> to 12<sup>th</sup> weeks after the first operation [36] to avert implant failures such as screw breakage or loosening. Removal of suture-button devices is generally unnecessary or is suggested after successful surgical procedures [20]. The lower rate of second procedures in the DF group was similar to the rates that were reported in previously published studies [23–25,32] and could indicate the superiority of DFs in this regard.

The number of comparative trials, especially RCTs, included in our meta-analysis was relatively small due to the general scarcity for clinical cohort studies on this subject. However, we believe that there is no evidence of publication bias. We performed a thorough search to identify all of the online available studies or documents. Whether unpublished studies or research have been conducted is unknown. However, one limitation of the present study (this meta-analysis) was the relatively small participant or patient numbers, which could explain

why there were no statistically significant differences in the functional outcome, the incidence of the syndesmotic malreduction, or rate of postoperative complications.

The limited number of included studies or research contributed to functional scores analysis because the studies used several different score scales. Fewer than 6 studies provided data on AOFAS and OM scores. Therefore, the present meta-analytic results of all these functional scores illustrate a relatively lower reliability. Three of the 10 included studies were prospective RCTs. However, 7 of the 10 studies were prospective or retrospective cohort studies, which lack randomization. This causes selection bias because of the uneven allocation. Therefore, the further detailed RCTs are necessary to strengthen the present conclusions.

Few of the included studies provided the cost of hospitalization for surgical interventions. Therefore, data on economic factors and cost-effectiveness are limited for surgical treatments.

**Table 3.** The causes for second procedure in DF and SF groups.

| Causes of second procedures |  | Number of cases (n) |
|-----------------------------|--|---------------------|
| Dynamic fixation (DF)       | Routine removal of implant                       | 1                   |
|                             | Implant removal for superficial infection        | 3                   |
|                             | Implant removal for local implant irritation     | 7                   |
|                             | Revision to syndesmotom screw for deep infection | 1                   |
|                             |  | Total 12            |
| Static fixation (SF)        | Routine removal of implant                       | 75                  |
|                             | Revision to a hindfoot nail for subluxation      | 1                   |
|                             | Revision to a hindfoot nail for deep infection   | 1                   |
|                             | Implant removal for deep infection               | 1                   |
|                             | Implant removal for local implant irritation     | 14                  |
|                             | Revision for technically insufficient fixation   | 1                   |
|                             | Implant removal for prominence of the screw head | 1                   |
|                             |  | Total 94            |

## Conclusions

Our meta-analysis demonstrates that DF and SF can both achieve equal functional outcomes, overall postoperative complications, and incidence of syndesmotom malreduction. The incidence of second procedure was significantly higher with SF than with DF. However, a larger sample size and better-quality evidence are required before a firm recommendation can be made. Further comparative studies, especially for RCTs, are required before we can establish which internal fixation method is more effective for the surgical treatment of DTSIs.

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## Conflict of interest

None.



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