Should syndesmotic screws be removed or retained? A meta-analysis

Wanjin Qin

First Affiliated Hospital of Soochow University

Peng Yang

First Affiliated Hospital of Soochow University

Nanning Lv

The Second People's Hospital of Lianyungang

Kaiwen Chen

First Affiliated Hospital of Soochow University

Huilin Yang

First Affiliated Hospital of Soochow University

Minjie Shen (✉ shenminjie_suzhou@163.com)

First Affiliated Hospital of Soochow University

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Abstract

Background The aim of this study was to evaluate the different clinical outcomes after removing or retaining syndesmotic screws, and the difference in clinical outcomes after retaining broken or loose syndesmotic screws was also evaluated.

Methods A systematic literature search was performed using PubMed, Web of Science, EMBASE and the Cochrane Central Register of Controlled Trials. In this meta-analysis, we conducted online searches using the search terms “syndesmotic diastasis”, “syndesmotic injury”, “syndesmotic screw”, “syndesmotic fixation”, and “tibiofibular syndesmosis”. The analysis was performed on data from all the studies that met the selection criteria. Clinical outcomes were expressed as standard mean differences for continuous outcomes with 95 % confidence intervals. Heterogeneity was assessed using the χ^2 test and the I^2 statistic.

Results There were 2 randomized controlled trials (RCTs) and 6 observational articles included in this analysis. In the comparison between retained and removed screws and the comparison between broken or loose and removed screws, no significant difference was found in terms of visual analogue scale (VAS), Olerud-Molander Ankle Score (OMAS) and American Orthopaedic Foot and Ankle Society (AOFAS) ankle/hindfoot score. Broken or loose screws were associated with better AOFAS scores compared with removed or intact screws, and no significant difference was found in terms of VAS and OMAS scores.

Conclusions According to our analysis, there was no significant difference in clinical outcomes between removed and retained screws. Broken or loose screws were not associated with bad functional outcomes and may even lead to better function compared with removed or retained screws.

Background

To the best of our knowledge, no systematic review or meta-analysis has compared the different clinical results after removing or retaining syndesmotic screws. The primary goal of this study was to perform a meta-analysis to compare the clinical outcomes between removing and retaining syndesmotic screws, and the difference between broken or loose and removed screws was also evaluated.

Methods

Literature search

A systematic computerized literature search was performed using PubMed, Web of Science and the Cochrane. The electronic databases were searched for publication dates from January 1980 to December 2019. We used the following combination of Medical Subject Heading (MeSH) terms and textual words: (screw[MeSH Terms]) AND((syndesmotic diastasis) OR (syndesmotic injury) OR (syndesmotic fixation) OR (tibiofibular syndesmosis)). The search was not restricted to randomized controlled study (RCT) and was extended to non-RCT. The decision to include an article was primarily made based on title and abstract review, followed by full-text screening. All information sources were obtained from the articles, which were downloaded from the Soochow University website. The reference lists of all retrieved articles were studied for further identification of potentially relevant studies.

Inclusion and exclusion criteria

Trials with the following characteristics were included: (1) randomized controlled trials or clinical cohort trials, (2) comparisons between removing and retaining syndesmotic screws, (3) comparisons between broken or loose and removed screws, (4) patients without a confirmed history of ankle diseases, and (5) full-text articles. We excluded studies with low quality of inadequate data, involving patients with comorbid injuries involving other major organ systems or a history of lower limb surgery, articles with duplicate reports of earlier trials or post hoc analyses of data in randomized controlled trials and articles whose full text we were unable to acquire.

Two independent authors reviewed the abstracts of each article to determine which articles to include in the study. The authors jointly reviewed the full text of the articles meeting the inclusion criteria based on the abstract to determine agreement on the inclusion of the studies. In case of a discrepancy, a third author participated in the discussion until a consensus was reached.

Data extraction

A meta-analysis database was created from the included studies with the following categories: (1) study ID including author and year of publication; (2) study type and level of evidence; (3) number of patients; (4) male-to-female ratio; (5) patient age; (6) length of follow-up; (7) visual analog score (VAS) for pain; (8) Olerud Molander Ankle Score (OMAS); and (9) American Orthopaedic Foot and Ankle Society (AOFAS) score.

Quality assessment

The bias assessment for each RCT was conducted by method of risk of bias (ROB), which consisted of 7 domains: random sequence generation, allocation sequence concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other biases. The bias for each non-RCT was assessed with Risk of Bias Assessment tool for Non-randomized Study (RoBANS), domains of which were selection of participants, confounding variables, intervention(exposure) measurements, blinding outcome assessment, incomplete outcome data, selective outcome reporting, and other biases[1-4]. All the domains were evaluated as “low risk,” “high risk,” or “unclear.” These evaluations were performed by two independent reviewers and disagreements were resolved by discussion between 2 reviewers or with the entire research group.

Statistical analysis

The analysis was performed on data from all the studies that met the selection criteria. The meta-analysis was performed using Review Manager Version 5.3.1 (Cochrane Collaboration, Software Update, Oxford, United Kingdom). We assessed the standard mean difference (SMD) for continuous outcomes with 95% confidence intervals (CIs). A P value of 0.05 was set as the significance level. Heterogeneity was assessed using the Chi^2 test and the I^2 statistic, where I^2 was used to estimate the percentage of error resulting from the across-study variations. If $P>0.05$ was presented in an analysis, we considered a fixed-effects model, as the homogeneity of studies was satisfactory. Otherwise, we chose the random-effects model. Funnel plots were assessed by visual inspection to determine publication bias.

Results

Literature characteristics

The literature search strategy identified 2026 potential articles. According to the inclusion and exclusion criteria, a total of 8 articles were finally included in the meta-analysis[5-12]. A flowchart of the literature search is shown in **Fig. 1**. Two articles were excluded due to the absence of data on standard deviations. One article from Schepers et al. divided the removal group into two groups (<8 weeks and ≥ 8 weeks). Four articles set up 3 groups (intact, broken or loose, and removed screw). There were 2 randomized controlled trials and 6 observational articles included in this analysis. The characteristics of the included studies are summarized in Table. 1.

Table 1 Characteristics and quality assessment of the included studies.

First author (year)	Country	LoE	Group	Follow-up (months)	Fracture classification	Major findings
Tucker (2013)	UK	4 (2 retrospective cohorts)	Group 1 (n=43): Intact Group 2 (n=20): Removed	10-43	NP	Retained
Manjoo (2010)	Canada	4 (3 retrospective cohorts)	Group 1 (n=20): Intact Group 2 (n=10): Broken Group 3 (n=15): Removed	12-30	NP	An intact
Boyle (2014)	New Zealand	2b (Randomized controlled trial)	Group 1 (n=27): Retained Group 2 (n=24): Removed Group 3 (n=19): Broken/ Loose Group4 (n=4): Intact	12	NP	Removal of
Hamid (2009)	USA	4 (3 retrospective cohorts)	Group 1 (n=27): Intact Group 2 (n=10): Broken Group 3 (n=15): Removed	12-56	Danis-Weber: B, C	No difference
Kaftandziev (2015)	Macedonia	4 (3 retrospective cohorts)	Group 1 (n=46): Intact Group 2 (n=23): Removed Group 3 (n=13): Broken	>12	Danis-Weber: B, C	No statistical
Heck (2017)	Brazil	4 (2 retrospective cohorts)	Group 1 (n=11): Removed Group 2 (n=24): Intact	6	Lauge-Hansen: 2, 3, 4	Removal of
Høiness (2004)	Norway	2b (Randomized controlled trial)	Group 1 (n=30): Quadricortical, Removed Group 2 (n=34): Tricortical , Intact	12	AO: C	There were
Schepers (2013)	The Netherlands	4 (3 retrospective cohorts)	Group 1 (n=37): Removed <8 weeks Group 2 (n=44): Removed ≥8 weeks Group 3 (n=12): Intact	>18	Danis-Weber: B, C	The functional influence

LoE level of evidence, NP not provided.

Quality assessment

The risk of bias of all selected studies was illustrated in Figure 2(a: RCT, b: non-RCT). One RCT that was assessed as high risk in reporting bias. The most frequently biased domain was blinding bias, in which 2 RCTs were rated as unclear because they did not adequately describe the procedure for blinding. Two non-RCTs were rated as unclear in the domain of intervention because they mainly investigated the effect of the level of syndesmotic screw insertion on functional outcome. Of domains across all studies, 68.3% domains were determined as low risk; thus, the overall risk of bias was considered low [Fig. 2]. A discrepancy between reviewers was found in 16 of total 63 domains at first. After discussion, all discrepancies were resolved.

Comparison of VAS scores

The VAS score was documented in 6 studies [Fig. 3]. In the comparison between retained and removed screws, a fixed-effects model was used for analysis, and no significant difference was found between the groups (SMD, 0.06; 95 % CI -0.19, 0.31; $I^2 = 30\%$; $P=0.63$). In the comparison between broken or loose and removed screws (SMD, 0.24; 95 % CI -0.16, 0.64; $I^2 = 0\%$; $P=0.24$) and the comparison between broken or loose and intact screws (SMD, 0.01; 95 % CI -0.44, 0.46; $I^2 = 39\%$; $P=0.97$), there was no significant difference either.

Comparison of OMAS scores

The OMAS score was reported in 6 studies [Fig. 4]. There was significant heterogeneity in the comparison between retained and removed screws ($I^2 = 85\%$). A random-effects model was used for the analysis, and no significant between-group difference was found (SMD, -0.32; 95 % CI -0.96, 0.32; $I^2 = 85\%$; $P=0.33$). There was significant heterogeneity in the comparison between broken or loose and removed screws ($I^2 = 68\%$), and the comparison between broken or loose and intact screws also had significant heterogeneity ($I^2 = 87\%$). No significant between-group difference was found in either comparison (SMD, -0.44; 95 % CI -1.22, 0.34; $I^2 = 68\%$; $P=0.27$; SMD, 1.72; 95 % CI -0.10, 3.53; $I^2 = 87\%$; $P=0.06$, respectively).

Comparison of AOFAS scores

The AOFAS score was evaluated in 6 studies [Fig. 5]. No significant between-group difference was found in the comparison between retained and removed screws (SMD, -0.08; 95 % CI -0.32, 0.17; $I^2 = 0\%$; $P=0.55$). In the comparison between broken or loose and removed screws and the comparison between broken or loose and intact screws, a significant between-group difference was found in both comparisons (SMD, 0.51; 95 % CI 0.13, 0.88; $I^2 = 34\%$; $P=0.008$; SMD, 0.80; 95 % CI 0.36, 1.24; $I^2 = 0\%$; $P=0.0004$, respectively).

Discussion

Determining whether to remove syndesmotic screws in patients with disrupted syndesmosis after surgery is still controversial among surgeons. Supporters consider the syndesmosis to have already healed 8 to 12 weeks after surgery, which means that the screw is no longer necessary[13]. They reason that the presence of the screw may restrict fibula rotation and syndesmosis widening during normal walking. Removing the screw after 8 to 10 weeks has been advised to resume normal activities and avoid screw breakage[14-17]. However, several recent studies have described different opinions. They found similar outcomes between removed and retained screws. Therefore, we performed a meta-analysis to assess the clinical outcomes between screw removed and retained groups.

Manjoo et al[8] reported that intact syndesmosis screws were associated with worse functional outcomes compared with removed screws and concluded that intact syndesmosis screws ought to be removed. Miller et al[17] stated that the range of motion, AOFAS, and OMAS scores were all significantly improved by the first postoperative visit after screw removal. However, our review showed no significant difference in the VAS, OMAS, or AOFAS scores between the removed and retained groups. Therefore, we concluded that routine removal of syndesmosis screws is not recommended except in some special circumstances. For example, Tucker et al[9] suggested that syndesmosis screws increased the financial burden on patients and should only be removed in cases of symptomatic implants beyond 6 months postoperatively. Removing the screws can also mean a cost or risk. Tim et al[18] conducted a retrospective study of 76 patients, and a high complication rate of 22.4% occurred after removing the syndesmotic screw. Bostman et al[19] opposed routine screw removal for the large amount of needed resources and subsequent economic costs.

Some researchers in favor of routine removal fear the physical complaints following screw breakage[17, 20]. Paradoxically, the broken group had a better AOFAS score than the removed and retained groups in some studies, but there was no significant difference in the VAS or OMAS scores. Based on these results, we opposed the opinion that screw loosening and breakage could cause pain or dysfunction. We believe that the removal of broken or loosened screws is not necessary unless complaints such as infection or pain are made.

Tibiofibular clear space (TFCS), a measure of syndesmosis constraint, was measured in several studies. Unfortunately, the data were inadequate for analysis. Manjoo et al[8] reported a slightly narrowed tibiofibular clear space accompanied by worse functional outcome in patients with intact screws compared with removed, fractured, or loose screws. However, no significant difference was found in the other three studies. Hsu et al[21] found that removal of the syndesmotic screw at six weeks increased the risk of syndesmotic diastasis recurrence but did not lead to a deterioration in ankle function. Whether the removal of syndesmotic screws will influence TFCS and the effects of TFCS on the clinical outcome is unknown, and further study in this area is necessary[22].

However, there are several limitations in this study. 1) Heterogeneity among the studies was unavoidable because of racial and age differences. Due to the content limitation of the included literature, subgroup analysis could not be conducted according to the diameter of the screws, the number of screws and the different operative methods (tricortical or quadricortical syndesmosis fixation) used. 2) Only 2 RCTs and 6 retrospective studies were included; the power of the tests for our analysis would have increased if more studies had been included. 3) Only English-language publications were included in our meta-analysis.

Conclusion

Overall, there is no significant difference in clinical outcomes between removed and retained screws. Broken or loose screws are not associated with bad functional outcome and may even lead to better function compared with removed or retained screws. We suggest that the screws should be retained, and removal of syndesmotic screws should only be indicated in symptomatic patients.

Abbreviations

RCT: Randomized controlled trials

VAS: Visual analogue scale

OMAS: Olerud-Molander Ankle Score

AOFAS: American Orthopaedic Foot and Ankle Society

TFCS: Tibiofibular clear space

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

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Authors' contributions

MJS and HLY conceived and designed the study. WJQ and PY collected the data. WJQ and KWC analyzed and interpreted the patient data. WJQ and>NNL wrote the paper. All authors read and approved the final manuscript. All authors have read the journal policies and have no issues relating to journal policies. All authors have seen the manuscript and approved to submit to your journal. The work described has not been submitted elsewhere for publication, in whole or in part.

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Competing interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article. ICMJE forms for all authors are available online.

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Figures

Figure 1

Flowchart showing the results of the literature search

Figure 2

Quality assessment for extracted studies (A) risk of bias (ROB) for randomized controlled study, (B) Risk of Bias Assessment tool for Non-randomized Study (RoBANs) for non-randomized study. (Green color: low risk of bias, red color : high risk, yellow color : unclear risk of bias)

Figure 3

Forest plots showing VAS scores. A: retained screws versus removed screws; B: broken or loose screws versus removed screws; C: broken or loose screws versus intact screws

Figure 4

Forest plots showing OMAS scores. A: retained screws versus removed screws; B: broken or loose screws versus removed screws; C: broken or loose screws versus intact screws

Figure 5

Forest plots showing AOFAS scores. A: retained screws versus removed screws; B: broken or loose screws versus removed screws; C: broken or loose screws versus intact screws

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