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

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 "tibiobular syndesmosis". The analysis was performed on individual patient 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 Chi 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

Syndesmotic diastasis, which occurs in 13–23% of ankle fractures, is normally caused by high-energy injuries and requires reduction and fixation[1–5]. The contact area of the tibiotalar joint can decrease by 42% after widening of the ankle mortise by 1 mm[6]. Therefore, transsyndesmotic fixation with one or two metallic screws, which enhances the stability of the syndesmosis, is still the gold standard for the treatment of syndesmotic injuries[2–5]. However, whether syndesmotic screws should be routinely removed before resuming normal daily activities remains controversial.

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, EMBASE and the Cochrane Central Register of Controlled Trials. The electronic databases were searched for publication dates from January 1980 to December 2019. We used the following search terms and different combinations of Medical Subject Heading (MeSH) terms and textual words: "syndesmotic diastasis", "syndesmotic injury", "syndesmotic screws", "syndesmotic fixation", and "tibiobular syndesmosis". 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 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[7–10]. 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 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 Chi² test and the I² statistic, where I² 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 225 potential articles. According to the inclusion and exclusion criteria, a total of 8 articles were finally included in the meta-analysis[11–18]. 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 |
|---------------------|---------|-----|-------|--------------------|------------------------|
| Tucker (2013)       | UK      | 4 (2 retrospective cohorts) | Group 1 (n=43): Intact  
|                     |         |     |       | Group 2 (n=20): Removed | NP |
| Manjoo (2010)       | Canada  | 4 (3 retrospective cohorts) | Group 1 (n=20): Intact  
|                     |         |     |       | Group 2 (n=10): Broken  
|                     |         |     |       | Group 3 (n=15): Removed | NP |
| Boyle (2014)        | New Zealand | 2b (Randomized controlled trial) | Group 1 (n=27): Retained  
|                     |         |     |       | Group 2 (n=24): Removed  
|                     |         |     |       | Group 3 (n=19): Broken/ Loose  
|                     |         |     |       | Group 4 (n=4): Intact | 12 |
| Hamid (2009)        | USA     | 4 (3 retrospective cohorts) | Group 1 (n=27): Intact  
|                     |         |     |       | Group 2 (n=10): Broken  
|                     |         |     |       | Group 3 (n=15): Removed | NP |
| Kaftandziev (2015)  | Macedonia | 4 (3 retrospective cohorts) | Group 1 (n=46): Intact  
|                     |         |     |       | Group 2 (n=23): Removed  
|                     |         |     |       | Group 3 (n=13): Broken | >12 |
| Heck (2017)         | Brazil  | 4 (2 retrospective cohorts) | Group 1 (n=11): Removed  
|                     |         |     |       | Group 2 (n=24): Intact | 6 |
| Høiness (2004)      | Norway  | 2b (Randomized controlled trial) | Group 1 (n=30): Quadrincortical, Removed  
|                     |         |     |       | Group 2 (n=34): Tricortical, Intact | 12 |
| 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 |

LoE level of evidence, NP not provided.
Quality assessment

The risk of bias of all selected studies was illustrated in Fig. 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 syndesmatic 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; I² = 30%; P = 0.63). In the comparison between broken or loose and removed screws (SMD, 0.24; 95% CI -0.16, 0.64; I² = 0%; P = 0.24) and the comparison between broken or loose and intact screws (SMD, 0.01; 95% CI -0.44, 0.46; I² = 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 (I² = 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; I² = 85%; P = 0.33). There was significant heterogeneity in the comparison between broken or loose and removed screws (I² = 68%), and the comparison between broken or loose and intact screws also had significant heterogeneity (I² = 87%). No significant between-group difference was found in either comparison (SMD, -0.44; 95% CI -1.22, 0.34; I² = 68%; P = 0.27; SMD, 1.72; 95% CI 0.10, 3.53; I² = 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; I² = 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; I² = 34%; P = 0.008; SMD, 0.80; 95% CI 0.36, 1.24; I² = 0%; P = 0.0004, respectively).

Discussion

Determining whether to remove syndesmatic 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[19]. 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[20–23]. 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[14] 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[23] 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[15] 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[24] conducted a retrospective study of 76 patients, and a high complication rate of 22.4% occurred after removing the syndesmotic screw. Bostman et al[25] 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[23, 26]. 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.

Tibiobular clear space (TFCS), a measure of syndesmosis constraint, was measured in several studies. Unfortunately, the data were inadequate for analysis. Manjoo et al[14] reported a slightly narrowed tibiobular 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[27] found that removal of the syndesmotic screw at six weeks increased the risk of syndesmatic 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[28].

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
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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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References
[1] U L. Operative treatment of ankle fractures. Acta orthopaedica Scandinavica Supplementum. 1981;189:1-131.
[2] Purvis GD. Displaced, unstable ankle fractures: classification, incidence, and management of a consecutive series. Clin Orthop Relat Res. 1982;91-8.
[3] van den Bekerom MP, Lammé B, Hogervorst M, Bolhuis HW. Which ankle fractures require syndesmotic stabilization? J Foot Ankle Surg. 2007;46:456-63.
[4] Pena FA, Coetzee JC. Ankle syndesmosis injuries. Foot Ankle Clin. 2006;11:35-50, viii.
[5] Dattani R, Patnaik S, Kantak A, Srikanth B, Selvan TP. Injuries to the tibiofibular syndesmosis. J Bone Joint Surg Br. 2008;90:405-10.
[6] Hermans JJ, Beumer A, de Jong TA, Kleinrensink GJ. Anatomy of the distal tibiobular syndesmosis in adults: a pictorial essay with a multimodality approach. J Anat. 2010;217:633-45.

[7] Furlan AD, Pennick V, Bombardier C, van Tulder M, Editorial Board CBRG. 2009 updated method guidelines for systematic reviews in the Cochrane Back Review Group. Spine (Phila Pa 1976). 2009;34:1929-41.

[8] Schunemann HJ, Cuello C, Akl EA, Mustafà RA, Meerpohl J, Thayer K, et al. GRADE guidelines: 18. How ROBINS-I and other tools to assess risk of bias in nonrandomized studies should be used to rate the certainty of a body of evidence. J Clin Epidemiol. 2019;111:105-14.

[9] Schunemann HJ, Mustafa R, Brozek J, Santesso N, Alonso-Coello P, Guyatt G, et al. GRADE Guidelines: 16. GRADE evidence to decision frameworks for tests in clinical practice and public health. J Clin Epidemiol. 2016;76:89-98.

[10] Guyatt GH, Oxman AD, Vist G, Kunz R, Brozek J, Alonso-Coello P, et al. GRADE guidelines: 4. Rating the quality of evidence--study limitations (risk of bias). J Clin Epidemiol. 2011;64:407-15.

[11] Boyle MJ, Gao R, Frampton CM, Coleman B. Removal of the syndesmotic screw after the surgical treatment of a fracture of the ankle in adult patients does not affect one-year outcomes: a randomised controlled trial. Bone Joint J. 2014;96-B:1699-705.

[12] Hamid N, Loeffler BJ, Braddy W, Kellam JF, Cohen BE, Bosse MJ. Outcome after fixation of ankle fractures with an injury to the syndesmosis: the effect of the syndesmosis screw. J Bone Joint Surg Br. 2009;91:1069-73.

[13] Hoiness P, Stromsoe K. Tricortical versus quadricortical syndesmosis fixation in ankle fractures: a prospective, randomized study comparing two methods of syndesmosis fixation. J Orthop Trauma. 2004;18:331-7.

[14] Manjoo A, Sanders DW, Tieszer C, MacLeod MD. Functional and radiographic results of patients with syndesmotic screw fixation: implications for screw removal. J Orthop Trauma. 2010;24:2-6.

[15] Tucker A, Street J, Kealey D, McDonald S, Stevenson M. Functional outcomes following syndesmotic fixation: A comparison of screws retained in situ versus routine removal - Is it really necessary? Injury. 2013;44:1880-4.

[16] Schepers T, van der Linden H, van Lieshout EM, Niesten DD, van der Elst M. Technical aspects of the syndesmotic screw and their effect on functional outcome following acute distal tibiobular syndesmosis injury. Injury. 2014;45:775-9.

[17] Kaftandziev I, Spasov M, Trpeski S, Zafirova-Ivanovska B, Bakota B. Fate of the syndesmotic screw--Search for a prudent solution. Injury. 2015;46 Suppl 6:S125-9.

[18] Heck JML, Guareschi Junior R, Silva L, Guerra MTE. Supination-external rotation ankle fractures: analysis of clinical results after syndesmotic screw removal. Rev Bras Ortop. 2017;52:658-62.

[19] West TK. Injuries to the Distal Lower Extremity Syndesmosis. J Am Acad Orthop Surg. 1997;5:172-81.

[20] Bell DP, Wong MK. Syndesmotic screw fixation in Weber C ankle injuries–should the screw be removed before weight bearing? Injury. 2006;37:891-8.

[21] Needleman RL, Skrade DA, Stiehl JB. Effect of the syndesmotic screw on ankle motion. Foot Ankle. 1989;10:17-24.

[22] Peter RE, Harrington RM, Henley MB, Tencer AF. Biomechanical effects of internal fixation of the distal tibiobular syndesmotic joint: comparison of two fixation techniques. J Orthop Trauma. 1994;8:215-9.

[23] Miller AN, Paul O, Boraiah S, Parker RJ, Helfet DL, Lorich DG. Functional outcomes after syndesmotic screw fixation and removal. J Orthop Trauma. 2010;24:12-6.

[24] Schepers T, Van Lieshout EM, De Vries MR, Van der Elst M. Complications of syndesmotic screw removal. Foot Ankle Int. 2011;32:1040-4.

[25] Bostman O, Pihlajamaki H. Routine implant removal after fracture surgery: a potentially reducible consumer of hospital resources in trauma units. J Trauma. 1996;41:846-9.

[26] Melvin JS, Downing KL, Ogilvie CM. A technique for removal of broken cannulated tricortical syndesmotic screws. J Orthop Trauma. 2008;22:648-51.

[27] Hsu YT, Wu CC, Lee WC, Fan KF, Tseng IC, Lee PC. Surgical treatment of syndesmotic diastasis: emphasis on effect of syndesmotic screw on ankle function. Int Orthop. 2011;35:359-64.

[28] Jordan TH, Talarico RH, Schuberth JM. The radiographic fate of the syndesmosis after trans-syndesmotic screw removal in displaced ankle fractures. J Foot Ankle Surg. 2011;50:407-12.

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

### A

| Study or Subgroup | Retained Mean | SD | Total | Removed Mean | SD | Total | Weight | Std. Mean Difference IV, Random, 95% CI |
|-------------------|---------------|----|-------|--------------|----|-------|--------|----------------------------------------|
| Boyle 2014        | 83.5          | 19.8| 27    | 85.8         | 13.2| 24    | 17.5%  | -0.13 [-0.68, 0.42]                      |
| Hoiness 2004      | 88.8          | 14.6| 34    | 83.3         | 16.6| 30    | 18.0%  | 0.33 [0.17, 0.52]                        |
| Marjojo 2010      | 46.5          | 7.9 | 20    | 66.8         | 6.7 | 12    | 13.6%  | -2.64 [-3.64, -1.65]                     |
| Schepers 2013 (a) | 73            | 20  | 12    | 82           | 20  | 37    | 16.6%  | -0.44 [-1.10, 0.21]                      |
| Schepers 2013 (b) | 73            | 20  | 12    | 73           | 27  | 44    | 16.8%  | 0.00 [0.64, 0.64]                        |
| Tucker 2013       | 81.5          | 19.3| 26    | 75           | 12.9| 43    | 17.6%  | 0.42 [-0.11, 0.96]                       |

Total (95% CI): 125 [90.9, 169.6]

Heterogeneity: $I^2 = 53.7, CH^2 = 53.73, df = 5 (P < 0.00001), I^2 = 85$

Test for overall effect: $Z = 0.95 (P = 0.33)$

### B

| Study or Subgroup | Broken or loose Mean | SD | Total | Removed Mean | SD | Total | Weight | Std. Mean Difference IV, Random, 95% CI |
|-------------------|----------------------|----|-------|--------------|----|-------|--------|----------------------------------------|
| Boyle 2014        | 85                   | 16.2 | 19    | 85.8         | 13.2| 24    | 51.5%  | -0.05 [-0.66, 0.55]                     |
| Marjojo 2010      | 62.2                 | 4.9  | 44    | 66.6         | 6.7 | 12    | 48.5%  | -0.85 [-1.51, -0.21]                    |

Total (95% CI): 63 [42.9, 83.6]

Heterogeneity: $I^2 = 68.2, CH^2 = 63.08, df = 1 (P = 0.08), I^2 = 88$

Test for overall effect: $Z = 1.11 (P = 0.27)$
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

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- PRISMA2009checklist.doc