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Review Article

Clinical Evidence for Treatment of Distal Tibiofibular Syndesmosis Injury: A Systematic Review of Clinical Studies

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ABSTRACT

No consensus had been reached about the optimal treatment for syndesmotic fixation. We performed a review of randomized controlled trials (RCTs) to assist in clarifying many of the controversies that were debated for years despite new technology and options. PubMed, Embase, and the Cochrane Library were searched through specific terms and limits. Only RCTs were selected for final inclusion. Study screening and data extraction were performed independently by 2 reviewers. Thirteen RCTs, including 828 cases, met the inclusion criteria and are summarized in this review. Pooled results demonstrated that dynamic fixation had better functional outcomes as well as lower rates of malreduction and complications compared with syndesmotic screw fixation. Both absorbable screw and tricortical screw fixation showed similar results to quadricortical metallic screws. Therefore, dynamic fixation is recommended for the treatment of syndesmosis injuries.

Ankle fractures are common fractures in adults, with an increasing incidence (1), and are often associated with distal tibiofibular syndesmosis injuries (2). An intact syndesmosis complex is important for ankle stability (3), and syndesmotic instability has a detrimental effect on functional outcomes after surgery for ankle fracture (4). Thus, it is critical to acquire stable fixation of tibiofibular syndesmosis when undergoing fixation of ankle fractures combined with syndesmotic injuries (5). Although metallic screw fixation is a conventional treatment in syndesmosis repair, there are still inevitable problems that should be considered, such as screw loosening and breakage and reoperation for screw removal (6,7). In addition, the use of absorbable screws, as an alternative fixation, avoids the reoperation for removal of screws. But the biocompatibility, degradation process, and biomechanical properties have been uncertain (8,9). Recently, a dynamic suture-button fixation device has been described, specifically TightRope (Arthrex, Inc., Naples, FL). This device allows physiologic micromotion of the syndesmosis and avoids implant removal (10,11). However, patients with suture button might be at risk of implant irritation and syndesmotic fusion (12−14). In a recent study, the authors suggested that fixation of the posterior malleolus fracture could restore syndesmotic stability and lower the rate of syndesmotic fixation (15). To date, for the treatment of syndesmosis injury, controversies still exist regarding dynamic fixation or rigid fixation, tricortical fixation or quadricortical fixation, and metal screw or absorbable screw.

In view of these uncertainties, it is necessary to obtain the most reliable clinical evidence with regard to the treatment of tibiofibular syndesmosis instability. Previous reviews attempted to identify the optimal treatment for fixation of tibiofibular syndesmosis; however, those reviews included not only randomized controlled trials (RCTs) but also retrospective cohort studies or case series, which might introduce some bias and reduce the reliability of conclusions. Therefore, we performed this systematic review of RCTs and provide an evidence-based approach about the treatment of tibiofibular syndesmosis injury regarding static fixation versus dynamic fixation, metal screw versus absorbable screw, tricortical fixation versus quadricortical fixation, and with or without fixation.

Materials and Methods

The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines were followed while preparing this systematic review (16).

Search Strategy

PubMed, EMBASE, and the Cochrane Library were searched to identify relevant articles from their inception to July 2018. The search terms were as follows: (syndesmosis or syndesmotic or tibiofibular ligament or ankle fracture) AND (randomized controlled trial or controlled clinical trial or randomized). Only published articles were considered.

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In addition, reference lists of relevant articles were manually reviewed to identify additional trials.

Inclusion Criteria and Exclusion Criteria

Inclusion criteria: (I) RCTs; (II) instability of distal tibiofibular syndesmosis caused by trauma (with or without ankle fracture) requiring operative management; (III) reported data include 1 of the following outcomes at least: ankle functional scores, radiological outcomes, and complications; and (IV) the searches were restricted to the English language.

Exclusion criteria: (I) case reports, non-RCTs, and reviews; (II) pediatric or biomechanical studies; and (III) studies not published in English.

Two reviewers (G.L. and L.C.) independently selected eligible studies based on the above criteria. Titles and abstracts were first browsed. Then full texts were scrutinized if sufficient information could not be obtained from abstracts. Disagreements regarding which studies to include were resolved by discussion, and a third reviewer was consulted when necessary.

Data Abstraction

Two investigators (G.L. and M.G.) independently extracted the following basic information: first author, year of publication, number of patients, mean age, follow-up duration, fixation method of syndesmosis, and outcome measurement. The primary outcomes included Olerud-Molander ankle score (OMS), American Orthopaedic Foot and Ankle Society (AOFAS) (17,18) score at 6 and 12 months of follow-up, and postoperative complications. The secondary outcomes were as follows: visual analog scale (VAS), malreduction, range of motion (ROM) including dorsiflexion (DF) and plantar flexion, and radiological outcomes. Data in other forms (i.e., median, interquartile range) were converted to mean ± standard deviation (SD) according to Cochrane Handbook (19) and the method of Wan et al (20). When a consensus could not be reached, discrepancies were resolved by reexamining the source data and asking the opinion of a third author.

Risk of Bias Assessment

Two authors (G.L. and F.C.) assessed risk of bias of included studies independently according to the Cochrane Handbook for Systematic Reviews of Interventions, which includes 7 items: randomization, allocation concealment, blinding of participants, blinding of outcome assessors, incomplete outcome data, selective reporting, and other sources of bias (19). Based on information provided from included studies, each item was recorded by “Yes”, “No”, or “Unclear.” “Yes” indicates low risk of bias, “No” indicates high risk of bias, “Unclear” indicates lack of information or unknown risk of bias. Disagreement was resolved by the third author.

Statistical Analysis

The meta-analysis was performed by author G.L. with Review Manager (RevMan) version 5.0 (The Nordic Cochrane Centre, Copenhagen, 2010). For continuous outcomes, mean difference and 95% confidence interval (CI) were used to test the overall effect, and relative risk (RR) and 95% CI were calculated for dichotomous outcomes. Heterogeneity among studies was estimated using I^2 statistic, and I^2 >50% was considered as substantial heterogeneity (21), in which case the random-effect model was used. Otherwise, we choose the fixed-effect model. $p < .05$ was considered statistically significant.

Results

Study Characteristics

The selection process is shown in a flow diagram (Fig.). Thirteen RCTs (22−34), including 828 cases, met the inclusion criteria and are summarized in this review. Seven RCTs compared clinical outcomes of dynamic fixation versus traditional screw fixation in the treatment of unstable syndesmosis disruption, 3 RCTs compared clinical outcomes of tricortical screw fixation versus quadricortical screw fixation, and 3 RCTs compared clinical effects of absorbable screws versus traditional screws. The main characteristics of the included studies are summarized in Table 1.

Risk of Bias Assessment

All RCTs showed clear inclusion and exclusion criteria. Eight studies reported appropriate methods of random sequence generation. Ten studies provided information regarding allocation concealment. Other assessment, including blinding of participants and personnel and

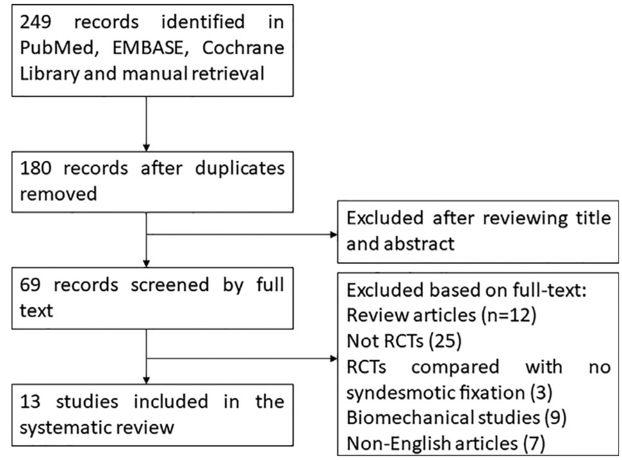

Figure. Flow diagram of selection of studies included in the review.

blinding of outcome assessment, were partially performed in included studies. The risk of bias summary is shown in Table 2.

Dynamic Fixation Versus Traditional Screw Fixation

Seven RCTs (22−28) including 358 patients compared clinical outcomes of dynamic fixation and syndesmotic screw fixation. Follow-up duration for every study ranged from 12 to 37 months. Suture button was employed in 6 studies, and elastic syndesmosis hook plate was used in 1 study. Syndesmosis screws were routinely removed in 3 studies, and in another 4 studies they were removed only if local irritation occurred. We conducted statistical analyses of the 2 fixation methods in terms of function scores, VAS score, and complications. Pooled results demonstrated that dynamic fixation had significantly higher OMS scores at 6 and 12 months of follow-up and higher AOFAS scores at 12 months compared with the syndesmotic screw fixation group. Patients in the dynamic fixation group had lower VAS scores at 6 and 12 months after operation than those in the syndesmotic screw fixation group. The dynamic fixation group had no significantly better DF; however, the ROM of plantar flexion was higher in the dynamic fixation group at 12 months of follow-up (Table 3). The rate of malreduction in the dynamic fixation group was significantly lower than in the screw group. All included studies reported complications, including infection, foreign body reaction, broken screws, and loss of reduction. Pooled results demonstrated that the complications rate was significantly higher in the screw fixation group (Table 4).

Absorbable Screws Versus Metallic Screws

Three RCTs (29−31) including 238 patients were concerned with comparison of absorbable screws and metallic screws. Kaukonen et al (29) published an RCT comparing absorbable polylevolactic acid screw (n = 20) with quadricortical metallic screw fixation (n = 18). The mean follow-up time was 35 months. All metallic screws were routinely removed at 8 weeks or later. They confirmed that there were no significant differences with regard to the rate of return to previous physical activity level, ROM, ankle swelling, and medial joint spaces between the 2 groups (29). Thordarson et al (30) performed an RCT including 32 patients, of whom 17 were treated with polylactic acid screws and 15 with quadricortical screws. No significant differences were found in ROM and pain between groups during 11 months of follow-up. All metallic screws were removed at average 13.4 weeks; absorbable screws were not removed (30). Sun et al (31) published an RCT study

Table 1
Characteristics of included studies

Author	Number (Male/Female)	Age	Follow-Up Duration	Fracture Types	Comparison		Location	Main Outcome Measurement
Andersen et al. (22)	64/33	44.5	2 yr	With or without OTA/AO type 44-C	One tight rope	A 4.5-mm quadricortical screw	Not mentioned	AOFAS, OMS, VAS, complications, radiographic measurements
Coetzee and Ebeling (23)	17/7	36.5	2.3 yr	Not mentioned	Two right rope	Two quadricortical screws	Not mentioned	AOFAS, ROM, complications
Colcuc et al. (24)	41/13	37	1 yr	Weber B (20.4%), Weber C (13%); isolated (44.4%), Maisonneuve (22.2%)	One tight rope	A 3.5-mm tricortical screw	3.5 cm above the ankle	OMS, AOFAS, VAS, Complications
Kortekangas et al. (25)	27/16	44.7	37 mo	Lauge-Hansen type; PER IV	One tight rope	A 3.5-mm tricortical screw	Not mentioned	AOFAS, OMS, VAS, ROM, complications, malreduction, radiographic measurements
Laflamme et al. (26)	51/19	39.7	1 yr	AO/OTA type; 44-B (17.1%), 44-C (82.9%)	One tight rope	A 3.5-mm quadricortical screw	2 cm above the ankle	AOFAS, OMS, VAS, ROM, radiographic evaluation
Xian et al. (27)	14/11	47.5	1 yr	Lauge-Hansen type; SER stage 3 (20%), stage 4 (52%), PER stage 4 (28%)	One elastic syndesmosis hook plate	Two 3.5-mm tricortical screws	3 cm above the ankle	ROM, VAS, malreduction, complications, interval to return to work
Zhan et al. (28)	28/25	44.5	12 mo	Lauge-Hansen type; SER stage 3 (30.2%), stage 4 (49.1%), PER stage 4 (20.8%)	An absorbable anchor	Two 3.5-mm tricortical screws	2 cm above the ankle	OMS, ROM, VAS, complications, malreduction
Kaukonen et al. (29)	20/18	44.3	35 mo	AO/OTA type; 44-B (10.5%), 44-C (89.5%)	One 4.5-mm PLLA screw	One 4.5-mm metallic screw	Not mentioned	ROM, complications, radiographic measurements
Thordarson et al. (30)	25/7	29.8	11 mo	PER ankle fractures	One 4.5-mm PLA screw	One 4.5-mm metallic screw	Not mentioned	ROM, pain, complications
Sun et al. (31)	98/70	38.5	55.8 mo	Lauge-Hansen type; SER (48.8%), PAD (16.1%), PER (35.1%)	One 4.5-mm PLLA screw	One 4.5-mm metallic screw	2 to 3 cm above the ankle	ROM, pain, Baird score, complications, radiographic measurements
Hoiness and Stromsoe (32)	32/32	42.1	1 yr	AO/OTA type; 44-B (45.3%), 44-C (54.7%)	Two 3.5-mm tricortical screws	One 4.5-mm quadricortical screw	2 to 3 cm above the ankle	OMS, ROM, complications, radiographic measurements
Moore et al. (33)	85/35	33	5 mo	AO/OTA type 44-C	One 3.5-mm tricortical screw	One 3.5-mm quadricortical screw	Not mentioned	Loss of reduction, complications
Wikeroy et al. (34)	24/24	49.3	8.4 yr	AO/OTA type; 44-B (39.6%), 44-C (60.4%)	Two 3.5-mm tricortical screws	One 4.5-mm quadricortical screw	Not mentioned	OMS, ROM, VAS, SF-36, radiographic measurements

Abbreviations: AOFAS, American Orthopaedic Foot & Ankle Society; mo, months; PA, pronation abduction; PER, pronation external rotation; SER, supination external rotation; yr, years.

Table 2
Risk of bias analysis of randomized controlled trials

Study	Randomization	Allocation Concealment	Blinding of Participants	Blinding of Outcome Assessors	Incomplete Outcome Data	Selective Reporting	Other Sources
Andersen et al. (22)	+	+	+	–	+	+	?
Coetzee and Ebeling (23)	?	?	+	–	+	+	?
Colcuc et al. (24)	+	+	+	?	–	+	?
Kortekangas et al. (25)	+	+	+	+	?	+	?
Laflamme et al. (26)	+	+	+	+	+	+	?
Xian et al. (27)	?	?	?	?	–	?	?
Zhan et al. (28)	–	–	?	?	?	+	?
Kaukonen et al. (29)	+	+	+	+	+	+	?
Thordarson et al. (30)	?	+	?	?	+	?	?
Sun et al. (31)	+	+	–	?	+	+	+
Hoiness and Stromsoe (32)	+	+	+	?	+	+	+
Moore et al. (33)	?	?	?	?	–	–	?
Wikeroy et al. (34)	+	+	+	+	+	+	?

+, low risk of bias; ?, unclear risk of bias; –, high risk of bias.

Table 3
Data analysis for comparison of dynamic fixation versus traditional screw fixation

Outcomes	Studies	Patients	Analysis Method	MD [95% CI]	*p* Value	Heterogeneity, %
OMS at 6 mo	4	259	Inverse variance, random	9.47 [2.19 to 16.75]	.01	73
OMS at 12 mo	5	299	Inverse variance, fixed	4.95 [2.10,7.81]	.0007	0
AOFAS at 6 mo	4	230	Inverse variance, random	2.97 [−2.61 to 8.56]	.30	65
AOFAS at 12 mo	4	228	Inverse variance, fixed	3.59 [0.86 to 6.32]	.01	41
VAS at 6 mo	4	258	Inverse variance, fixed	−0.58 [−0.93 to −0.23]	.001	0
VAS at 12 mo	6	320	Inverse variance, fixed	−0.47 [−0.78 to −0.16]	.003	0
Dorsiflexion at 12 mo	3	103	Inverse variance, fixed	0.60 [−0.78 to 1.98]	.40	15
Plantarflexion at 12 mo	3	103	Inverse variance, fixed	3.13 [1.02 to 5.24]	.004	0

Abbreviations: AOFAS, American Orthopaedic Foot & Ankle Society; CI, confidence interval; MD, mean difference; mo, months; OMS, Olerud-Molander ankle score; VAS, visual analog scale.

Table 4
Data analysis for comparison of complications and malreduction in each group

Outcomes	Studies	Patients	Analysis Method	RR [95% CI]	*p* Value	Heterogeneity, %
01. Complications	7	358	Mantel-Haenszel, fixed	0.26 [0.15 to 0.43]	<.00001	40
01. Malreduction	3	118	Mantel-Haenszel, fixed	0.34 [0.12 to 1.01]	.05	0
02. Complications	3	238	Mantel-Haenszel, random	2.60 [0.53 to 12.83]	.24	59

Abbreviations: CI, confidence interval; RR, relative risk.
01, Comparison of dynamic fixation versus traditional screws fixation; 02, Comparison of absorbable screws and metallic screws.

including 86 patients treated with polylevolactic acid screws and 82 patients treated with metallic screws. There was no statistically significant difference in the Baird score between the groups. Patients in the absorbable screws group had increased DF and plantar flexion compared with those in the metallic group. Mean ROM in the 2 groups was similar. They reported that 26 of 86 patients in the absorbable screw group had a mild to moderate foreign body reaction, whereas only 4 of 82 patients in the metallic screw group had a mild foreign body reaction. The rates of screw removal were 94.2% and 90.2%, respectively, in the polylevolactic acid screw group and the metallic screw group (31). All included studies reported complications, including infection, foreign body reaction, heterotopic ossification, and broken screws. We extracted available data from these 3 studies for meta-analysis, and pooled results demonstrated that there was no significant difference in the rate of complications between 2 groups, with high heterogeneity (Table 4).

Tricortical Fixation Versus Quadricortical Fixation

Three RCTs (32−34) involving 232 patients were included for comparison of tricortical fixation and quadricortical fixation. Hoiness et al (32) published an RCT comparing two 3.5-mm tricortical screws (n = 34) with one 4.5-mm quadricortical screw (n = 30). Tricortical screw fixation significantly improved OMS scores and alleviated pain at 3 months of follow-up compared with the quadricortical group, but there were no significant differences after 1 year. There were no significant differences in DF and complications between the groups during follow-up. In this study, the quadricortical screws were removed after 2 months, whereas the tricortical screws were removed only if symptomatic (32). Moore et al (33) published an RCT including 59 patients treated with cortical screws placed through 3 cortices and 61 patients treated with cortical screws placed through 4 cortices. There were no significant differences in loss of reduction, screw breakage, and hardware removal at 150 days of follow-up between the 2 groups (33). Wikeroy et al (34) published an RCT to assess long-term outcomes after 2 types of syndesmosis fixation, comparing 2 tricortical screw fixation with 1 quadricortical screw fixation. There were no statistical differences regarding OMS score, degree of osteoarthritis, and VAS score. Patients in the quadricortical screw group had better DF activity than those in the tricortical screw group at 8.4 years of follow-up (34). Data from the 3 studies could not be extracted for statistical analysis because the number of studies was not enough.

Discussion

Accurate reduction and fixation of syndesmotic injury in unstable ankle fractures are critical factors in preventing long term disability of the ankle. Inadequate treatment of syndesmosis leads to advanced secondary arthrosis and instability that correlates with poor clinical outcomes. There are multiple techniques for treating tibiofibular syndesmotic instability, and studies had not provided definitive evidence for stabilization of the syndesmosis. Therefore, we believed that a systemic review was required to compare the efficacy and safety of different approaches for syndesmotic instability in ankle fractures. This systematic review provides an evidence-based foundation about different treatment approaches for tibiofibular syndesmosis injury. Pooled results demonstrate that dynamic fixation had significantly higher functional scores and lower VAS scores at 6 and 12 months of follow-up compared with syndesmotic screw fixation. The rates of malreduction and complications in the dynamic fixation group were significantly lower than in the screw group. Absorbable screw fixation showed similar functional outcomes and complication rates compared to metallic screw fixation. Tricortical screw fixation achieved similar functional outcomes compared to quadricortical syndesmotic screws.

Metallic screw fixation was a conventional treatment for syndesmotic instability; however, this approach had become controversial, because it provided rigid fixation (11) and could lead to biomechanical alteration and a series of inevitable problems, such as screw loosening, breakage, and reoperation for screw removal (6,7). Screw removal facilitated restoration of the normal tibiofibular relationship and avoided screw breakage, but it meant a second operation with additional economic burden. Routine screw removal was also associated with a higher rate of postoperative infections (35). However, a review confirmed that there were no differences in outcomes between retained or removed screws (36). Recently, dynamic fixation has been advocated in many studies. A biomechanical study demonstrated that suture button device was comparable to quadricortical 3.5-mm syndesmotic screws in terms of the effect on fibula motion during cyclic physiological loading (37). One of the advantages of this device is that it does not require routine removal and is more cost-effective (38).

In this review, 7 RCTs compared clinical outcomes of dynamic fixation and syndesmotic screw fixation. Syndesmosis screws were routinely removed in 3 studies, and in another 4 studies they were removed only if local irritation occurred. The study demonstrated that dynamic fixation had significantly higher functional scores and lower VAS scores at 6 and 12 months of follow-up compared with syndesmotic screw fixation. The rate of malreduction was independently performed because it was a poor predictor for prognosis (5). Although the surgeon's incompetence at the time of surgery might be 1 of the factors that lead to the malreduction of ankle fracture, patients included in both arms in each RCT were comparable, and operative procedures and postoperative rehabilitation were similar. Therefore, malreduction reflected whether the 2 fixation methods could accurately achieve reduction. We demonstrated that the rate of malreduction in the dynamic fixation group was significantly lower than in the screw group. Studies have shown that dynamic fixation provided more accurate reduction than syndesmotic screw fixation (5,39). It should be noted that syndesmotic overcompression was possible, and heightened awareness was demanded at the time of reduction (40). The complications reported in the included studies were infection, soft-tissue irritation, discomfort, screw breakage, and so on. We found that dynamic fixation showed a lower risk of complications than screw fixation. A review by Zhang et al (41) reported that the dynamic fixation group had similar functional outcomes and complication rates compared to the syndesmotic screw fixation group. It was noted that only 3 of 10 studies were RCTs in that review, and low-quality studies were limited to draw a reliable conclusion. However, we performed this systematic review by incorporating 7 randomized controlled trials to draw a firm conclusion. It was deduced that dynamic fixation allowed a more physiological micromotion of distal tibiofibular syndesmosis (42) while maintaining adequate syndesmosis stability, and was therefore associated with better functional results and lower rates of malreduction and complications (39).

Recently, the use of absorbable screws has gained some popularity in syndesmosis fixation. Good clinical results have been reported following the use of absorbable screws for fixation of tibiofibular syndesmosis (43,44). One advantage of absorbable screws is that they do not need to be removed. Besides, biomechanical studies showed that an absorbable screw is biomechanically equivalent to a similar-diameter stainless steel screw for repair of syndesmosis disruption (9,45). It seems that absorbable screws could produce equivalent syndesmotic stability to that of metallic screws. We found that absorbable screw fixation had similar results to metal screw method for the reconstruction of tibiofibular syndesmosis. Although the meta-analysis showed no statistical difference in the complications rate, the heterogeneity was large. Previous studies reported that absorbable screws were associated with delayed inflammatory reactions and sterile effusions (46,47). A study by Sun et al (31) included in this review showed that absorbable screws were associated with a higher foreign body reaction (30.2%) compared with metallic screws (4.9%). The degradation of absorbable screws was usually accompanied by inflammatory reactions. Foreign body reaction was 1 of the postoperative complications, and it also might be 1 disadvantage of absorbable screws compared with metallic screws.

Tricortical screw fixation has been reported to repair syndesmotic disruption (48). Markolf et al (49) confirmed that there were no significant differences in the stability of syndesmosis sprains between tricortical screw and quadricortical screw fixation. Three RCTs in this review demonstrated that tricortical screw fixation had similar clinical outcomes to quadricortical screw method for the fixation of tibiofibular syndesmosis. Miller et al (50), in a biomechanical study, reported that there was no significant difference in biomechanical property between the dynamic implant and the tricortical screw, indicating that tricortical screw fixation might allow a micromotion of syndesmosis without the need for screw removal. According to that review, tricortical screws were removed if symptoms occurred. The advantage of the quadricortical screw may be that it is easy to remove after screw breakage (50).

The present study has several limitations. Although the included studies were all RCTs, some studies were of low quality; random sequence generation, allocation concealment, and blinded assessments were unclear in some studies, which influence the conclusion. Another limitation was that fracture types, surgical techniques, rehabilitation strategies, and outcome measurements varied in these studies, but groups of patients included in both arms in each study were comparable. In addition, because the number of included studies was not sufficient, we could not perform statistical analysis except comparing screw fixation with dynamic fixation. More high-quality RCTs with large samples are proposed.

In conclusion, dynamic fixation had better functional outcomes as well as lower rates of malreduction and complications compared with syndesmotic screw fixation. Both absorbable screw and tricortical screw fixation showed similar results with quadricortical metallic screw fixation. Therefore, dynamic fixation is recommended for the treatment of syndesmosis injuries.

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