Comparison of Suture Button and Syndesmotic Screw for Ankle Syndesmotic Injuries

A Meta-analysis of Randomized Controlled Trials

Baoyun Xu,* MD, Shanshan Wang,[†] MMed, Jindong Tan,* MMed, Wan Chen,*[‡] MD, and Kang-lai Tang,*[‡] MD

Investigation performed at Southwest Hospital of Army Medical University, Chongqing, China

Background: The syndesmotic screw (SS) and suture button (SB) fixation methods are both widely used for the reduction of ankle syndesmotic injury, with varying outcomes.

Purpose: To review recently published randomized controlled trials (RCTs) to assess the outcomes between SS and SB fixation for ankle syndesmotic injury.

Study Design: Systematic review; Level of evidence, 1.

Methods: The PubMed, Embase, ClinicalTrials.gov, and Cochrane databases were searched for relevant RCTs published between 1966 and 2021 according to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. Eligible studies were RCTs comparing SS and SB fixation for ankle syndesmotic injury. The risk of bias was evaluated using the Cochrane Risk of Bias tool. Primary outcomes included complications, malreduction, and unplanned reoperation, and secondary outcomes were the American Orthopaedic Foot & Ankle Society (AOFAS) score, Olerud-Molander ankle score (OMAS), and EuroQoI-5 Domain (EQ-5D) score. The mean difference (MD) and risk ratio (RR) were calculated for continuous and dichotomous outcomes, respectively. Random- or fixed-effects model was applied according to heterogeneity.

Results: Of 389 studies, 8 RCTs involving 512 patients were included. Overall, 257 patients received SS fixation and 255 patients received SB fixation. The 2 groups did not differ significantly in malreduction (RR, –0.06; 95% CI, –0.18 to 0.07) or EQ-5D (MD, 0.01; 95% CI, –0.01 to 0.03). However, the SB group showed significant advantages over the SS group in complications (RR, 0.42; 95% CI, 0.26 to 0.66), unplanned reoperation (RR, 0.62; 95% CI, 0.43 to 0.89), AOFAS score (MD, 3.04; 95% CI, 1.77 to 4.31), and OMAS (MD, 4.51; 95% CI, 1.54 to 7.48). The risk of bias of the included studies was acceptable.

Conclusion: The results showed that there were no significant differences between the SS and SB groups in malreduction and EQ-5D scores. However, the SB group had significantly better local irritation rates, unplanned reoperation rates, AOFAS scores, and OMASs.

Keywords: syndesmotic injury; suture button; syndesmotic screw; meta-analysis

The syndesmosis is a micromovement joint composed of the distal fibula, tibia, and a complex of 4 ligaments, which is important to maintain ankle stability.^{4,17,28} Syndesmotic injuries account for 5% to 10% of ankle sprains and 20% of ankle fractures,^{16,31,33} typically caused by supraphysiologic ankle external rotation.^{13,38} Syndesmotic injury accompanied with ankle fracture usually requires surgery and correct reduction of the syndesmosis, which is critical to prevent further deterioration of the ankle joint, such as osteoarthritis, and sustainable chronic pain.^{3,7,36}

The gold standard of fixation for syndesmotic injury is syndesmotic screw (SS) fixation.^{25,41} The disadvantages of SSs include screw breakage, local irritation, syndesmosis malreduction, nonanatomic reduction, the need for removal, unclear screw size and number, and an unspecific number of cortices penetrated.^{12,23,25} The suture button (SB) was introduced to address these problems. The SB is known for promoting early healing and anatomic reduction and does not require regular removal.^{9,35,40} Moreover, the SB has demonstrated similar or better biomechanical results and equivalent strength compared with the SS.^{1,8}

Several studies have compared the advantages and disadvantages of SSs and SBs; however, it remains unclear

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whether the SB is preferable to the SS.^{2,5,14,15} In addition, numerous systematic reviews and meta-analyses, both randomized controlled trials (RCTs)^{9,27,34} and mixed RCTs and non-RCTs,^{21,39,40} have been conducted to find out the best approach, but their evidence and results have varied. In the first group of reviews,^{9,27,34} the included RCTs were not the latest ones, and their outcomes were insufficient; in the second group,^{21,39,40} the quality of evidence was limited by the included studies.

The purpose of the current study was to conduct a metaanalysis of the latest RCTs to assess complication rate, malreduction, unplanned reoperation, and functional outcomes between SS and SB fixation methods for syndesmotic injury.

METHODS

Study Selection

From 1966 to September 2021, we searched for relevant studies published from 1966 to September 2021 from the Embase, PubMed, ClinicalTrials.gov, and Cochrane databases. Search terms for PubMed included "endobutton," "button?," "endobutton," "tightrope," "suture button," "flexible fix*," "syndesmo*," "distal tibiofibular syndesmosis," "syndesmotic injury," "screw?," "syndesmo* screw?," and "rigid fix*," and we also searched within the reference lists of other articles.^{9,21,27,34,39,40}

All the RCT studies were included if they compared the outcomes of SBs and SSs in patients with syndesmotic injury. Exclusion criteria included (1) non-English studies, (2) cadaveric studies, (3) the same follow-up group of patients at different follow-up times, and (4) duplicate studies.

Two authors (B.X. and S.W.) independently reviewed the titles and abstracts of all the studies to exclude unrelated studies; the remaining studies were evaluated by reading the full text. Any disagreements were addressed by discussion or by involving a third author (W.C.).

Data Extraction

We retrieved baseline study information, including publication year, sample size, mean age, interventions, fracture types, follow-up, and percentage of patients analyzed. The primary outcomes were complications (local irritation, implant failure, and infection), malreduction (side-to-side difference in syndesmotic width of ≥ 2 mm between normal and injured ankles^{18,24}), and unplanned reoperation for accidental reasons (eg, local irritation and infection). The secondary outcomes were functional scores, including the American Orthopaedic Foot & Ankle Society (AOFAS) score, OlerudMolander ankle score (OMAS), and EuroQol-5 Domain (EQ-5D) score. Two authors (B.X. and S.W.) extracted the data independently and then compared the final results, and any discrepancies were addressed by discussion.

Quality Assessment

The methodological quality of the included RCTs was evaluated by 2 independent investigators (J.T. and S.W.). The RCTs were assessed with the Cochrane Risk of Bias tool, which includes 7 biases: (1) random sequence generation, (2) allocation concealment, (3) blinding of participant and personnel, (4) blinding of outcome assessment, (5) incomplete outcome data, (6) selective reporting, and (7) other bias. Each part was classified as low risk, high risk, or unclear. Any disagreements were addressed via discussion or by the senior investigator (K.T.).

Data Analysis

Dichotomous data were analyzed using risk ratios (RRs) and 95% CIs, and continuous variables were analyzed using mean differences (MDs) and 95% CIs (if an RCT provided median values, then the *P* value, interquartile range, and mean \pm SD would be calculated according to corresponding statistical methods).^{22,37} Acceptable heterogeneity between the included studies was defined as $I^2 \leq 50\%$ and P > .1. Under this circumstance, a fixed-effects model was applied; otherwise, a random-effects model was applied. All calculations were performed using Revman (Version 5.4; Cochrane). A funnel plot was made to evaluate the publication bias, and sensitivity analysis was performed to provide a robust result.

RESULTS

Search Findings and Study Characteristics

A total of 389 studies were yielded after the electronic search. After duplicates were removed, the remaining studies were first screened by title and abstract, and then by full text. Ultimately, 8 RCTs, $^{5,6,18-20,29,30,32}$ all published between 2009 and 2021, were included in this metaanalysis. The study retrieval process is shown in Figure 1. We included 2 studies 18,20 whose follow-up patients were the same because their results were reported at different times. The 8 included RCTs $^{5,6,18-20,29,30,32}$ involved 512 patients

The 8 included RCTs^{3,5,16-22,23,30,32} involved 512 patients with syndesmotic injuries, 255 of whom received SB and 257 of whom received SS fixation. The average follow-up was 33.7 months and the average age was 42.5 years. According to the available information, there were 59

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[‡]Address correspondence to Kang-lai Tang, MD, or Wan Chen, MD, Southwest Hospital of Army Medical University, No. 30 Gaotanyan Street, Shapingba District, Chongqing, China (email: tangkanglai@hotmail.com or chenwanfred@foxmail.com).

^{*}Sports Medicine Center, Southwest Hospital of Army Medical University, Chongqing, China.

[†]Department of Pain and Rehabilitation, Xinqiao Hospital of Army Medical University, Chongqing, China.

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patients with Maisonneuve fractures, 31 with Weber C, 11 with Weber B, 274 with AO-44C, and 10 with AO-44B fractures; 7 studies^{5,6,18-20,29,32} used TightRope as an SB, 1 study³⁰ used Ziptight, 5 studies^{6,18,20,30,32} used tricortical screws, 3 studies^{5,19,29} used quadricortical screws, 6 studies^{6,18-20,30,32} used 3.5-mm SSs, 1 study²⁹ used 4.5-mm SSs, and 1 study⁵ used SSs from 3.5 to 6 mm (Table 1).

Quality Assessment and Risk of Bias

Overall, the quality of included studies was acceptable; 50% showed an unclear or high risk of performance bias, and 75% showed a unclear or high risk of detection bias, and 25% had a high risk of detection bias, and 12.5% had a high risk of reporting bias. (Figure 2).



Figure 1. Flowchart of study screening and selection using PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. RCT, randomized controlled trial.

Primary Outcomes

Complications. All studies reported complications: 7 studies^{5,6,18-20,30,32} reported local irritation and infection (deep or superficial), and 6 studies^{6,18-20,29,30} reported implant failure. This calculation did not show much heterogeneity ($I^2 = 15\%$; P = .27), and the SS group showed significantly higher risk of complication (RR, 0.42; 95% CI, 0.26-0.66). There was no significant difference in the subgroups of infection (RR, 1.69; 95% CI, 0.62-4.59) and implant failure (RR, 0.39; 95% CI, 0.14-1.09). The main significant difference, however, was observed in the local irritation section (RR, 0.23; 95% CI, 0.11-0.46) (Figure 3).

Malreduction. Five studies^{18,20,29,30,32} reported data on malreduction. Studies that did not use the defined standard for malreduction (ie, side-to-side difference in syndesmotic width of ≥ 2 mm) were excluded from the meta-analysis. Across all the studies, there was no significant difference between the SB and SS groups (RR, -0.06; 95% CI, -0.18 to 0.07). The heterogeneity was a little higher than the standard ($I^2 = 52\%$; P = .08) (Figure 4).

Unplanned Reoperation

Eight studies^{5,6,18-20,29,30,32} reported the date of unplanned reoperation after the primary surgery, and a significant difference was observed between the SB and SS groups (RR, 0.62; 95% CI, 0.43-0.89; $I^2 = 38\%$; P = .13) (Figure 5).

Secondary Outcomes

AOFAS Score. Five studies^{5,6,19,29,30} reported the AOFAS score at different follow-up times. The data showed acceptable heterogeneity ($I^2 = 42\%$; P = .03), and a significant difference was found between the 2 groups (MD, 3.04; 95% CI, 1.77 to 4.31). There was no significant difference 2 years after the surgery (MD, 2.46; 95% CI, -0.26 to 5.18),

TABLE 1 Characteristics of the Included Studies a

	Sample Size (allocated)	Sample Size (analyzed)	Mean age	Males	In	terventions	Fractu	re Туре	Follow-up (months) SB/SS	Percentage of analyzed
Study	SB/SS	SB/SS	SB/SS	SB/SS	SB	SS	SB	SS		
Lehtola 2021	21/22	16/17	51.7	13/13	1 TightRope	1 tricortical 3.5mm	9 Maisonneuve, 12 Weber C	9 Maisonneuve, 12 Weber C	85.2/85.2	76.7%
Ræder 2020	48/49	48/49	46±14.8/43±16.2	34/30	1 TightRope	1 quadricortical 4.5mm	15 Maisonneuve 31 others	14 Maisonneuve 35 others	60/60	100%
Ræder 2020	58/55	48/47	44±15/48±14	35/30	1 Ziptight	1 tricortical 3.5mm	113 A	O-44C	24/24	84.1%
Sanders 2019	50/53	NA	41±12/38±14	38/38	1 TightRope	2 tricortical 3.5mm	103 AO-44C		12/12	85%
Colcuc 2018	32/30	26/28	35/39	19/22	1/2 TightRope	1 tricortical 3.5mm	5 Weber B, 3 Weber C, 13 isolated, 5 Maisonneuve	6 Weber B, 4 Weber C, 11 isolated, 7 Maisonneuve	12/12	87.1%
Laflamme 2015	34/36	33/32	40.1±14.8/39.3±12.4	25/26	1 TightRope	1 quadricortical 3.5mm	5 AO-44B, 29 AO-44C	5 AO-44B, 29 AO-44C	12/12	93.1%
Kortekangas 2015	21/22	21/19	46±14.8/43.5±15.7	13/14	1 TightRope	1 tricortical 3.5mm	9 Maisonneuve, 12 Weber C	9 Maisonneuve, 12 Weber C	36/37	93.0%
Coetzee 2009	12/12	8/9	35/38	9/8	2 TightRope	2 quadricortical 3.5/4.5/6 mm	NA ^a	NA ^a	27/27	70.1%

^aNA, not available; AO, ; SB, suture button; SS, syndesmotic screw.



Figure 2. (A) Risk of bias of the included studies. (B) A visual summary of the risk of bias. Ræder_2 refers to Ræder et al³⁰; Ræder_5 refers to Ræder et al.²⁹

but a significant difference was observed at follow-up periods of \leq 3 months (MD, 3.21; 95% CI, 0.13 to 6.29), 6 months (MD, 2.91; 95% CI, 0.33 to 5.49), 12 months (MD, 2.76; 95% CI, 0.37 to 5.15), and 5 years (MD, 5.40; 95% CI, 1.09 to 9.71) (Figure 6).

Olerud-Molander Ankle Score. Six studies^{6,19,20,29,30,32} reported OMAS data and evident heterogeneity was found $(I^2 = 62\%, P = .0004)$. The total effects favored the SB group (MD, 4.51; 95% CI, 1.54-7.48); only 1 subgroup (1 year after the surgery) showed a significant difference (MD, 4.40; 95% CI, 1.48-7.33). Subgroups of ≤ 3 months (MD, 5.27; 95% CI, -0.9 to 11.45), 6 months (MD, 6.49; 95% CI, -2.20 to 15.17), 24 months (MD, 2.17; 95% CI, -13.31 to 17.65), and more than 36 months (MD, 0.16; 95% CI, -17.56 to 17.87) showed no difference between the 2 groups (Figure 7).

EQ-5D Score. Three studies^{29,30,32} reported the EQ-5D score. The data showed no significant difference between the SB and SS groups. The heterogeneity was acceptable (MD, 0.01; 95% CI, -0.01 to 0.03; $I^2 = 44\%$; P = .05), and similar results were found at follow-up periods of ≤ 3 months (MD, 0.05; 95% CI, -0.01 to 0.1), 6 months (MD, 0.04; 95% CI, 0.00 to 0.07), 12 months (MD, 0.01; 95% CI, -0.08 to 0.02), and 5 years (MD, 0.00; 95% CI, -0.07 to 0.07) (Figure 8).

Publication Bias

The funnel plot of studies reporting data on unplanned reoperation was asymmetric, indicating a potential risk of publication bias (Figure 9).

DISCUSSION

Overall, our study results indicated that SB fixation has lower complication rates and equivalent or better functional results than SS fixation. Six outcomes were adopted in our study to evaluate the performance between SB and SS fixation, of which 4 outcomes—AOFAS score (MD, 3.04; 95% CI, 1.77 to 4.31), OMAS (MD, 4.51; 95% CI, 1.54 to 7.48), complications (RR, 0.42; 95% CI, 0.26 to 0.66), and unplanned reoperation (RR, 0.62; 95% CI, 0.43 to 0.89)—indicated advantages for the SB group over the SS group. For the remaining outcomes, the EQ-5D score (MD, 0.01; 95% CI, -0.01 to 0.03) and malreduction (RR, -0.06; 95% CI, -0.18 to 0.07) were similar between the SB and SS groups.

Our primary outcomes consisted of malreduction, unplanned reoperation, and complications. After analyzing 5 studies, ^{18,20,29,30,32} we found that the SB group had similar results for malreduction to the SS group, with the heterogeneity being a little higher ($I^2 = 52\%$; P = .08) than the

	SB		SS			Risk Ratio	Risk Ratio					
Study or Subgroup				Total	Weight	M-H, Fixed, 95% Cl						
1.6.1 Local irritation	Lycins	Total	Lycins	Total	weight	W-11, 11Xeu, 35% CI	III-11, 11Xed, 35 % CI					
Coetzee 2009	1	12	0	12	0.9%	3.00 [0.13, 67.06]						
Colcuc 2018	1	26	0	28	0.8%	3.22 [0.14, 75.75]						
Kortekangas 2015	, o	20	3	19	6.4%	0.13 [0.01, 2.36]						
Laflamme 2015	0	33	11	32	20.5%	0.04 [0.00, 0.69]						
Lehtola 2021	0	16	4	17	7.7%	0.12 [0.01, 2.02]						
Ræder_2 2020	4	48	11	47	19.5%	0.36 [0.12, 1.04]						
Sanders 2019	0	50	7	53	12.8%	0.07 [0.00, 1.20]						
Subtotal (95% CI)		206	'	208	68.7%	0.23 [0.11, 0.46]						
Total events	6	200	36	200	001170	0.20 [0.11, 0.40]						
Heterogeneity: $Chi^2 = 8.39$, $df = 6$ (P = 0.21); $l^2 = 28\%$												
Test for overall effect:	•			- 20 %								
restion overall ellect.	2 - 4.10	(1 - 0.0	,001)									
1.6.2 Screw breakage	e											
Colcuc 2018	0	26	1	28	2.5%	0.36 [0.02, 8.42]						
Kortekangas 2015	0	21	3	19	6.4%	0.13 [0.01, 2.36]						
Laflamme 2015	1	13	0	32		7.07 [0.31, 163.21]						
Lehtola 2021	0	16	1	17	2.6%	0.35 [0.02, 8.08]						
Ræder_2 2020	0	48	1	47	2.7%	0.33 [0.01, 7.82]						
Ræder 5 2020	0	48	3	49	6.1%	0.15 [0.01, 2.75]						
Subtotal (95% CI)		172	0	192	20.8%	0.39 [0.14, 1.09]						
Total events	1		9			•						
Heterogeneity: Chi ² =	4.28. df=	5 (P =	0.51); I ² :	= 0%								
Test for overall effect:												
1.6.3 Infection												
Coetzee 2009	1	12	0	12	0.9%	3.00 [0.13, 67.06]						
Colcuc 2018	0	26	2	28	4.2%	0.21 [0.01, 4.28]						
Kortekangas 2015	1	21	0	19	0.9%	2.73 [0.12, 63.19]						
Laflamme 2015	2	33	0	32	0.9%	4.85 [0.24, 97.31]						
Lehtola 2021	1	16	0	17	0.9%	3.18 [0.14, 72.75]						
Ræder_2 2020	1	48	1	47	1.8%	0.98 [0.06, 15.20]						
Sanders 2019	1	50	0	53	0.9%	3.18 [0.13, 76.20]						
Subtotal (95% CI)		206		208	10.4%	1.69 [0.62, 4.59]	-					
Total events	7		3									
Heterogeneity: Chi ² =				= 0%								
Test for overall effect:	Z = 1.02	(P = 0.3	31)									
Total (95% CI)		584		608	100.0%	0.42 [0.26, 0.66]	•					
Total events	14	504	48	000	.00.070	0.42 [0.20, 0.00]	•					
Heterogeneity: Chi ² =		- 19/5		2-15	×.							
Test for overall effect:				1 - 13			0.001 0.1 1 10 1000					
Test for subaroup diff		· · · · · · · · · · · · · · · · · · ·		- 2/P	/200.0-	P - 90 100	Favours SB Favours SS					
restion suburoub unit	erences.		10.21. 01	- 2 (r* -	- 0.000).	- 00.470						

Figure 3. Forest plots of complications between the suture button (SB) and syndesmotic screw (SS) groups. M-H, Mantel-Haenszel. Ræder_2 refers to Ræder et al³⁰; Ræder_5 refers to Ræder et al.²⁹

	SB		SS			Risk Difference	Risk Difference
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% Cl	M-H, Random, 95% Cl
Kortekangas 2015	1	21	3	19	20.8%	-0.11 [-0.30, 0.08]	
Lehtola 2021	1	13	2	16	17.9%	-0.05 [-0.27, 0.17]	
Ræder_2 2020	19	46	13	45	20.1%	0.12 [-0.07, 0.32]	+
Ræder_5 2020	28	39	26	37	19.2%	0.02 [-0.19, 0.22]	+
Sanders 2019	7	46	18	46	22.1%	-0.24 [-0.41, -0.06]	
Total (95% CI)	165		163	100.0%	-0.06 [-0.18, 0.07]	-	
Total events	56		62				
Heterogeneity: Tau ² =	0.01; Ch	%	-0.5 0 0.5				
Test for overall effect:	-0.5 0 0.5 Favours SB Favours SS						

Figure 4. Forest plots of malreduction rate between the suture button (SB) and syndesmotic screw (SS) groups. M-H, Mantel-Haenszel. Ræder_2 refers to Ræder et al³⁰; Ræder_5 refers to Ræder et al.²⁹

acceptable standard ($I^2 \leq 50\%$; P > .1). Two previously published meta-analyses^{34,40} also reported the pooled results of malreduction, with their results showing that the

SB group had a significantly lower rate in malreduction (odds ratio [OR], 0.4; 95% CI, 0.21-0.76 for Xu et al⁴⁰; RR, 0.15; 95% CI, 0.04-0.56 for Shimozono et al³⁴). After the

	SB		SS			Risk Ratio	Risk Ratio			
Study or Subgroup	Events Total I		Events	Total Weight		M-H, Fixed, 95% Cl	M-H, Fixed, 95% Cl			
Coetzee 2009	1	12	1	12	1.7%	1.00 [0.07, 14.21]				
Colcuc 2018	1	26	1	28	1.6%	1.08 [0.07, 16.35]				
Kortekangas 2015	1	21	3	19	5.2%	0.30 [0.03, 2.66]				
Laflamme 2015	2	33	12	32	20.3%	0.16 [0.04, 0.67]				
Lehtola 2021	5	16	2	17	3.2%	2.66 [0.60, 11.80]				
Ræder_2 2020	10	48	17	47	28.6%	0.58 [0.29, 1.13]				
Ræder_5 2020	15	48	16	49	26.4%	0.96 [0.54, 1.71]				
Sanders 2019	2	50	8	53	12.9%	0.27 [0.06, 1.19]				
Total (95% CI)		254		257	100.0%	0.62 [0.43, 0.89]	•			
Total events	37		60							
Heterogeneity: Chi ² = 11.25, df = 7 (P = 0.13); l ² = 38%										
Test for overall effect: Z = 2.59 (P = 0.010) 0.005 0.1 1 10 Feature Favours SB Favours SS										

Figure 5. Forest plots of unplanned reoperation between the suture button (SB) and syndesmotic screw (SS) groups. M-H, Mantel-Haenszel. Ræder_2 refers to Ræder et al³⁰; Ræder_5 refers to Ræder et al.²⁹

study or Subgroup	Mean	SB	Total	Mean	SS SD	Total	Weight	Mean Difference IV, Fixed, 95% Cl	Mean Difference IV, Fixed, 95% Cl
.1.1 AOFAS <3m	mean	00	Totta	mean	00	Totta	Freight		
Colcuc 2018	73	20	26	71	15	28	1.8%	2.00 [-7.49, 11.49]	
aflamme 2015		10.8	33		15.3	32	3.9%	8.00 [1.54, 14.46]	
Ræder_2 2020	67	10	54	66	13	52	8.2%	1.00 [-3.43, 5.43]	
Ræder_5 2020		19.1	46		16.1	45	3.1%	3.80 [-3.45, 11.05]	
Subtotal (95% CI)	02.0	10.1	159	00.1	10.1	157	17.0%	3.21 [0.13, 6.29]	
leterogeneity: Chi ² =	316 df	= 3 (P		$ ^{2} = 59$	6			012 1 [0110, 0120]	
est for overall effect:				,1 - 07					
.1.2 AOFAS 6m									
Coetzee 2009	80	31	12	724	26.8	12	0.3%	7.60 [-15.59, 30.79]	•
Colcuc 2018	87	11	26	90	9	28	5.6%	-3.00 [-8.38, 2.38]	
aflamme 2015		11.3	33		12.3	32	4.9%	3.30 [-2.45, 9.05]	
Ræder_2 2020		12.2	53	87.6	16	54	5.6%	1.50 [-3.89, 6.89]	
Ræder_5 2020		10.7	44		10.7	43	8.0%	7.60 [3.10, 12.10]	
Subtotal (95% CI)	51.0	10.7	168	04.2	10.7	169	24.3%	2.91 [0.33, 5.49]	-
leterogeneity: Chi ² =	9.74 df	= 4 (P		· I ² = 57	96	100	2410/0	2101 [0100, 0140]	
est for overall effect:					~				
.1.3 AOFAS 12m									
Coetzee 2009	02.2	29.4	12	70.2	32.7	12	0.200	100 00 00 00 00	•
Colcuc 2018	83.2 91	29.4	26	/9.2	32.7	28	7.8%	4.00 [-20.88, 28.88]	
aflamme 2015	93.1	9.3	33		12.7	32	5.5%	0.00 [-4.56, 4.56]	
		9.3	53		11.4	52	7.0%	3.20 [-2.22, 8.62]	
Ræder_2 2020						52 39	7.0%	0.50 [-4.32, 5.32]	
Ræder_5 2020	94.9	8.4	46 170	87.7	12.3	163	28.2%	7.20 [2.64, 11.76]	
Subtotal (95% CI)	C 00 46			. 17 . 00	01	105	28.2%	2.76 [0.37, 5.15]	
leterogeneity: Chi ² = est for overall effect:				1, 1-= 33	70				
.1.4 AOFAS 24m									
	01.0	40.4		00.0	475		0.00	2 00 1 4 2 27 4 0 5 71	
Coetzee 2009		16.1	8		17.5	9		2.60 [-13.37, 18.57]	
Ræder_2 2020	94.5	9.9	48	95.6	7.6	47	12.8%	-1.10 [-4.64, 2.44]	
Ræder_5 2020	95.3	7.7	45 101	87.4	12.3	41 97	8.4%	7.90 [3.51, 12.29]	
Subtotal (95% CI)	0.70	- 2 (5		01.17 - 0	0.04	97	21.9%	2.46 [-0.26, 5.18]	
Heterogeneity: Chi ² = Test for overall effect:				8); 1~ = 8	0%				
		1							
.1.5 AOFAS 60m							0.74	5 10 11 00 C T	
Ræder_5 2020	97.2	6.2	39	91.8	11.6	35	8.7%	5.40 [1.09, 9.71]	
Subtotal (95% CI)			39			35	8.7%	5.40 [1.09, 9.71]	
leterogeneity: Not ap est for overall effect:			0.01)						
							100.00		
otal (95% CI)			637			621	100.0%	3.04 [1.77, 4.31]	· · · · · · · · · · · · · · · · · · ·
leterogeneity: Chi ² =					42%				-10 -5 0 5 10
est for overall effect:	7 - 4 60	I/P < I	1 00001	1					Favours SS Favours SB

Figure 6. Forest plots of American Orthopaedic Foot & Ankle Society (AOFAS) scores between the suture button (SB) and syndesmotic screw (SS) groups. IV, inverse variance; m, months. Ræder_2 refers to Ræder et al³⁰; Ræder_5 refers to Ræder et al.²⁹

		SB			SS			Mean Difference	Mean Difference		
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI		
1.2.1 OMAS ≤3m											
Colcuc 2018	51	24	26	37	14	28	4.4%	14.00 [3.42, 24.58]			
Laflamme 2015	68.8	16.6	33	60.2	20.6	32	5.1%	8.60 [-0.51, 17.71]			
Ræder_5 2020		25.3	44		15.3	45	5.3%	-0.30 [-9.01, 8.41]			
Sanders 2019		18.2	50		21.3	53	5.9%	1.20 [-6.44, 8.84]			
Subtotal (95% CI)			153			158	20.7%	5.27 [-0.90, 11.45]	•		
Heterogeneity: Tau ² =	18.88:	Chi ² =	5.74 dt	f= 3 (P =	= 0.12	$ ^{2} = 48$	3%	•			
Test for overall effect:				- (748973				
1220116.0											
1.2.2 OMAS 6m											
Colcuc 2018	90	14	26	89	13	28	6.2%	1.00 [-6.22, 8.22]	T		
Laflamme 2015		16.3	33		17.4	32	5.6%	7.30 [-0.90, 15.50]			
Ræder_5 2020		14.6	44	66.5	23	43	5.7%	18.90 [10.78, 27.02]			
Sanders 2019	69.6	22.2	50	70.6	19.9	53	5.6%	-1.00 [-9.16, 7.16]			
Subtotal (95% CI)			153			156	23.1%	6.49 [-2.20, 15.17]	-		
Heterogeneity: Tau ² =	62.17;	Chi² =	14.46,	df = 3 (F	9 = 0.0	02); I² =	79%				
Test for overall effect:	Z=1.48	6 (P = 0	0.14)								
1.2.3 OMAS 12m											
Colcuc 2018	93	12	26	90	12	28	6.7%	3.00 [-3.41, 9.41]			
Laflamme 2015	93.3	10.2	33	87.7	12.2	32	7.3%	5.60 [0.12, 11.08]			
Ræder 2 2020	88	21	53		18.3	52	6.0%	-1.00 [-8.53, 6.53]	-		
Ræder 5 2020	94.6	8.4	46		19.2	39	6.7%	7.80 [1.30, 14.30]			
Sanders 2019	84.9	17	50		21.7	53	6.0%	4.90 [-2.61, 12.41]			
Subtotal (95% CI)	••		208		2	204	32.8%	4.40 [1.48, 7.33]	•		
Heterogeneity: Tau ² =	0.00 [.] C	hi ² = 3		= 4 (P =	n 49\·						
Test for overall effect:			•	10	0.40/,	0 /0					
1.2.4 OMAS 24m											
	00.0	40.4	17		40	15	0.00/	5 00 / 40 45 0 05			
Ræder_2 2020		19.1	47	94	13	45	6.6%	-5.80 [-12.45, 0.85]			
Ræder_5 2020	98.2	3.8	46	88.2	19.2	41	7.0%	10.00 [4.02, 15.98]			
Subtotal (95% CI)			93			86	13.6%	2.17 [-13.31, 17.65]			
Heterogeneity: Tau ² =				, df = 1 ((P = 0.)	0005);1	*= 92%				
Test for overall effect:	Z = 0.27	r (P = 1	J.78)								
1.2.5 OMAS >36m											
Lehtola 2021	78	20.2	16	88	20.2	17	3.2%	-10.00 [-23.79, 3.79]			
Ræder_5 2020	98.2	3.8	39	90	19.3	35	6.7%	8.20 [1.70, 14.70]			
Subtotal (95% CI)			55			52	9.8%	0.16 [-17.56, 17.87]			
Heterogeneity: Tau ² =	135.36	Chi ² =	5.47,	df = 1 (F	= 0.0	2); 2 = 8	32%				
Test for overall effect:	Z = 0.02	2 (P = 0	0.99)								
Total (95% CI)			662			656	100.0%	4.51 [1.54, 7.48]	♦		
	23.52	Chi ² =		df = 16 (P = 0						
- ,	Heterogeneity: Tau ² = 23.52; Chi ² = 42.29, df = 16 (P = 0.0004); l ² = 62% Test for overall effect; $Z = 2.97$ (P = 0.003)										
Test for subaroup diff		•		df = 4 (8	- = n q	(7) I ² =	0%		Favours SS Favours SB		
. Sotion suburous unit			0.00.		- 0.0		- /0				

Figure 7. Forest plots of Olerud-Molander ankle score (OMAS) between the suture button (SB) and syndesmotic screw (SS) groups. IV, inverse variance. Ræder_2 refers to Ræder et al³⁰; Ræder_5 refers to Ræder et al.²⁹

comparison, the most evident difference we found was that these author groups included 2 articles that we did not, because we thought those studies failed to meet our eligibility criteria for malreduction. Laflamme et al¹⁹ reported on loss of reduction as evaluated by lateral tibiofibular clear space with a normal value of <6 mm. Colcuc et al⁶ reported that no postoperative malreduction occurred.

Unplanned reoperation is important in the aspects of patient satisfaction and cost-effectiveness. Our result also favors the SB group. Most patients underwent surgery due to local irritation of the screw; we thus included more RCTs than other published articles^{9,27} to obtain more precise results. Moreover, Ramsey and Friess³¹ investigated the cost-effectiveness of SS versus SB fixation. In terms of the health care system, they used a decision-tree model to examine the outcomes of syndesmosis repair surgery and

found that the screw removal rate (SRR) and the number of devices applied had an impact on cost-effectiveness, with the SB being more cost-effective when the SRR was \geq 17.5%, whereas the SS was more cost-effective when the SRR was \leq 13.7%.

As for complications, we observed that the SS group demonstrated significantly more complications than the SB group. We analyzed 3 types of complication (local irritation, implant failure, and infection), of which only local irritation showed a significant difference between the groups, which is why the total effect favored the SB group. Local irritation might be an innate disadvantage for the screws, according to the literature^{10,27}; it is often caused by the prominence of the screw head due to a lack of soft tissues around the surgery site. The SB was well-designed and there were some surgical modifications to help reduce local irritation

		SB			SS			Mean Difference	Mean Difference		
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% Cl	IV, Fixed, 95% Cl		
1.3.1 EQ-5D ≤3m											
Ræder_2 2020	0.7	0.15	53	0.56	0.3	53	4.9%	0.14 [0.05, 0.23]			
Ræder_5 2020	0.63	0.31	44	0.61	0.15	45	3.9%	0.02 [-0.08, 0.12]			
Sanders 2019	0.63	0.19	50	0.64	0.22	53	6.3%	-0.01 [-0.09, 0.07]			
Subtotal (95% CI)			147			151	15.1%	0.05 [-0.01, 0.10]	-		
Heterogeneity: Chi ² = 6.33, df = 2 (P = 0.04); I ² = 68%											
Test for overall effect:	Z=1.78	6 (P = (0.08)								
1.3.2 EQ-5D 6m											
Ræder_2 2020	0.84	0.23	54	0.84	0.23	54	5.3%	0.00 [-0.09, 0.09]			
Ræder_5 2020		0.15	44		0.23	41	5.8%	0.09 [0.01, 0.17]			
Sanders 2019	0.87	0.1	50		0.14	53	18.2%	0.03 [-0.02, 0.08]	+		
Subtotal (95% CI)	0.01	0.1	148	0.04	0.14	148	29.2%		•		
Heterogeneity: Chi ² =	2.34 df	= 2 (P		12 = 16	96	110	LOIL	0.01[-0.00, 0.01]	•		
Test for overall effect:		•		/. · - · ·	10						
restion overall ellect.	2-1.30	, (i – (.03)								
1.3.3 EQ-5D 12m											
Ræder_2 2020	0.93	0.15	53		0.15	52	12.1%	0.00 [-0.06, 0.06]			
Ræder_5 2020	0.93	0.15	40	0.88	0.15	36	8.7%	0.05 [-0.02, 0.12]	+		
Sanders 2019	0.88	0.12	50	0.91	0.21	53	9.3%				
Subtotal (95% CI)			143			141	30.1%	0.01 [-0.03, 0.04]	•		
Heterogeneity: Chi ² =	2.83, df	= 2 (P	= 0.24); I ^z = 29	9%						
Test for overall effect:	Z = 0.28) (P = ().78)								
1.3.4 EQ-5D 24m											
Ræder 2 2020	0.03	0.15	48	0.06	0.08	47	171%	-0.03 [-0.08, 0.02]			
Ræder_5 2020	0.33	0.15	46		0.15	41	17.170	Not estimable			
Subtotal (95% CI)		0	94	0.03	0.15	88	17.1%	-0.03 [-0.08, 0.02]	•		
Heterogeneity: Not ap	nlicable					00		-0.00 [-0.00, 0.02]	-		
Test for overall effect:	•		1 2 2 1								
1.3.5 EQ-5D 60m											
Ræder_5 2020	0.93	0.15	39	0.93	0.15	35	8.5%	0.00 [-0.07, 0.07]	<u> </u>		
Subtotal (95% CI)			39			35	8.5%	0.00 [-0.07, 0.07]	-		
Heterogeneity: Not ap	plicable										
Test for overall effect:	Z = 0.00) (P = 1	.00)								
Total (95% CI)			571			563	100.0%	0.01 [-0.01, 0.03]			
Heterogeneity: Chi ² =	10.01	f = 10		061-18-	4 4 94	303	100.0%	0.01[-0.01, 0.05]			
Test for overall effect:			•	05), 1 =	4470				-0.2 -0.1 0 0.1 0.2		
Test for subgroup dif		•		df = A / B	D - 0 1	6) 12-	20 6 %		Favours SS Favours SB		
restion suburoub dif	erences	. Units	- 0.91.	ui = 4 (i	- 0.1	0), F ≅	30.3%				

Figure 8. Forest plots of EuroQoI-5 Domain (EQ-5D) between the suture button (SB) and syndesmotic screw (SS) groups. IV, inverse variance. Ræder_2 refers to Ræder et al.³⁰; Ræder_5 refers to Ræder et al.²⁹

caused by the SB.^{11,26} Therefore, as mentioned above, many patients underwent unplanned reoperations, which caused significant complications.

The AOFAS, OMAS, and EQ-5D results were extracted as secondary outcomes. Some studies also reported range of motion^{5,18,19,29,30} and Manchester Oxford Foot Questionnaire³⁰ and Foot and Ankle Disability Index results,^{6,32} but these data were not pooled because of limited related studies and different measuring methods. These functional scales are commonly adopted to assess ankle function.

In our research, the SB group had a significantly higher AOFAS score than the SS group at the 3- to 12-month follow-up periods after surgery, which may be attributed to the reported advantages, such as allowing physiological movement, earlier rehabilitation, earlier weightbearing, and earlier return to sports.^{18,19} The AOFAS score, however, was similar at the 24-month follow-up. According to other published meta-analyses, 24 months was the longest follow-up period pooled. Nevertheless, we pooled the data AOFAS scores for 60 months, and they showed significant improvement in the SB group. The results varied in different studies. Xu et al⁴⁰ found a significant difference only at 3 months and 24 months. The other 2 studies^{27,34} only analyzed the results at 12 months and were accompanied by high heterogeneity ($I^2 = 86\%$ and 82%, respectively). At the 12-month follow-up, the SB group showed significant improvement in OMAS; most articles showed similar results in this regard. Interestingly, 1 study²⁷ misused the original data and indicated nonsignificant differences,



Figure 9. Funnel plot of data on unplanned reoperation between the suture button and syndesmotic screw groups. RR, risk ratio.

although the result was actually significantly different after recalculation. The EQ-5D can be used for assessing pain, activities, anxiety, and depression, which showed similar results between the 2 groups. Moreover, the overall higher functional scores are also supported by an experimental biomechanical study,¹ which indicated that the SB technique could produce better physiologic micromotion of the tibiofibular joint.

Limitations

Our study has several limitations. First, performance and detection bias remained unclear or at high risk among the included RCTs, which may have affected the results of the functional scores. Second, the number of SSs and the number of cortices penetrated were not consistent, and we did not study these variables in our study. Third, 2 outcomes (OMAS and malreduction) showed a slightly higher heterogeneity, which might be due to different surgical methods, fracture types, and varying radiological evaluation methods. It is worth mentioning, however, that there are various fracture patterns, and their treatments also vary, which may affect postoperative outcomes. To provide more precise data, future RCTs could break down their results by fracture type.

CONCLUSION

Our results showed there were no significant differences between the SB group and the SS group in malreduction and EQ-5D scores. However, compared with SS fixation, SB fixation demonstrated a statistically lower local irritation rate and unplanned reoperation rate, and the functional AOFAS score and OMAS were improved.

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