Article

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Comparison of Outcomes Between Suture Button Technique and Screw Fixation Technique in Patients With Acute Syndesmotic Diastasis: A Meta-analysis of Randomized Controlled Trials

Nikolai Ramadanov, MD[1,2], Simon Bueschges[3], and Dobromir Dimitrov, Prof. MD[4]

Abstract

Background: Our aim was to compare the outcome between suture button (SB) stabilization and syndesmotic screw fixation (SF) in patients with acute syndesmotic diastasis.

Methods: A systematic literature search up to June 30, 2021, was performed to identify randomized controlled trials (RCTs) comparing outcomes of SB with SF techniques in patients with acute syndesmotic diastasis. We calculated mean differences for continuous outcomes, using the Hartung-Knapp-Sidik-Jonkman method, and odds ratio for dichotomous outcomes, using the Mantel-Haenszel method.

Results: Eight RCTs involving 569 patients met the inclusion criteria, 1 RCT with level I evidence, and 7 RCTs with level II evidence. The meta-analysis showed that the SB technique had a higher AOFAS score <6 months and 12 months postoperatively (MD = 4.74, 95% CI 1.68-7.80, $P = .01$; and MD = 5.42, 95% CI 1.50-9.33, $P = .02$) and reduced the risk of implant irritation (OR = 0.31, 95% CI 0.11-0.89, $P = .03$), implant failure (OR = 0.06, 95% CI 0.02-0.23, $P < .01$), and reoperation (OR = 0.43, 95% CI 0.22-0.83, $P = .01$). The 2 approaches did not differ in further functional outcomes or postoperative complications.

Conclusion: Because functional outcomes showed no relevant difference between both SB and SF, the advantage of SB appears to be in the lower risk for postoperative complications. The SB technique led to fewer cases of implant irritation, implant failure, and reoperation compared with SF.

Level of Evidence: Level I, meta-analysis of RCTs.

Keywords: screw, suture button, ankle, diastasis, syndesmosis

Introduction

Ankle injuries are the most common lower extremity injuries.[9] They represent a sequence of bone and/or ligament lesions[23] that lead to acute syndesmotic diastasis (acute syndesmotic instability) in about a quarter of cases.[23,33] Adequate surgical treatment of the acute syndesmotic diastasis is of great importance, because otherwise there is a high risk of very limited function of the ankle joint.[8,33,43] Being the conventional surgical treatment, syndesmotic screw fixation (SF) is known to be associated with complications such as implant irritation, loosening or breakage, and limited range of motion (ROM).[13,41] For these reasons, there have been

[1]Department of Emergency Medicine, University Hospital Jena, Friedrich Schiller University, Jena, Thüringen, Germany
[2]Center of Orthopaedics and Traumatology, University Hospital Brandenburg an der Havel, Brandenburg Medical School Theodor Fontane, Germany
[3]Department of Statistics, Faculty of Medicine, University of Salamanca, Salamanca, Spain
[4]Department of Surgical Propaedeutics, Faculty of Medicine, Medical University of Pleven, Pleven, Bulgaria

Corresponding Author:
Nikolai Ramadanov, MD, Department of Emergency Medicine, University Hospital Jena, Friedrich Schiller University, Am Klinikum 1, Jena, Thüringen 07747, Germany.
Email: nikolai.ramadanov@gmail.com

attempts of alternative methods of surgical treatment such as a dynamic stabilization. The usage of suture buttons (SBs) seems to be a very promising surgical technique for dynamic stabilization of the acute syndesmotic diastasis.[30,39] Although some meta-analyses on this topic are available, some do not provide reliable results and others followed poor statistical methods.[4,10-12,14,26,29,36,45-47] The specialist literature still has room for high-quality studies on this subject. We formulated the following PICO (population, intervention, control, and outcomes) question: In human participants in acute syndesmotic diastasis injury, is the SB technique superior compared with the SS technique in functional outcome and complications? Furthermore, we examined the consistency of our results with similar meta-analyses.

Methods

Literature Search and Study Selection

We followed the PRISMA-P guidelines. The review protocol was registered with PROSPERO on July 25, 2021, and finally approved on August 27, 2021 (CRD42021269965) at http://www.crd.york.ac.uk/PROSPERO/. We searched PubMed without restrictions to publication date or language up to June 30, 2021, for relevant randomized controlled trials (RCTs), building a BOOLEAN search strategy: [(syndesmotic screw OR screw fixation) AND (ankle fracture OR syndesmosis)]. Furthermore, we searched Google Scholar for relevant RCTs and checked citations of screened studies and reviews. First, we scanned titles and abstracts to select RCTs for further consideration. Then, we scanned the full texts of the selected articles for inclusion. The decision on inclusion of each RCT was determined by the consensus between the 2 independent reviewers (NR and DD).

Inclusion/Exclusion Criteria and Types of Outcome

We included all RCTs that directly compared SB with SF in acute syndesmotic diastasis injuries in human participants. We excluded all RCTs that did not provide outcome of interest and that reported any dynamic stabilization methods other than SB. We measured functional outcome and postoperative complications. Most of the RCTs provided information on the functional outcome, using AOFAS, OMA, or ROM. The American Orthopaedic Foot & Ankle Society (AOFAS) ankle-hindfoot scale from 0 to 100 points is divided into 3 parts describing pain, function, and alignment, with 100 being the best result.[19] The Olerud-Molander Ankle (OMA) scale from 0 to 100 points is a self-reported functional scoring system, with 100 being the best score.[28] We accepted the evaluation of AOFAS and OMA at <6, 6, 12, or ≥24 months postoperatively. We used the time points with the largest number of observations of reported AOFAS and OMA, in case that it was observed more than once <6 or ≥24 months postoperatively. The normal ROM of the ankle joint is approximately 15 degrees for dorsiflexion (extension) and 30 degrees for plantarflexion.[37] It strongly reflects the function of the joint. Complication is defined as a secondary adverse event, or development leads to a more difficult course of therapy. Postoperative complications such as implant irritation, implant failure (including screw breakage), joint malreduction, reoperation (including planned removal), and other complications were investigated.

Data Extraction and Risk of Bias and Level of Evidence Assessment

Two reviewers (NR and DD) extracted the following data: first author, year of publication, number of patients, patient characteristics, follow-up period, implant used, and fracture type. In several cases, standard deviation (SD) had to be calculated by the statistician, because some RCTs reported only the range of numbers. The SD calculation was conducted according to the following formula: (higher range value – lower range value)/4.[16,17] In case that the RCTs provided different information on intention to treat (ITT) and per protocol (PP) analysis, we used the numbers from the ITT analysis. We assessed the RCTs for their risk of bias and level of evidence, according to Cochrane's Risk of Bias 2 (RoB 2) tool and the guidelines of the Centre for Evidence-Based Medicine.[3,38]

Meta-analysis: Measures of Treatment Effect

In our statistics, the SB group was named "experimental group" and the SF group was named "control group." We tested both fixed (FE) and random effects (RE) models. RE models provided more reliable results, so we proceeded as follows: We calculated mean differences (MDs) with 95% CIs for continuous outcomes, using the Hartung-Knapp-Sidik-Jonkman method and an RE model. We calculated the odds ratio (OR) and their 95% CIs for dichotomous outcomes, using the Mantel-Haenszel method and an RE model. Study weighting was performed by inverse variance. We calculated prediction intervals to estimate where to expect the next data point sampled. We calculated the t test to determine statistically significant differences between the means of the 2 groups. We used a significance level of $P = .05$. Heterogeneity was assessed using Cochrane's Q test (P value $<.10$ is indicative of heterogeneity) and Higgins test I^2 (low heterogeneity: <25%, moderate heterogeneity: 25%-75%, and high heterogeneity: >75%).[18] All statistic calculations were conducted by a professional statistician, using the R packages meta and metafor.[35,42] We presented our results in Forest, Baujat, and Funnel plots.

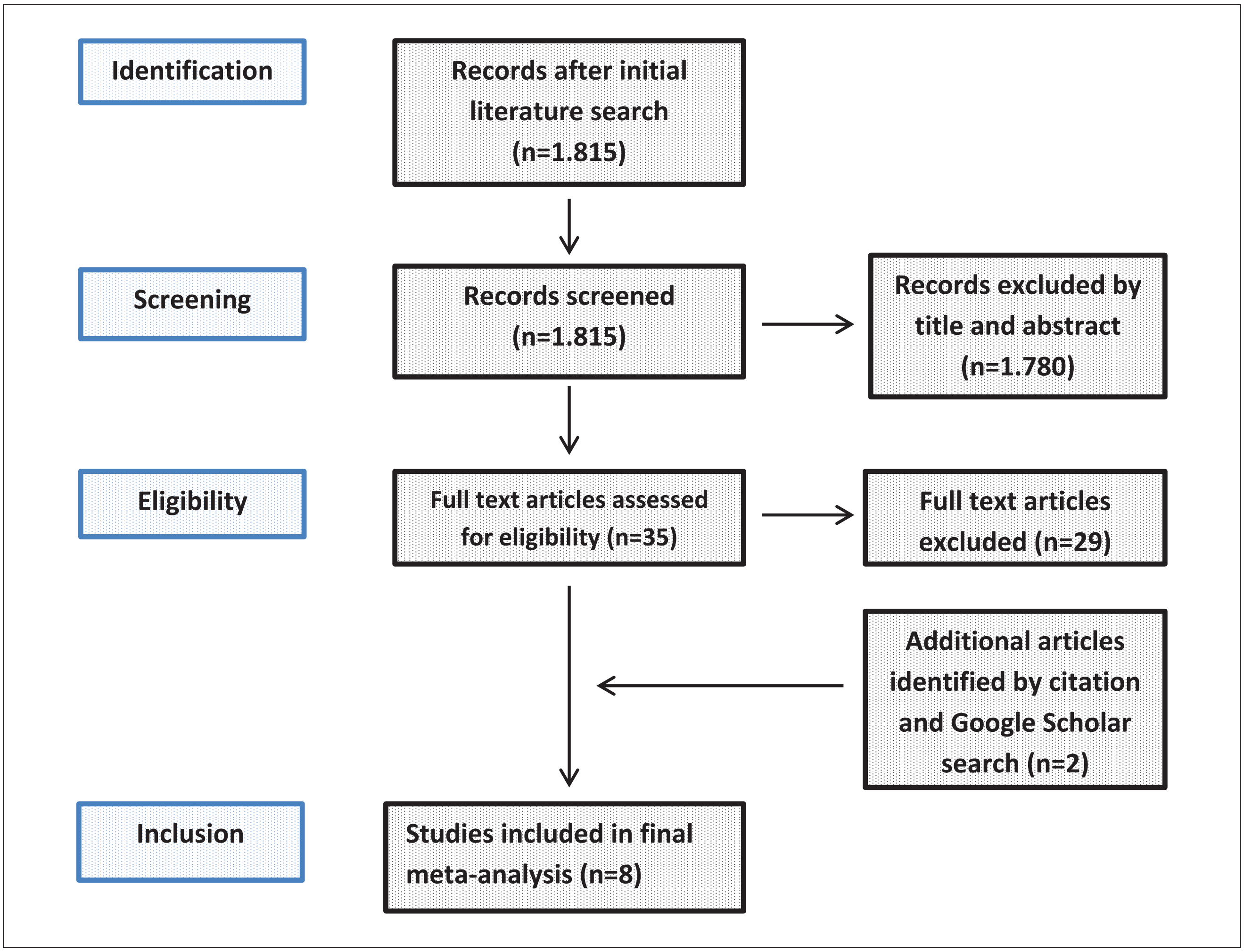


Figure 1. PRISMA flow diagram.

Results

Study Identification and Selection

Overall, 1815 studies were found in initial literature search and screened by titles and abstracts according to our predefined inclusion criteria, as noted in the PRISMA flow diagram (Figure 1). After full-text analysis, 7 RCTs left for further consideration.[1,6,21,22,31,32,34] Two of them used the same initial data.[1,32] We included the study that gave us more information and had the lower risk of bias.[32] Furthermore, we identified 1 more RCT by citation search[5] and by search of Google Scholar,[14] leaving a total of 8 RCTs for inclusion in final meta-analysis.[5,6,14,21,22,31,32,34]

Characteristics of the RCTs

Table 1 shows the main characteristics of the 8 included RCTs. These studies were published between 2009 and 2020, altogether involving 569 patients. Two hundred seventy-eight of the included patients (average age 40.6 years) were operated with SB, and 291 of the included patients (average age 40 years) were operated with SF. The sample size of these trials ranged from 24 to 113 patients, and the follow-up period ranged from 12 to 60 months. Four of 8 RCTs did not report SD.[5,14,31,32] All studies were published in English language. The follow-up period ranged from 12 to 60 months. The RCTs included all kind of ankle injuries (fractures and ligament ruptures) leading to acute syndesmotic diastasis, requiring operative treatment. Table 2 shows the summarized risk of bias assessment. One study of 8 was an anonymized RCT with a level I evidence[6]; the other 7 studies were non anonymized RCTs with level II evidence.[5,14,21,22,31,32,34]

Functional Outcomes

AOFAS

AOFAS score <6 months postoperatively. Data on 399 patients (including 195 patients with SB and 204 patients with SF) were pooled from 5 RCTs. Compared with the

Table 1. Main Characteristics of the 8 Included RCTs.

Study	Sample Size, n	Surgical Approach, n		Age, y, Mean (SD)		Gender, male/Female, n		Follow-up Period, mo		Implant Used		Planned Implant Removal
	Pts	SB	SF	SB	SF	SB	SF	SB	SF	SB	SF	
Coetzee and Ebeling (2009)[5]	24	12	12	35 (9)	38 (9)	9/3	8/4	27	27	2 tightrope, except of 1 with 1 tightrope	4.0-mm, 4.5-mm, and 6.5-mm screws	No
Colcuc et al (2018)[6]	54	26	28	35 (11)	39 (11)	19/7	22/6	12	12	1 knotless tightrope	One 3.5-mm screw, 4 cortices	Planned screw removal
Giza et al (2019)[14]	65	32	33	38 (15)	31 (9)	8/24	9/24	12	12	1 or 2 tightropes, knotless or not	1 or 2 screws	No
Kortekangas et al (2015)[21]	43	21	22	46 (15)	44 (16)	13/8	14/8	36	39	1 tightrope	One 3.5-mm screw, 3 cortices	No
Laflamme et al (2015)[22]	70	34	36	40 (15)	39 (12)	25/9	26/10	12	12	1 tightrope	One 3.5-mm screw, 3 cortices	No
Raeder et al (2020)[31]	113	55	58	44 (15)	48 (14)	35/20	30/38	24	24	1 knotless tightrope	One 3.5-mm screw, 3 cortices	No
Raeder et al (2020)[32]	97	48	49	46 (15)	43 (16)	34/14	30/19	60	60	1 tightrope	One 4.5-mm screw, 4 cortices	Planned screw removal
Sanders et al (2019)[34]	103	50	53	41 (12)	38 (14)	39/11	38/15	12	12	1 knotless tightrope	Two 3.5-mm screws, 3 cortices	8 of 53 SF patients had planned screw removal

Abbreviations: Pts, patients; SB, suture button; SF, screw fixation; RCT, randomized controlled trials.

Table 2. Risk of bias summary.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias	Overall risk of bias
Andersen et al. 2018[1]	Y	Y	N	Y	Y	Y	High
Coetzee and Ebeling 2009[5]	U	U	Y	N	N	U	High
Colcuc et al. 2018[6]	Y	Y	Y	Y	Y	Y	Low
Giza et al. 2019[14]	Y	Y	N	Y	Y	U	High
Kortekangas et al. 2015[21]	Y	Y	Y	Y	Y	U	Moderate
Laflamme et al. 2015[22]	Y	Y	N	U	Y	Y	High
Raeder et al. 2020[31]	Y	Y	Y	Y	U	Y	Moderate
Raeder et al. 2020[32]	Y	Y	Y	Y	U	Y	Moderate
Sanders et al. 2019[34]	Y	Y	Y	Y	N	Y	High

Abbreviations: Y, yes; N, no; U, unclear.

SF group, the AOFAS <6 months postoperatively was 4.7 points higher in the SB group (MD = 4.74, 95% CI 1.68-7.80, I^2 = 27%, P = .01; Figure 2).

AOFAS score 6 months postoperatively. Data on 423 patients (including 207 patients with SB and 216 patients with SF) were pooled from 6 RCTs. There was no difference in AOFAS scores 6 months postoperatively between the SB and SF groups (MD = 0.63, 95% CI −3.11 to 4.36, I^2 = 75%, P = .68; Figure 2).

AOFAS score 12 months postoperatively. Data on 423 patients (including 207 patients with SB and 216 patients with SF) were pooled from 6 RCTs. Compared with the SF group, the AOFAS scores 12 months postoperatively was 5.4 points higher in the SB group (MD = 5.42, 95% CI 1.50-9.33, I^2 = 88%, P = .02; Figure 2).

AOFAS score ≥24 months postoperatively. Data on 234 patients (including 115 patients with SB and 119 patients with SF) were pooled from 3 RCTs. There was no difference in AOFAS ≥24 months postoperatively between the SB and SF groups (MD = 5.60, 95% CI −7.41 to 18.60, I^2 = 98%, P = .21; Figure 2).

OMA

OMA score <6 months postoperatively. Data on 324 patients (including 158 patients with SB and 166 patients with SF) were pooled from 4 RCTs. There was no difference in OMA score <6 months postoperatively between the SB and SF groups (MD = 4.81, 95% CI −5.45 to 15.08, I^2 = 68%, P = .23; Figure 2).

OMA score 6 months postoperatively. Data on 324 patients (including 158 patients with SB and 166 patients with SF) were pooled from 4 RCTs. There was no difference in OMA score 6 months postoperatively between the SB and SF groups (MD = 6.17, 95% CI −5.70 to 18.05, I^2 = 88%, P = .20; Figure 2).

OMA score 12 months postoperatively. Data on 480 patients (including 234 patients with SB and 246 patients with SF) were pooled from 6 RCTs. There was no difference in OMA score 12 months postoperatively between the SB and SF groups (MD = 4.00, 95% CI −0.96 to 8.96, I^2 = 90%, P = .09; Figure 2).

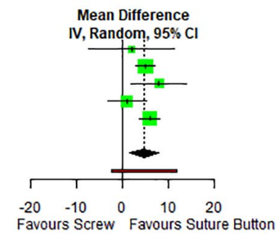
OMA score ≥24 months postoperatively. Data on 253 patients (including 124 patients with SB and 129 patients

Functional outcome

AOFAS < 6 months postoperatively

	Suture Button			Screw				Mean Difference
Study	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Colcuc et al. 2018	73.00	20.00	26	71.00	15.00	28	5.9%	2.00 [-7.49; 11.49]
Giza et al. 2019	63.00	2.00	32	58.00	6.00	33	31.8%	5.00 [2.84; 7.16]
Laflamme et al. 2015	79.00	11.00	34	71.00	15.00	36	11.8%	8.00 [1.86; 14.14]
Raeder et al. 2020	67.00	10.00	55	66.00	13.00	58	18.8%	1.00 [-3.26; 5.26]
Raeder et al. 2020[2]	64.00	6.00	48	58.00	5.00	49	31.6%	6.00 [3.80; 8.20]
Total (95% CI)			**195**			**204**	**100.0%**	**4.74 [1.68; 7.80]**
Prediction interval								**[-2.44; 11.92]**

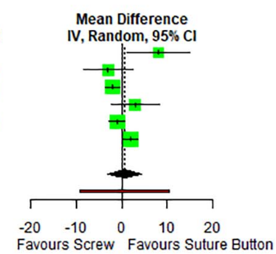
Heterogeneity: Tau^2 = 3.8735; Chi^2 = 5.47, df = 4 (P = 0.24); I^2 = 27%
Test for overall effect: t_4 = 4.30 (P = 0.01)



AOFAS 6 months postoperatively

	Suture Button			Screw				Mean Difference
Study	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Coetzee and Ebeling 2009	76.00	9.00	12	68.00	8.00	12	10.4%	8.00 [1.19; 14.81]
Colcuc et al. 2018	87.00	11.00	26	90.00	9.00	28	13.1%	-3.00 [-8.38; 2.38]
Giza et al. 2019	90.00	3.00	32	92.00	4.00	33	21.0%	-2.00 [-3.72; -0.28]
Laflamme et al. 2015	87.00	11.00	34	84.00	12.00	36	13.1%	3.00 [-2.39; 8.39]
Raeder et al. 2020	87.00	4.00	55	88.00	5.00	58	21.1%	-1.00 [-2.67; 0.67]
Raeder et al. 2020[2]	89.00	4.00	48	87.00	4.00	49	21.2%	2.00 [0.41; 3.59]
Total (95% CI)			**207**			**216**	**100.0%**	**0.63 [-3.11; 4.36]**
Prediction interval								**[-9.19; 10.44]**

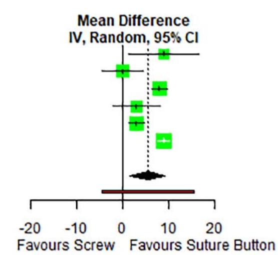
Heterogeneity: Tau^2 = 10.3905; Chi^2 = 20.33, df = 5 (P < 0.01); I^2 = 75%
Test for overall effect: t_5 = 0.43 (P = 0.68)



AOFAS 12 months postoperatively

	Suture Button			Screw				Mean Difference
Study	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Coetzee and Ebeling 2009	85.00	9.00	12	76.00	10.00	12	9.2%	9.00 [1.39; 16.61]
Colcuc et al. 2018	91.00	9.00	26	91.00	8.00	28	14.8%	0.00 [-4.56; 4.56]
Giza et al. 2019	98.00	3.00	32	90.00	4.00	33	20.7%	8.00 [6.28; 9.72]
Laflamme et al. 2015	93.00	9.00	34	90.00	13.00	36	13.4%	3.00 [-2.21; 8.21]
Raeder et al. 2020	93.00	5.00	55	90.00	4.00	58	20.8%	3.00 [1.32; 4.68]
Raeder et al. 2020[2]	96.00	3.00	48	87.00	4.00	49	21.2%	9.00 [7.59; 10.41]
Total (95% CI)			**207**			**216**	**100.0%**	**5.42 [1.50; 9.33]**
Prediction interval								**[-4.63; 15.47]**

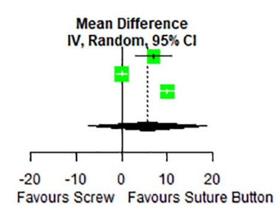
Heterogeneity: Tau^2 = 10.7811; Chi^2 = 41.79, df = 5 (P < 0.01); I^2 = 88%
Test for overall effect: t_5 = 3.55 (P = 0.02)



AOFAS ≥ 24 months postoperatively

	Suture Button			Screw				Mean Difference
Study	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Coetzee and Ebeling 2009	94.00	5.00	12	87.00	5.00	12	30.4%	7.00 [3.00; 11.00]
Raeder et al. 2020	97.00	3.00	55	97.00	3.00	58	34.9%	0.00 [-1.11; 1.11]
Raeder et al. 2020[2]	96.00	3.00	48	86.00	4.00	49	34.7%	10.00 [8.59; 11.41]
Total (95% CI)			**115**			**119**	**100.0%**	**5.60 [-7.41; 18.60]**
Prediction interval								**[-69.28; 80.47]**

Heterogeneity: Tau^2 = 25.5954; Chi^2 = 122.38, df = 2 (P < 0.01); I^2 = 98%
Test for overall effect: t_2 = 1.85 (P = 0.21)



OMA < 6 months postoperatively

	Suture Button			Screw				Mean Difference
Study	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Colcuc et al. 2018	51.00	24.00	26	37.00	14.00	28	18.6%	14.00 [3.42; 24.58]
Laflamme et al. 2015	69.00	17.00	34	60.00	21.00	36	21.7%	9.00 [0.07; 17.93]
Raeder et al. 2020[2]	30.00	8.00	48	30.00	5.00	49	34.9%	0.00 [-2.66; 2.66]
Sanders et al. 2019	54.00	18.00	50	53.00	21.00	53	24.7%	1.00 [-6.54; 8.54]
Total (95% CI)			**158**			**166**	**100.0%**	**4.81 [-5.45; 15.08]**
Prediction interval								**[-22.31; 31.93]**

Heterogeneity: Tau^2 = 29.3212; Chi^2 = 9.30, df = 3 (P = 0.03); I^2 = 68%
Test for overall effect: t_3 = 1.49 (P = 0.23)

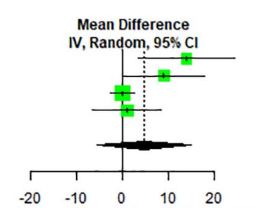


Figure 2. *(continued)*

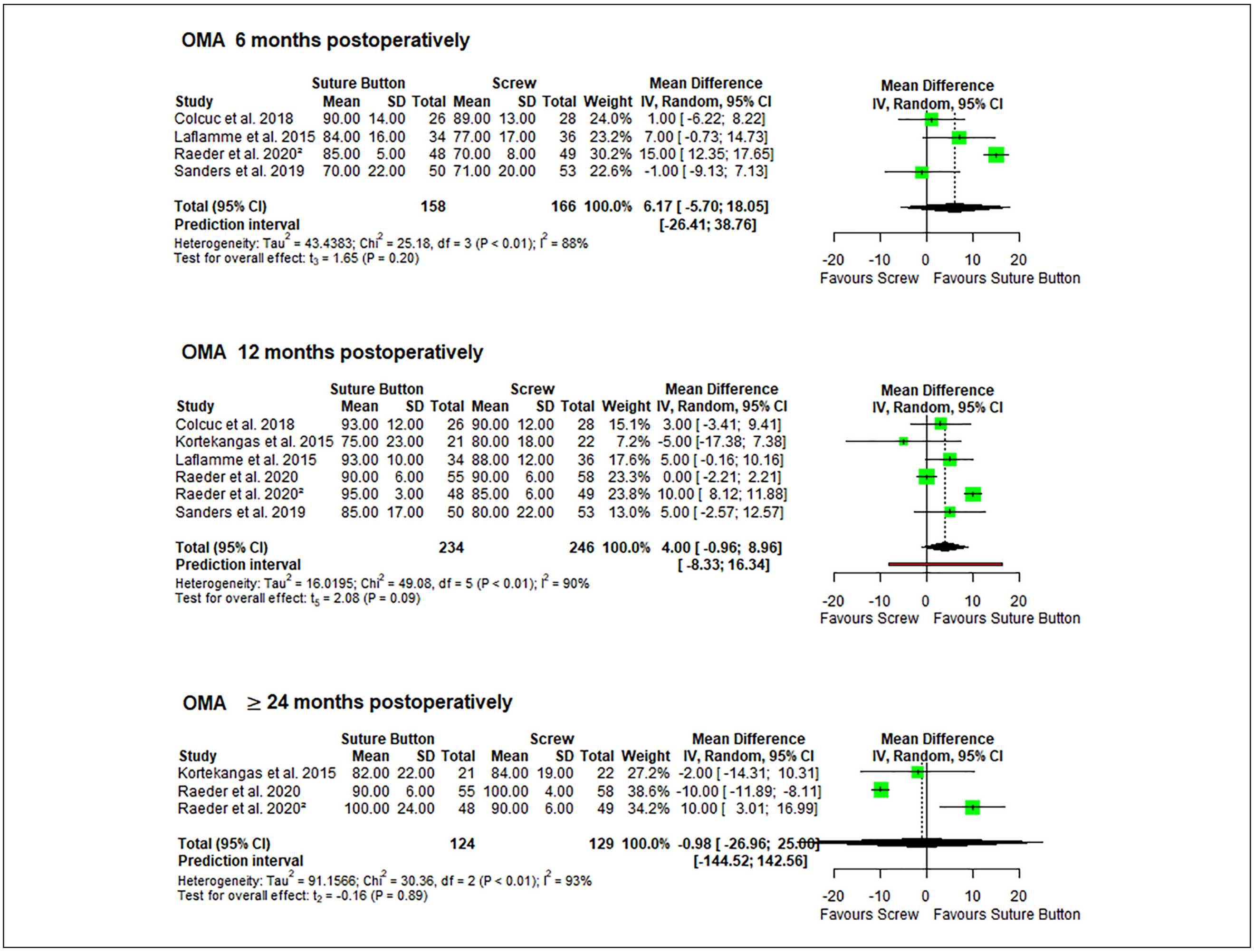


Figure 2. Forest plot of functional outcome (AOFAS and OMA) between SB and SF techniques. AOFAS, American Orthopaedic Foot & Ankle Society score; IV, inverse variance; OMA, Olerud-Molander Ankle score.

with SF) were pooled from 3 RCTs. There was no difference in OMA score ≥24 months postoperatively between the SB and SF groups (MD = 0.98, 95% CI −26.96 to 25.00, I^2 = 93%, P = .89; Figure 2).

ROM

Dorsiflexion 6 months postoperatively. Data on 207 patients (including 101 patients with SB and 106 patients with SF) were pooled from 3 RCTs. There was no difference in dorsiflexion 6 months postoperatively between the SB and SF groups (MD = 1.44, 95% CI −1.29 to 4.17, I^2 = 0%, P = .15; Figure 3).

Dorsiflexion ≥ 12 months postoperatively. Data on 304 patients (including 149 patients with SB and 155 patients with SF) were pooled from 4 RCTs. There was no difference in dorsiflexion ≥12 months postoperatively between the SB and SF groups (MD = −0.84, 95% CI −5.44 to 3.77, I^2 = 89%, P = .60; Figure 3).

Plantarflexion 6 months postoperatively. Data on 207 patients (including 101 patients with SB and 106 patients with SF) were pooled from 3 RCTs. There was no difference in plantarflexion 6 months postoperatively between the SB and SF groups (MD = 0.61, 95% CI −9.52 to 10.73, I^2 = 66%, P = .82; Figure 3).

Plantarflexion ≥12 months postoperatively. Data on 304 patients (including 149 patients with SB and 155 patients with SF) were pooled from 4 RCTs. There was no difference in plantar flexion ≥12 months postoperatively between the SB and SF groups (MD = 1.62, 95% CI −4.86 to 8.10, I^2 = 51%, P = .48; Figure 3).

Complications

Implant irritation. Data on 472 patients (including 230 patients with SB and 242 patients with SF) were pooled from 7 RCTs. Compared with the SF group, the

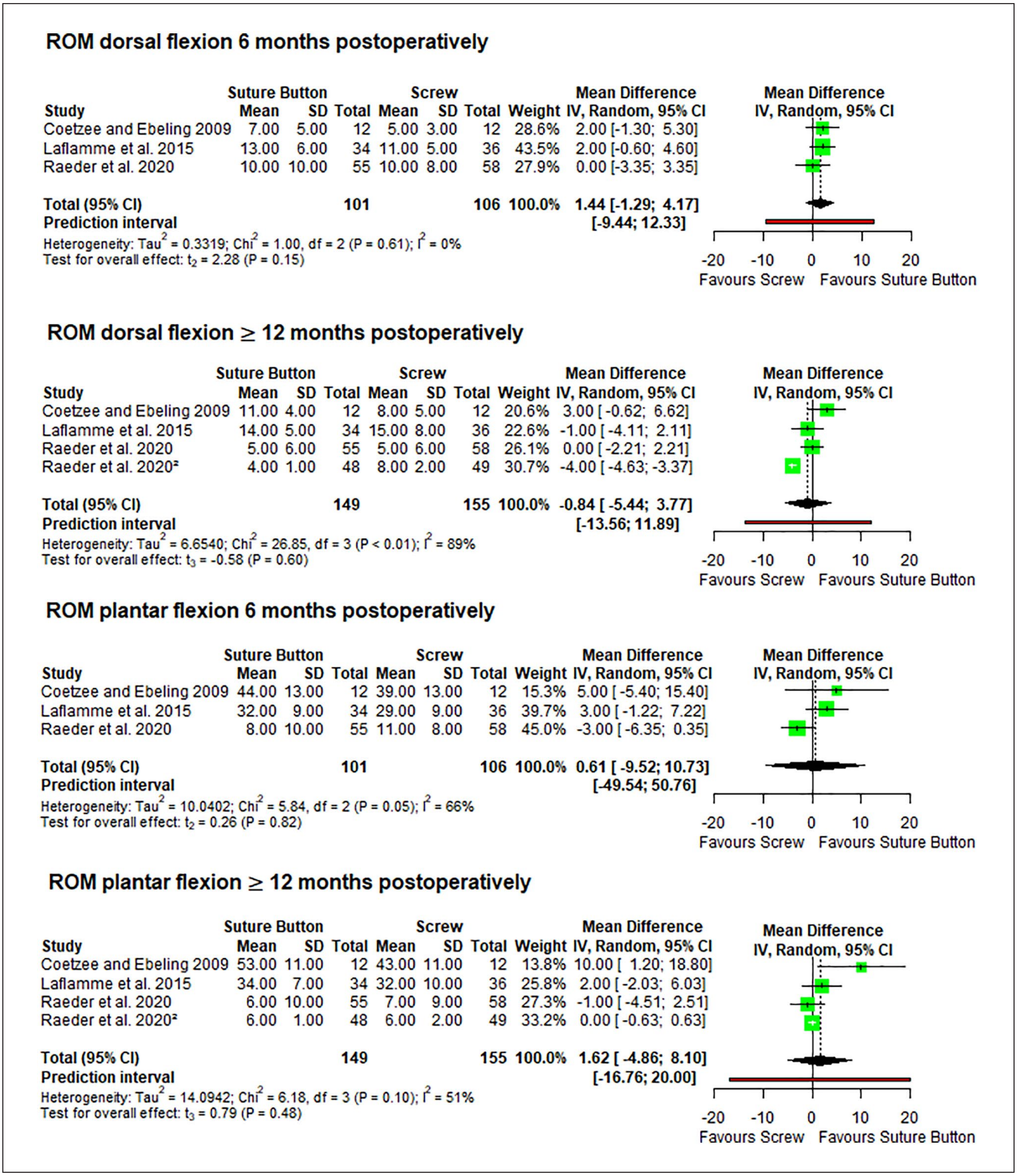


Figure 3. Forest plot of functional outcome (ROM) between the SB and SF techniques. IV, inverse variance; ROM, range of motion.

frequency of risk for implant irritation was lower in the SB group (OR = 0.31, 95% CI 0.11-0.89, I^2 = 22%, P = .03; Figure 4).

Implant failure. Data on 401 patients (including 196 patients with SB and 205 patients with SF) were pooled from 6 RCTs. Compared with the SF group, the frequency

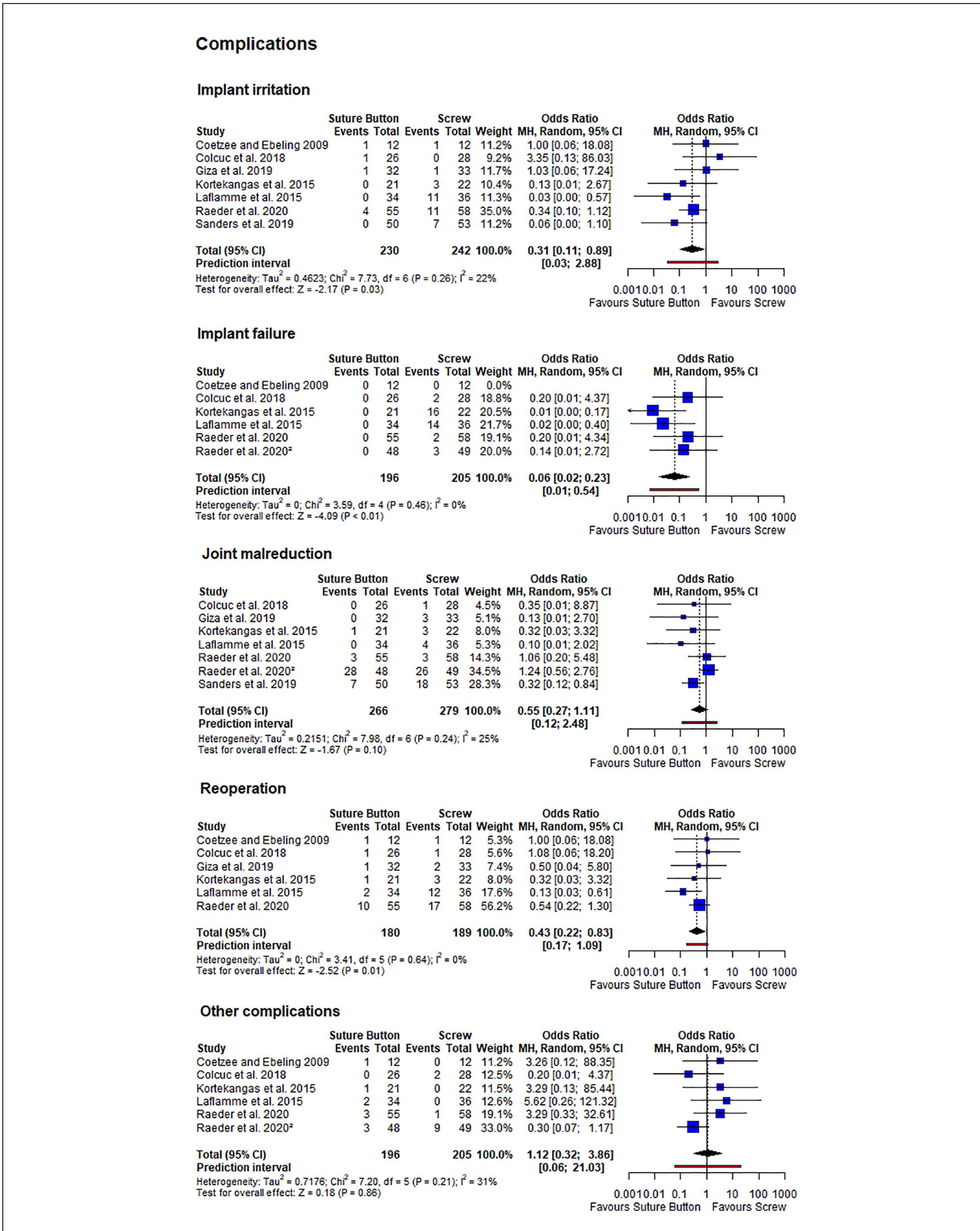


Figure 4. Forest plot of complications rates between the SB and SF techniques. MH, Mantel-Haenszel.

of risk for implant failure was lower in the SB group (OR = 0.06, 95% CI 0.02-0.23, $I^2 = 0\%$, $P < .01$; Figure 4).

Joint malreduction. Data on 545 patients (including 266 patients with SB and 279 patients with SF) were pooled from 7 RCTs. There was no difference in the frequency of joint malreduction between the SB and SF groups (OR = 0.55, 95% CI 0.27-1.11, $I^2 = 25\%$, $P = .10$; Figure 4).

Reoperation. Data on 369 patients (including 180 patients with SB and 189 patients with SF) were pooled from 6 RCTs. Compared with the SF group, the frequency of risk for reoperation was lower in the SB group (OR = 0.43, 95% CI 0.22-0.83, $I^2 = 0\%$, $P = .01$; Figure 4).

Other complications. Data on 401 patients (including 196 patients with SB and 205 patients with SF) were pooled from 6 RCTs. There was no difference in the frequency of other complications between the SB and SF groups (OR = 1.12, 95% CI 0.32-3.86, $I^2 = 31\%$, $P = .86$; Figure 4).

Baujat and Funnel plots are given in the supplemental material.

Discussion

Eight RCTs with 569 patients were included in this meta-analysis. The SB group consisted of 278 patients, and the SF group consisted of 291 patients. One study among 8 was an anonymized RCT with a level I evidence,[6] the other 7 studies were nonanonymized RCTs with level II evidence.[5,14,21,22,31,32,34] The value of this meta-analysis results from the limitation of inclusion criteria to RCTs and use of high-quality statistical methods. It offers the highest sample size of all RCT meta-analyses[11,15,29,36] on this topic (Table 3). However, our meta-analysis concentrated only on decisive outcome parameters in order to maintain transparency of the results. SB showed slightly better functional results. The main advantage of SB is in the lower risk for postoperative complications compared with SF. The SB technique had fewer cases of implant irritation, implant failure, and reoperation. Joint malreduction and other complications showed no difference between SB and SF.

We measured the functional outcome with information on AOFAS and OMA scores and ROM. SB showed slightly better functional results. The AOFAS score <6 months postoperatively was 4.7 points higher and 12 months postoperatively 5.4 points higher in the SB group compared with the SF group. AOFAS scores 6 and ≥ 24 months postoperatively, OMA score, and ROM showed no difference between the SB and SF groups. The minimal clinically important difference is the smallest change in patient outcome that would require a change in patient management.[24] Because there are no fixed reference values for the ankle with regard to the minimal clinically important difference, we can only estimate that a difference of about 5 does not seem clinically relevant. Therefore, it is questionable whether a change in the surgical techniques by the operators is justified on the basis of functional outcome.

Our findings showed major differences in postoperative complications regarding implant irritations, implant failure, and reoperation. The incidence of implant irritations occurred in 3% of patients operated with the SB technique and in 11% of patients operated with the SF technique. Local tissue irritation is a frequent reason for implant removal in cases with SF. Furthermore, it is believed that the SB knot is more tolerable for the tissue than the screw head. The incidence of implant failure occurred in 0% of patients operated with SB technique and in 18% of patients operated with the SF technique, which is a very obvious advantage for the SB technique. The fact that the SB implant is flexible and the SF is rigid might play a role in regard to implant failure. Some studies have shown it is possible to initiate full weightbearing earlier following SB technique.[7,27,40] Earlier full weightbearing might cause screw breakage before the syndesmosis healing process is complete. Malreduction of the syndesmosis is a very important predictor of the long-term outcome after treatment of ankle fractures.[43] However, we did not find any difference in malreduction between the 2 groups. In this context, however, 1 detail must be taken into account. The study by Raeder et al[32] had a very high contribution to the overall result, as it is obvious from the Baujat plot (see supplemental material), which had a study weight of 34.5% (see Figure 4). The results of this study differ significantly from the rest of the included RCTs with regard to malreduction. The incidence of syndesmotic malreduction occurred in 58% of patients operated with the SB technique and in 53% of patients operated with the SF technique in the RCT by Raeder et al.[32] It occurred in 5% of patients operated with SB technique and in 14% of patients operated with the SF technique in the rest of the included RCTs. The very high incidence of syndesmotic malreduction in both SB and SF groups examined in the RCT by Raeder et al[32] might be explained by the fact that their research group determined the radiologic position of the syndesmosis by CT scan. In addition, this study had the longest follow-up period. The incidence of reoperation occurred in 9% of patients operated with the SB technique and in 14% of patients operated with the SF technique. The higher reoperation rate is certainly a consequence of the higher complication rate with the SF technique than the SB technique. Other complications did not show any difference between the SB and SF techniques. There is 1 possible complication that neither RCT might have considered. Is it conceivable that the SB construct stretches or even erodes into the bone over time. A broken screw is very clearly visible in conventional radiographs; the elongation within the SB construct is less visible. A fairer and more accurate comparison would be the assessment of the radiologic diastase

Table 3. Comparison with related meta-analyses.

Meta-analysis (year)	Sample Size	Studies Included	Comment
Chen et al (2019)[4]	397	3 RCTs 6 non-RCTs	Almost same studies included as Fan et al (2019)[10] and Gan et al (2019)[12]
Fan et al (2019)[10]	420	3 RCTs 7 non-RCTs	Same studies included as Gan et al (2019)[12]
Gan et al (2019)[12]	282	5 RCTs	Same RCTs included as Onggo et al (2020)[29] Shimozono et al (2019),[36] different sample size, partly different results
Gan et al (2019)[12]	420	3 RCTs 7 non-RCTs	Same studies included as Fan et al (2019)[10]
Grassi et al (2020)[15]	335	7 RCTs	All types of dynamic fixation techniques
McKenzie et al (2019)[26]	275	2 RCTs 4 non-RCTs	Lowest sample size
Onggo et al (2020)[29]	280	5 RCTs	Same RCTs included as Gan et al (2019),[12] Shimozono et al (2019),[36] different sample size, partly different results
Shimozono et al (2019)[36]	285	5 RCTs	Same RCTs included as Gan et al (2019),[12] Onggo et al (2020),[29] different sample size, partly different results
Xie et al (2018)[45]	539	5 RCTs 6 non-RCTs	–
Xu et al (2021)[46]	654	6 RCTs 6 non-RCTs	Highest sample size
Zhang et al (2017)[47]	390	3 RCTs 6 non-RCTs	Almost same studies included as Fan et al (2019)[10] and Gan et al (2019)[12]

Abbreviation: RCT, randomized controlled trial.

between the 2 constructs under CT scan. Another major point of discussion is that some of the included RCTs had planned screw removal[6,32,34] and others did not.[5,14,21,22,31] This acts as a confounding factor on the outcome parameters "reoperation" and "implant failure." However, it must be said that the planned screw removal still is a reoperation with all the associated risks. If a screw removal is not planned, a screw breakage after achieving full weightbearing is not unlikely. However, this must also be viewed critically, as a delayed diastasis can also occur in due course after screw breakage.

By making an overview of related meta-analyses, some peculiarities catch the eye (Table 3). There are 4 related RCT meta-analyses.[11,15,29,36] First of all, the 2019 meta-analysis by Grassi et al[15] included 335 patients from 7 RCTs providing information on all types of dynamic stabilization techniques.[1,5,6,21,22,25,44] Two of them reported results of surgery by wire cerclages[25] and elastic hook plates.[44] Therefore, the results are comparable to a limited extent. However, the 2019 meta-analysis by Grassi et al[15] found that dynamic fixation of syndesmotic injuries reduced the risk of complications and reoperation and improved clinical outcomes as compared to static screw fixation. Three further related RCT meta-analyses[11,29,36] included exactly the same 5 RCTs.[1,5,6,21,22] All of these RCTs were found in our literature search. However, we excluded one of them, namely, the 2018 RCT by Andersen et al[1] that used the same initial data as another RCT[32] we found. Therefore, we included the RCT that gave us more information and had the lower risk of bias, namely, the 2020 RCT by Raeder et al.[32] Furthermore, we found 3 more RCTs[14,31,34] that were not found in the related RCT meta-analyses.[11,15,29,36] When comparing the 3 meta-analysis, it is immediately noticeable that although the same RCT were included, different statements were made regarding the sample size, namely, 282 patients in the 2020 meta-analysis by Gan et al,[11] 280 patients in the 2020 meta-analysis by Onggo et al,[29] and 285 patients by Shimozono et al in 2019.[36] A very important limitation of the 2019 RCT meta-analysis by Shimozono et al[36] was that the authors performed statistics using an FE model. The authors should have avoided FE models because such models underperform in the presence of any heterogeneity. RE models are more conservative, provide better estimates with wider CIs, and the results are more scientifically generalizable.[2,20] However, the 2019 RCT meta-analysis by Shimozono et al[36] found that the SB technique improved functional outcomes and reduced the risk of implant breakage and joint malreduction as compared to the SF technique. The 2020 meta-analysis by Gan et al[11] and the 2020 meta-analysis by Onggo et al[29] were performed using RE models. Onggo et al[29] even tested FE and RE models as we did in our study. When comparing the 2 RCT meta-analyses, it is noticeable that in addition to different total sample sizes, different data were extracted for AOFAS and OMA scores 12 months postoperatively and DF and PF 6 months postoperatively, leading to different results and partly different conclusions. Another difference between both meta-analyses is that the 2020 meta-analysis by Onggo et al[29] distinguished between types of postoperative complications, whereas the 2020 meta-analysis by Gan et al[11] presented postoperative complications as one single outcome parameter. However, the 2020 meta-analysis by Onggo et al[29] found that the SB technique improved AOFAS score 12 months postoperatively and reduced the risk for implant failures compared with the SF technique. The 2020 meta-analysis by Gan et al[11] stated that the SB technique improved functional outcomes and reduced the risk for overall postoperative complications compared with the SF technique.

When comparing the non-RCT meta-analyses,[4,10,12,26,45,46,47] it is again noticeable that several of them included exactly the same studies, namely, the 2019 meta-analysis by Fan et al[10] and the 2019 meta-analysis by Gan et al,[12] or almost the same studies, namely, the 2019 meta-analysis by Chen et al[4] and the 2017 meta-analysis by Zhang et al.[47] The 2019 meta-analysis by McKenzie et al[26] had a very small sample size considering that it was not limited to RCTs. Considering good scientific practice, some of these meta-analyses were unnecessary to publish. However, their overall results were in consistency with the results of the RCT meta-analyses.

We identified the following limitations of this meta-analysis: first, this meta-analysis did not consider the possible influence of the operating surgeon and the use of different implant brands; second, there are differences between the included RCTs in the number, positioning, and size of screws and the number of SBs used; third, there are differences between the included RCTs in ankle injury patterns; fourth, the information on postoperative complications was collected at different time points among the included RCTs; fifth, in some RCTs, there was planned implant removal and in others not, which influences the outcome parameter "reoperation." All of these points might have an impact on the results. Nevertheless, there are still not enough RCTs to conduct a meta-analysis taking into account these limitations.

Conclusions

Our overall findings suggested slightly better outcomes of SB compared with SF. Because functional outcomes showed no relevant difference between SB and SF, the advantage of SB appears to be a lower risk for postoperative complications. The SB technique was found to have fewer cases of implant irritation, implant failure, and reoperation compared with SF.

Author Note

Nikolai Ramadanov author is now affiliated to Center of Orthopaedics and Traumatology, University Hospital Brandenburg an der Havel, Brandenburg Medical School Theodor Fontane, Germany.

Ethical Approval

Ethical approval was not sought for the present study because this is a systematic review and meta-analysis.

Declaration of Conflicting Interests

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ORCID iD

Nikolai Ramadanov, MD, https://orcid.org/0000-0003-4669-8187

Supplemental Material

Supplementary material is available online with this article.

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