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A Systematic Review and Meta-Analysis on Treatment of Ankle Fractures With Syndesmotic Rupture: Suture-Button Fixation Versus Cortical Screw Fixation

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ABSTRACT

Ankle fractures accompanied by syndesmotic rupture are a complex challenge for orthopedic surgeons. Sufficient reduction and stabilization of the syndesmosis are important to prevent early degeneration of the ankle joint and to optimize clinical outcomes. The purpose of the study was to systematically review the literature comparing the suture-button fixation method with the cortical screw fixation method when treating syndesmotic rupture. For this, a systematic review of the literature was performed that included Cochrane, PubMed, and Embase. The following search terms were used: *ankle fractures, syndesmosis rupture, tibiofibular syndesmosis injury, ankle joint, tightrope,* and *suture button*. Inclusion criteria were comparison studies, acute ankle fractures with syndesmotic rupture, adult patients, and Coleman score >60. Cadaveric studies, chronic instability, open fractures, polytrauma, and arthropathies were exclusion criteria. Two investigators independently reviewed titles and relevant abstracts. Reoperation and malreduction rates were compared in a meta-analysis. Six studies with 275 patients were included: 2 randomized controlled trials and 2 prospective and 2 retrospective cohort studies. All studies used similar surgical techniques. Functional outcomes (American Orthopedic Foot and Ankle Society scale and the Olerud-Molander score) were not quantitatively comparable. No significantly less number of malreduction events were detected in the suture-button group (risk ratio = 0.19, 95% confidence interval 0.03 to 1.04, $p = .06$). Significantly lower reoperation rate was detected in the suture-button group (risk ratio = 0.21, 95% confidence interval 0.06 to 0.69, $p = .01$). We conclude that the suture-button technique showed a significantly lower reoperation rate and tendency toward less malreduction and better American Orthopedic Foot and Ankle Society scale scores. This finding is clinically relevant; however, this conclusion is primarily based on 2 studies, and therefore the interest for further research increases.

Ankle fractures are common, with an annual incidence of 107 to 187 per 100,000 person-years (1–3). Syndesmotic rupture is associated with ankle fractures in 10% to 13% of patients (4, 5) and is a complex challenge for orthopedic surgeons. Malreduction and persistent unstable syndesmosis can evolve toward earlier degeneration of the ankle joint and poor clinical outcomes (6–9).

The ideal treatment of the syndesmotic injury is to recreate the anatomy and preserve the dynamic ability of the syndesmosis. The conventional treatment of syndesmotic rupture is a cortical screw through 3 or 4 cortices 2 cm superior to the tibiotalar joint (10,11). This method does not respect the dynamic properties of the syndesmosis and leads to a wide range of complications including malreduction, screw breakage, and a high risk of a second operation due to the need for screw removal (12–18).

Recently, the suture-button fixation method has gained interest, and its use has increased rapidly. This method uses a flexible stabilization device developed to allow physiologic motion. Furthermore, implant removal is not necessary. Slightly different devices have been invented,

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but all devices consist of a nonabsorbable suture between 2 metallic buttons implanted across the syndesmosis. Biomechanical investigations have demonstrated that the strength of the suture-button is comparable to that of a tricortical 3.5-mm cortical screw (19–21). Still, there is no consensus on the use of suture-button fixation, and the standard fixation method remains the cortical screw. Studies referring to a special suture-button technique (Tightrope®; Arthrex Inc, Naples, FL) recently proposed better functional and clinical outcomes (22). Only a few comparison studies have investigated the functional and clinical outcomes. Two reviews (23,24) have shown promising results using the suture-button fixation method compared with the cortical screw fixation. However, these reviews do not take all relevant considerations into account. Both reviews did not limit the literature and included various studies without a control group. Furthermore, Chen Wang et al (23) reviewed several different methods. These broad limits could lead to biased outcomes and consequently reduce the reliability and validity of their conclusions.

Additionally, new studies have since been published, and we find it necessary to obtain the most reliable studies comparing the suture-button method with the cortical screw fixation. We hypothesize that the suture-button fixation is superior to the classic screw fixation.

Materials and Methods

This systematic review was organized according to the recommended guidelines and was written in accordance with the 2009 Preferred Reporting Items for Systematic Reviews and Meta-analyses checklist (25).

Search Strategy

From July 2016 to October 5, 2016, the first 2 authors (A.M. and K.H.) independently searched PubMed, Embase, The Cochrane Database of Systematic Reviews, and the reference lists of systematic reviews of relevant studies. The following search terms were used: *ankle fractures, syndesmosis rupture, tibiofibular syndesmosis injury, ankle joint, tightrope*, and *suture button.*

This search strategy was confirmed by a librarian specializing in research (26): (“ankle fractures”[MeSH Terms] OR (“ankle”[All Fields] AND “fractures”[All Fields]) OR “ankle fractures”[All Fields] OR (“ankle”[All Fields] AND “fracture”[All Fields]) OR “ankle fracture”[All Fields]) OR (syndesmosis[All Fields] AND rupture[All Fields]) OR “tibiofibular syndesmosis injury”[All Fields] OR (“ankle joint”[MeSH Terms] OR (“ankle”[All Fields] AND “joint”[All Fields]) OR “ankle joint”[All Fields]) AND tightrope[All Fields] OR ((“sutures” [MeSH Terms] OR “sutures”[All Fields] OR “suture”[All Fields]) AND button[All Fields]).

Inclusion and Exclusion Criteria

This review included studies on patients with closed growth plates (defined by a minimum age of 14 years) with ankle fracture with syndesmotic rupture who had undergone surgery within 3 weeks of injury. Only studies comparing fixation of the syndesmosis in ankle fractures with the suture-button technique versus the cortical screw fixation method were included. The following outcomes were of interest: American Orthopedic Foot and Ankle Society (AOFAS) scale score (27,28), malreduction, reoperation rate, and time to preinjury activities.

The Coleman methodology score (29) for clinical studies is based on 10 specific criteria, and only studies with a Coleman score of ≥60 were included.

Exclusion criteria were cadaver studies, chronic instability, open fractures, polytrauma, and diabetic or neuropathic arthropathy. Furthermore, systematic reviews were excluded because of risk of duplicated data.

Study Selection

The same 2 authors independently reviewed all titles and abstracts for relevance. If these data were not sufficient, the full text was retrieved to allow the application of inclusion and exclusion criteria. Additionally, all reference lists from relevant systematic reviews were reviewed to verify that no studies eligible for inclusion were missing. Furthermore, the 2 authors independently scored all eligible studies for the Coleman score (29).

Data Collection

Level of evidence was assigned to the included studies according to the classification from Wright et al (30). Patient demographics, number of patients, follow-up period, surgical technique details, outcome measurements, and comparative results (*p* value) were extracted and recorded by A.M. and K.H. For continuous variables such as age, follow-up periods, and outcome scores, the mean ± standard deviation (SD) and range were collected if reported (Table 1).

Table 1
Overview of study demographics

Source	Number of Patients	Age, Mean (Range), y	Surgical Method (Postoperative Treatment)	Follow-Up, Mean (Range), mo	Completeness of 1-y Follow-Up	Level of Evidence
Kocadal et al (36)	52 patients	44.1 (16 to 65)	Screw: 3.5-mm cortical screw inserted in 4 cortices	16.7 mo (6 to 43)	Not stated	3
	26 screw	44.8 (16 to 65)	SB: ZipTight fixation	Not stated		
	26 SB	43.3 (16 to 61)	(similar)	Not stated		
				Indicated removal†		
Seyhan et al (34)	32 patients	32.5 (19 to 60)	Screw: 4.5-mm cortical screw inserted in 4 cortices	14.6 mo (12 to 50)	100%	3
	17 screw	32.0	SB: Tightrope (Arthrex)	Not stated		
	15 SB	33.2	(Similar)	Not stated		
				Indicated removal†		
Laflamme et al (32)	70 patients	Not stated	Screw: 3.5-mm inserted in 4 cortices	Not stated*	93%	1
	36 screw	39.3*	SB: TightRope (Arthrex)	Not stated		
	34 SB	40.1	(similar)	Not stated		
				Indicated removal†		
Kortekangas et al (31)‡	43 patients	Not stated	Screw: 3.5-mm inserted in 3 cortices	Not stated	100%	1
	22 screw	43.5 (20 to 73)	SB: Tightrope (Arthrex)	37 mo*		
	21 SB	46.0 (20 to 79)	(similar)	36 mo		
				Indicated removal†		
Naqvi et al (33)	46 patients	Not stated	Screw: 3.5-mm or 4.5-mm inserted in 4 cortices	30 mo (18 to 42)	Not stated*	2
	23 screw	39.8 (18 to 65)	SB: Tightrope (Arthrex)	29 mo (18 to 41)		
	23 SB	41.7 (24 to 69)	(Similar)	30.3 mo (18 to 41)		
				Regular removal		
Thornes et al (35)*	32 patients	Not stated	Screw: not stated	Not stated	Not stated	2
	16 screw	31.0 (17 to 51)	SB: #5 braided polyester suture (Ethibond Excel)	Not stated		
	16 SB	32.0 (19 to 74)	(Earlier weight bearing allowed in SB group)	Not stated		
				Indicated removal†		

Abbreviations: SB, suture-button; screw, syndesmosis screw.
* Was contacted and has sent data.
† Was contacted, no reply.
‡ Reasons for reoperation were infection, implant irritation, and implant failure.

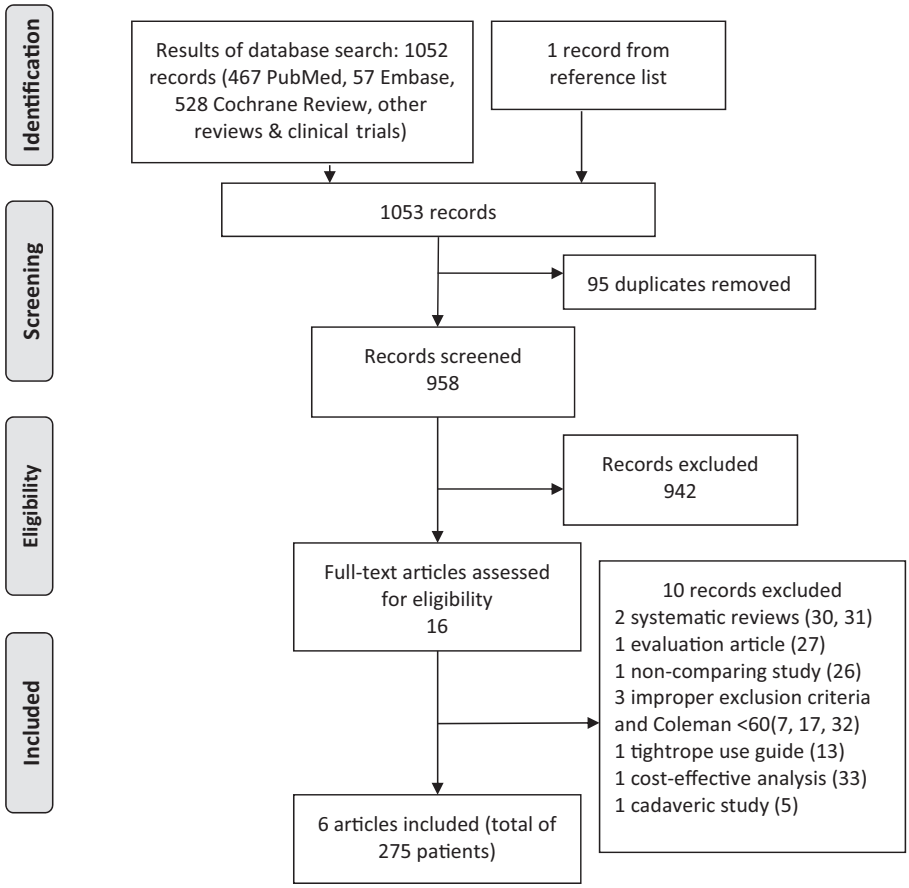

Fig. 1. Flow diagram outlining the process of the study selection.

AOFAS scale and Olerud-Molander (OM) scores are the most commonly reported functional outcome scores for these injuries. Postoperative AOFAS scale and OM scores were collected in this systematic review. Also, malreduction, reoperation rate, and time to return back to previous daily activities were collected if reported. When relevant data were missing in the article, authors were contacted.

AOFAS scale and OM scores range from 0 to 100, with higher scores indicating better function. Malreduction was radiographically measured 1 cm above the tibia plafond and defined as either >2 mm of difference in the width of syndesmosis compared with the contralateral ankle or a distance >6 mm between the medial side of the fibula and the incisural surface of the tibia.

Number of reoperations in the follow-up period was converted to percentages, and definitions of return to daily activity were reviewed.

Data Analysis

A narrative systematic review was primarily chosen rather than a formal quantitative analysis because of the potential for bias in observational studies and because of the fact that there was substantial heterogeneity among included studies. Nevertheless, meta-analysis was completed on comparable data consisting of malreduction and reoperation rate. Cochrane Review Manager 5.3 was used to analyze data.

Bias

There can be inherent selection bias in retrospective studies because of the lack of randomization and prospective comparative control groups. Performance bias could appear based on the operating surgeon's different abilities and experience. Insufficient blinding could result in information bias, and clinical susceptibility bias could occur if predisposing diseases are not taken in to account. The 2 authors reviewed the selected studies using the Cochrane handbook risk of bias assessment, to ensure that authors minimized bias while recognizing the limits present within the studies.

Results

A flow diagram outlining the process for the literature review and study selection is shown in Fig. 1. The primary search in PubMed, Embase, and the Cochrane databases resulted in 1052 records. Furthermore, 1 record from the reference lists was enrolled. After the removal of duplicates, 958 records remained. A review of all titles allowed exclusion of articles unrelated to this topic. Sixteen full-text articles were assessed for eligibility; 6 studies remained after the application of inclusion/exclusion criteria.

Two randomized controlled trials, 2 prospective, and 2 retrospective cohort studies were identified, including a total of 275 patients. Demographic data and surgical techniques are illustrated in Table 1, and outcome data are illustrated in Table 2.

Included Studies

Surgical Techniques

All 6 studies started by fixing the lateral and/or medial and/or posterior malleolar fracture. Following the fracture fixation, syndesmotic reduction was performed. In Maisonneuve fractures only, syndesmotic reduction was completed.

All screw fixations were made with either 3.5-mm or 4.5-mm syndesmotic screws through 3 or 4 cortices.

Different suture-button devices were used; thus, in 4 studies (31–34), the Tightrope was used. Thornes et al (35) constructed their own suture-button device using one #5 braided polyester suture (Ethibond Excel®; Ethicon, Johnson & Johnson, Somerville, NJ) looped twice through the 2 center holes of 2 endobuttons (Acufex®; Smith & Nephew Inc, Andover, MA), and Kocadal et al (36) used the ZipTight fixation system (Biomet Sports Medicine, Warsaw, IN). Although different suture-button devices were used, the surgical approach was similar; the suture-button device was

Table 2
Functional and clinical outcomes for the studies reviewed

Source	AOFAS, Mean ± SD (Range), *p* Value	OM, Mean ± SD (Range), *p* Value	Malreduction, *p* Value	Reoperation %, (R) *p* Value	Time to Return to Daily Activities
Kocadal et al (36)	Screw: 86.1 ± 14 SB: 88.1 ± 9.2 *p* = .4*	Not stated	Not stated	Screw: 38.5% (10/26) SB: 3.85% (1/26)	Not stated
Seyhan et al (34)	Screw: 62.06 ± 12.37 SB: 65.0 ± 10.34 *p* = .475† Screw: 93.35 ± 6.93 SB: 93.73 ± 7.38 *p* = .889‡	Not stated	Not stated	Screw: 100% (17/17) SB: 40% (6/15)	Not stated
Laflamme et al (32)	Screw: 70.6 ± 15.3 (45 to 100) SB: 78.6 ± 10.8 (58 to 96) *p* = .016† Screw: 89.9 ± 12.7 (60 to 100) SB: 93.1 ± 9.3 (72 to 100) *p* = .255‡	Screw: 60.2 ± 20.6 (20 to 95) SB: 86.8 ± 16.6 (30 to 90) *p* = .067† Screw: 87.7 ± 12.2 (65 to 100) SB: 93.3 ± 10.2 (65 to 100) *p* = .046‡	<6 mo PO: *p* > .05 ≥6 mo PO: *p* < .05 (>6-mm tibio-fibular space)	Screw: 33.3% (12/36) SB: 5.9% (2/34) *p* = .006	Tendency to faster in SB group
Kortekangas et al (31)	Not stated	Screw: 80 SB: 75‡	PO: *p* > .9 2 y: *p* = .33 (>2 mm side to side)	Screw: 13.64% (3/22) SB: 4.76% (1/21)	Not stated
Naqvi et al (33)	Screw: 86.52 ± 9.6 (65 to 100) SB: 89.56 ± 8.6 (69 to 100) *p* = .26§	Not stated	*p* = .04 (>2 mm side to side)	Screw: 100% (23/23) SB: Not stated	Tendency earlier weightbearing in SB group
Thornes et al (35)	Screw: 80 SB: 91 *p* = .01† Screw: 83 SB: 93 *p* = .04‡	Not stated	Not stated	Screw: 75% (12/16) SB: 0% (0/16) *p* = .001	Faster in SB group

Abbreviations: SB, suture-button; screw, syndesmosis screw.
* Score assessment at final follow-up. Specific time not stated.
† 3 mo postoperatively.
‡ 12 mo postoperatively.
§ At least 18 mo postoperatively.

pulled through a drill-hole (plate hole if present) through all 4 cortices by a needle from the lateral side. Once the oblong button was passed through the medial tibia cortex, pulling the free ends on the lateral side of fibula tightened the suture and applied further syndesmotic stabilization. A hand-tied knot secured the device, although 1 study (36) did not describe a locking knot but instead a locking button. All 6 studies placed the syndesmotic reduction equipment approximately 2 to 2.5 cm above the tibial plafond, but Naqvi et al (33) describes the use of 2 syndesmotic screws in 3 cases and 2 suture-buttons in 7 cases, without further description of placement of the extra device.

Four studies (32–34,36) controlled syndesmosis reduction through fluoroscopy. Kortekangas et al (31) checked syndesmosis reduction using intraoperative computed tomography (CT). If the CT suggested malreduction, the syndesmosis was visualized and evaluated, and when necessary refixed. Naqvi et al (33) used the image intensifier to check syndesmotic malposition before applying the reduction device. Although specificity of intraoperative tests (external rotation and hook test) is known to be very high, none of the mentioned studies addressed the issue of a limited sensitivity for detection of instability (37). In 1 study, Thornes et al (35) state that all stages of the technique were observed using a radiographic image intensifier; besides this, no radiologic method is used to confirm syndesmotic reduction.

Postoperative treatment was the same in the screw and suture-button group in 5 studies. Two studies (32,33) immobilized the ankle and were non-weightbearing for 6 weeks. Kortekangas et al (31) also immobilized the ankle, for 6 weeks, but allowed partial weightbearing. Kocadal et al (36) immobilized the ankle for 3 weeks, followed by active and passive movement and partial weightbearing. At 6 weeks, full weightbearing was allowed. Seyhan et al (34) immobilized the ankle for 2 weeks. After 2 weeks, pressure socks were applied, keeping the ankle in neutral position. Patients were non-weightbearing. After 6 weeks, partial weightbearing was allowed.

Thornes et al (35), immobilized the ankle for 6 weeks, allowing partial weightbearing after 2 weeks in the suture-button group. In the group stabilized with screws, weightbearing was not allowed before 6 weeks postoperatively. Furthermore, 2 studies (31,33) described additional physiotherapy rehabilitation.

Two studies (33,34) routinely removed syndesmotic screws, whereas the rest only removed the implants if necessary (i.e., pain, irritation, infection).

Outcomes

Relevant outcomes for this systematic review are reported in Table 2. Five studies (32–36) reported AOFAS scale scores. Only 3 (32,34,35) of these reported time of score assessment. Scores at 3 and 12 months are stated in Table 2. Scores were reported with mean ± SD values except by Thornes et al (35), where only the mean was reported. All 3 studies report a *p* value and define significant difference at *p* = .05. Kocadal et al (36) report mean± SD AFOAS scores from final follow-up. Specific time points of assessments were not reported, although mean follow-up and range were stated. In Naqvi et al (33), patients were followed in the clinic at 2 weeks, 6 weeks, and 3 months, postoperatively. Furthermore, patients were reviewed after at least 18 months. Mean ± SD AOFAS scores were reported without stating from which follow-up.

Two studies (31,32) reported OM scores. Scores at 3 and 12 months are stated in Table 2. It should be noted that the *p* value stated by Kortekangas et al (31) was calculated from the average score between 1- and 2-year follow-up.

Three studies (31–33) obtained radiographs for the quantitative evaluation of malreduction. Laflamme et al (32) stated there were no significant differences in malreduction directly postoperatively or at 3-month follow-up, although at 6- and 12-month follow-up, malreduction is significantly less in the suture-button group (respectively, $p = .02$ and $p = .008$). Kortekangas et al (31) state no significant difference intraoperatively or at 2-year follow-up. Naqvi et al (33) state a significant difference postoperatively ($p = .04$) favoring the suture-button group, but no specific time of assessment is stated. It should be noted that 2 studies (31,33) diagnose malreduction when radiographs show >2 mm of difference in the width of the syndesmosis compared with the contralateral ankle, and 1 study (32) diagnoses malreduction when radiographs showed lateral tibiofibular clear space >6 mm. Based on earlier literature (38), these measures are comparable because the average posterior width of the syndesmosis on CT scans corresponds to the tibiofibular clear space on anteroposterior radiographs.

All observed reoperations during the individual studies' follow-up periods were extracted, and the percentage of such operations was calculated. In all studies, reoperations occurred in more cases in the screw group. Two studies (33,34) routinely removed screws; 4 studies removed screws only if necessary.

Three studies (32–34) commented on time to return to work and time to return to full weightbearing. All 3 studies show a tendency toward faster return in the suture-button group.

Bias

As shown in Table 1, the 6 included studies are of very different levels of evidence. Fig. 2 shows risk of bias in a summary table.

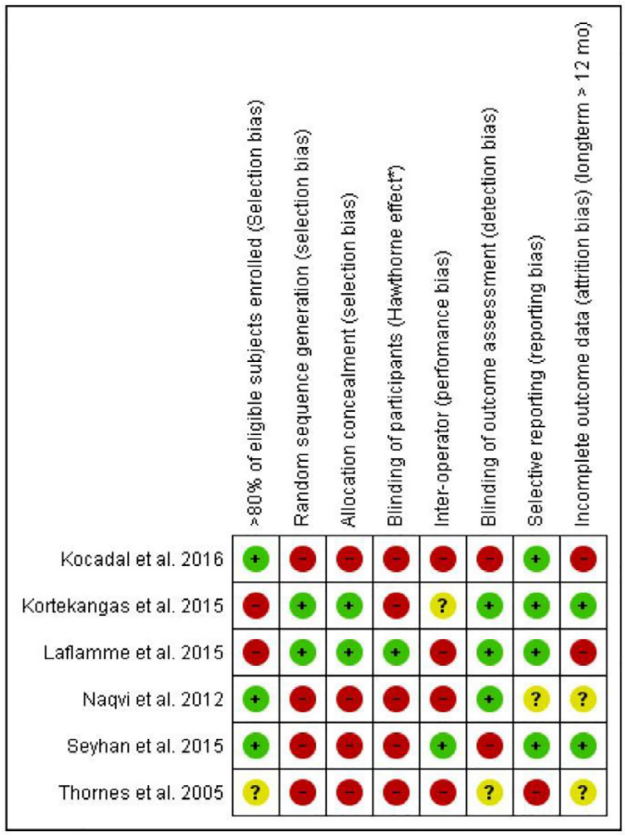

Fig. 2. Risk of bias summary.

Two studies (34,36) are retrospective studies, which exclude the possibility of randomization and blinding, thus allowing high risk of selection, detection, and patient reporting bias, although inclusion and exclusion criteria were reported. Both studies include >80% of eligible subjects, and no indication of reporting bias is found. Kocadal et al (36) include 52 subjects compared with Seyhan et al (34), who include 32 subjects, although Seyhan et al completes 1-year follow-up and performance bias is minimized due to having only 1 surgeon.

Two prospective studies (33,35) with high risk of selection and patient reporting bias due to lack of randomization and blinding of patients, were included, although both studies reported inclusion and exclusion criteria. Both studies have multiple surgeons, but Thornes et al (35) have only 1 single surgeon performing the suture-button technique. This should minimize performance bias in the suture-button group but does not exclude further performance bias. Naqvi et al (33) includes >80% of eligible patients and attempts to minimize detection bias by blinding an independent evaluator. The loss at 1-year follow-up is unclear in both studies. Selective reporting bias was a risk in both studies. Naqvi et al (33) lacks information about time of score assessment. Thornes et al (35) lacks precise stating of SD and has an obvious conflict of interest, due to an author being the inventor of the suture-button technique. Both author groups were contacted. Naqvi et al (33) replied that AOFAS scores were from the final follow-up, and Thornes et al (35) replied that SD was approximately 5.

Two randomized controlled trials with acceptable randomization and allocation were included (31,32). Both trials were registered on ClinicalTrials.gov. Laflamme et al (32) was a double-blinded study, whereas Kortekangas et al (31) only blinded the evaluator; 78% and 72% of eligible subjects were enrolled, respectively.

Laflamme et al (32) conducted a multicenter trial, and Kortekangas et al (31) conducted a single-center trial, although the number of surgeons were not reported in either trial. In Laflamme et al (32), 5 patients were lost to follow-up. No explanation was stated. Furthermore, no mean follow-up period was stated, although clinical evaluation was done at 3, 6, and 12 months postoperatively.

In Kortekangas et al (31), 2 patients were lost to follow-up after the 1-year evaluation. No explanation was stated. The follow-up period was at least 2 years, mean 36 months, in the suture-button group and 37 months in the cortical screw group.

It should be noted that it is not possible to blind the radiological evaluator in any of the studies.

Meta-Analysis

As mentioned, there were substantial differences between the 6 included studies. Two randomized controlled trials (31,32) were included, and meta-analysis on relevant data was completed.

Both studies obtained radiographic outcomes to evaluate the presence of malreduction. Kortekangas et al (31) reported number of events. Number of events from Laflamme et al (32) was obtained via mail correspondence with the author. Meta-analysis based on these data is shown in Fig. 3. Due to a low heterogeneity ($I^2 = 0$), a fixed-effects model was used. The analysis showed no statistically significant lower number of events of malreduction in either group (RR = 0.19, 95% confidence interval 0.03 to 1.04, $p = .06$), although it should be noted that the malreduction was diagnosed at different follow-up times. Laflamme et al (32) evaluated malreduction at 1-year follow-up, and Kortekangas et al (31) evaluated malreduction at 2-year follow-up.

Meta-analysis on reoperation was also completed. In 1 study (34), the cortical screw was routinely removed and, therefore, does not represent a general risk of reoperation. The other 4 studies (31,32,35,36) represent an average reoperation rate of 3.63% (range 0% to 5.9%) in the suture-button group and an average of 40.11% (range 13.64% to 75%) in the cortical screw group. Based on the comparability, the 2 randomized

Fig. 3. Meta-analysis of malreduction rate.

controlled trials (31,32) were included. The 2 studies (31,32) reported the number of reoperations within the individual follow-up period. This second operation was mainly done due to infection, implant irritation, and implant failure. The meta-analysis analyzing the reoperation rate extracted from the 2 studies is shown in Fig. 4. Fixed-effects model was used due to low heterogeneity ($I^2 = 0\%$). The risk for reoperation was statistically significant lower in the suture-button group (RR = 0.21, 95% confidence interval 0.06 to 0.69, $p = .01$).

Low heterogeneity was found in both meta-analyses, but we recognize that heterogeneity will be hard to detect when including only 2 studies.

Discussion

Based on the published literature, no final conclusion on whether the suture-button technique is superior to the cortical screw in terms of functional outcomes could be drawn. The current systematic review and additional meta-analysis show that the suture-button technique had a significantly lower reoperation rate than the standard cortical screw, however, no statistically significance was found in the malreduction rate.

In this systematic review, 6 studies were included based on predefined inclusion and exclusion criteria. The inclusion criteria were set to ensure that the most reliable studies were identified and, furthermore, additional exclusion criteria were set to minimize confounding.

Two reviews from 2012 and 2013 (23,24) are published; nevertheless, new studies of higher level of evidence were published since. Furthermore, 1 systematic review (39) on this topic was published in September 2016, although this systematic review included studies without a control group, which can reduce the reliability of the conclusions drawn in the comparing systematic review.

In isolated syndesmotic injuries, less anatomic structures are damaged, which could influence the healing process and clinical outcomes. To minimize this possibility, the current review limited the subjects to patients with ankle fractures accompanied by syndesmotic rupture. This inclusion criterion differs to the recent published systematic review and explains the exclusion of Coetzee et al (40).

In the Coleman Methodology score (29), the methodology of clinical studies is assessed by the use of subscores in 10 specific criteria. Eligible studies were scored and only studies with a total score of ≥60 were included in this review. It should be noted that this does not exclude all low-quality studies; nevertheless, it takes the most important validity criteria into account.

However, this systematic review still had limitations. The search strategy was performed in English, and therefore articles written in other languages may not have appeared. Furthermore, there is an inherent risk of publication bias due to only including published studies. To minimize this kind of bias, a search on ClinicalTrials.gov was performed. No significant studies on this topic were revealed. When in contact with Brian Thornes (35), we received a protocol and results from a recent unpublished study. This trial also compared the 2 methods but included 1 isolated syndesmotic injury and therefore could not be included in this review.

Five of the included studies (32–36) use AOFAS scores to evaluate the functional outcomes, and 2 studies (31,32) report OM scores. There is a tendency toward better AOFAS outcome scores in the suture-button group compared with the screw group; however, only Thornes et al (35) report significantly better outcomes. It should be noted that an author of this study is the inventor of Tightrope, and a conflict of interest must be considered. Furthermore, only Laflamme et al (32) blinds the patients to the treatment. Therefore, the Hawthorne effect, where patients report better outcomes due to expecting better treatment (41), cannot be eliminated. Even though 5 studies reported AOFAS scores, no meta-analysis on these were completed. Unfortunately, the scores were not comparable, due to several reasons: time of assessment was different and in some studies not stated. Although 3 studies (32,34,35) reported AOFAS scores from 3 and 12 months postoperatively, these data were not comparable in a meta-analysis because the possibility of selection bias was of such great variability. Two studies (31,32) reported OM scores. Unfortunately, Kortekangas et al (31) did not report the OM scores with mean ± SD values, and, therefore, no meta-analysis could be completed. The authors were contacted but did not reply. In this study no statistical difference between the suture-button group and the screw group was reported. Laflamme et al (32) reported statistical better OM scores after 1 year in the suture-button group compared with the screw group.

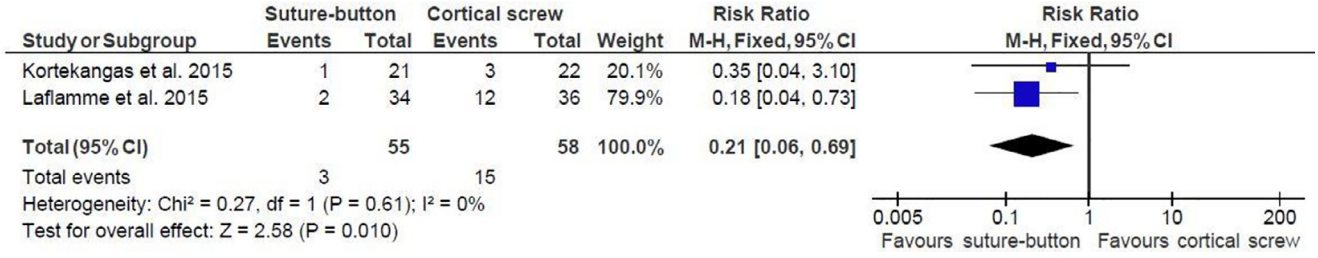

Fig. 4. Meta-analysis of reoperation rate.

The fixation with a suture-button does not have the same risk of breakage as the cortical screw and needs no routine removal. The necessity of a routinely carried out removal of the cortical screw is still a controversial topic. Removal of fixation material is associated with increased cost, missed workdays, potential infection, and other complications, and, therefore, a low removal rate is desirable (42,43). A recently published systematic review concluded that the currently available literature does not support routine elective removal of syndesmotic screws (44). However, the evidence level for this conclusion is so low that the authors decided to start a randomized controlled trial to establish a standard of care (45).

In this review, 5 studies (31,32,34–36) documented the number of patients, who underwent removal of fixation material, indicating that no regular removal was planned. Reasons for reoperation were infection, implant irritation, and implant failure. Specific times of reoperations were not clear in all studies.

Meta-analysis on the 2 randomized controlled trials was completed. Furthermore, 2 studies (35,36) reported reoperation rate. There was a possibility of several risks of bias. Both studies represent a risk of selection bias based on no documentation of including all eligible patients and no randomization. Although the authors recognized and minimized bias by demonstrating a table showing population demographics, Kocadal et al (36) reported too few parameters and Thornes et al (35) lack a statistical analysis to detect differences between the 2 groups. Furthermore, the lack of blinding may result in a tendency to favor reoperation in the cortical screw group. It should be noted that these 2 studies show a tendency to a lower reoperation rate in the suture-button group.

A concomitant issue to early removal of fixation material is the risk of developing recurrent syndesmotic diastasis (46). Malreduction alters the ankle mortise compromising the dynamic function of the ankle joint. This could lead to early degeneration and osteoarthritis.

Malreduction risk was retrieved from 3 studies showing an average malreduction rate of 1.6% (range 0% to 4.7%) in the suture-button group and 16.7% (range 12.5% to 21.7%) in the cortical screw group. Two studies (31,32) were included in a meta-analysis showing a tendency of fewer malreduction events in the suture-button group compared with the cortical screw group, although no significant difference was detected. It should be noted that because of the low number of events, the power of this result is low. Naqvi et al (33) showed a similar tendency, but no randomization was performed in this study, thus increasing the risk of confounding. Furthermore, no statistical analysis comparing the population demographics was performed. It should be noted that Naqvi et al (33) report that the malreduction in 4 of 5 patients occurred after screw removal.

Two studies (32,35) commented on time to return to previous work level, and 1 study (33) commented on time to full weightbearing. These outcomes were not possible to directly compare, due to different definitions. Although all 3 studies favor the suture-button technique regarding these aspects, statistical significance was only found by Thornes et al (35). It is important to note that Thornes et al (35) allowed earlier weightbearing in the suture-button group, which could lead to the better outcome. As mentioned earlier, the risk of screw breakage is larger than the risk of the suture-button device breaking and, therefore, patients in the screw group have to be immobilized for at least 6 weeks to make sure implant failure does not occur before healing of the syndesmosis. However, to compare the 2 methods truthfully regarding time to return to daily activities, the postoperative procedure should be standardized to be the same in both groups.

The literature search also revealed a recent cost-effectiveness analysis from September 2016 (47). Neary et al (47) found that the suture-button method overall is the more cost-effective option. Several variables have an influence on the cost-effectiveness. Most important is the need for a second operation. Neary et al (47) concluded that screw fixation only becomes more cost-effective than suture-button fixation when the screw hardware removal rate can be reduced to <10%. The current systematic review and meta-analysis reveal that even when the removal of the syndesmosis screw(s) was carried out only because of complications associated with the implant (i.e., infection, implant irritation, and implant failure), significantly more reoperations occurred in the screw group. However, a more detailed explanation regarding indications could not be extracted. Minimizing the risk for a second operation is of great clinical relevance for the patient and the health care system. Because of these findings, it is even more relevant to discover whether the suture-button technique actually is superior to the cortical screw. Better and larger randomized controlled trials on this topic should be performed to clarify whether there is an important clinical difference in the functional outcomes.

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