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To compare the efficacy between fixation with tightrope and screw in the treatment of syndesmotic injuries: A meta-analysis

BaiHang Chen[a], Chao Chen[a], ZeTian Yang[a], PeiZhen Huang[b], Hang Dong[b], ZhanPeng Zeng[b,*]

[a] Guangzhou University of Chinese Medicine, Guangzhou 510006, Guangdong, PR China
[b] Guangzhou University of Traditional Chinese Medicine, Department of Orthopaedic, Affiliated Hospital 1, Guangzhou 510405, Guangdong, PR China

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ABSTRACT

Background: To compare the efficacy between fixation with suture-button and screw in the treatment of syndesmotic injuries: a meta-analysis.
Methods: We comprehensively searched PubMed, Embase, and the Cochrane Library and performed a meta-analysis of randomized controlled trials (RCTs) and retrospective comparative studies (RTCs). We performed using Review Manager 5.2.
Results: Three RCTs and six retrospective studies were conducted, including a total of 397 patients. The significant differences of the fixation of suture-button were reported for AOFAS scores (at 3, 6 and 12 months follow-up), full-weight time, reoperation, malreduction and the rate of failure of fixation. There were no significant differences between the groups regarding complications of infection, VAS, OMAS, range of motion, TFCS, TFO and MCS.
Conclusions: Neither the functional outcome nor complications significantly differed between the fixation methods, but suture-button might lead to a quicker return to work. This analysis needs to be confirmed and updated by larger sample data and rigorously designed RCTs.

1. Background

Syndesmosis is one of the most important structures that stabilizes the ankle syndesmotic injury coexists in up to 11–13% of ankle fractures [1–3] and is caused by external rotation.

The current purpose of syndesmosis research is to maintain strong fixation of distal tibiofibular syndesmosis. At present, the common treatment methods for the syndesmosis is metal screw internal fixation. Screw fixation has been clinically confirmed to attain the features of accurate reduction and stabilization of the syndesmosis, which is necessary to prevent posttraumatic arthritis [4]. However, strong internal fixation could cause the inability to load weight and a loss of micro-movement of the syndesmosis in the early recovery stage.

The suture-button is a fiber-wire suture fixed by two metal cortical buttons between the tibia and fibula, which allows a certain degree of physiological micro-movement and early functional exercise. This device offers potential advantages, such as no requirement for implant removal, less risk of hardware pain and decreased risk of malreduction [5]. However, the device is still used less in clinical applications and has not been widely applied in clinical practice. In addition, patients with suture-button might be at risk of such problems as knot irritation and infection [6]. Peterson et al. [7] recommended ZipTight™ fixation system is the knotless suture button device for ankle syndesmosis repair which may reduces the risk of complications.

One previous systematic review evaluating suture-button fixation versus screw fixation was conducted by Wang et al. [8], which indicated that tightrope might be a more feasible approach to syndesmotic injuries because it results in higher American Orthopedic Foot and Ankle Society scores (AOFAS) and better ankle motion. However, this review only included two prospective comparative studies and one RCT, and the article provided one exclusion criterion (e.g., 'study subjects to be less than 20') without offering any reason for why they made this exclusion [9]. Moreover, this articledid not reported the AOFAS scores of different periods.

Suture-button and screw each have been the subject of several studies, even though several studies comparing tightrope and screw have been conducted, but most are small and present conflicting results. The aim of this study is to compare the effects and complications of ankle joints fixed by screw or suture-button

* Corresponding author.
E-mail address: zhanpengzeng@126.com (Z. Zeng).

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and to determine whether the suture-button is advantageous over the screw fixation.

2. Materials and methods

A prospective protocol of objectives, literature-search strategies, inclusion and exclusion criteria, outcome measurements, and methods of statistical analysis was prepared a priori according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) and Meta-Analysis of Observational Studies in Epidemiology (MOOSE) recommendations for study reporting [10,11].

2.1. Literature-search strategy

A literature search was performed in March 2017 without restriction to regions, publication types, or languages. The primary sources were retrieved by the electronic databases of PubMed, Web of Science, and the Cochrane Library. The following MeSH terms and their combinations were searched in: syndesmo* OR tibiofibular OR ankle OR distal fibula AND tightrope OR suture button OR dynamic fixation AND screw OR static fixation OR Syndesmotic screw. The Related Articles function was also used to broaden the search, and the computer search was supplemented with manual searches of the reference lists of all retrieved studies, review articles, and conference abstracts. When multiple reports describing the same population were published, the most recent or complete report was used [12].

2.2. Inclusion criteria

All available randomized controlled trials (RCTs) and retrospective comparative studies (RTCs) that compared suture-button with screw for treatment of distal tibiofibular syndesmotic injuries in all age groups if they met the following criteria:

(1) At least one of the quantitative outcomes mentioned in the next section of this paper [13–21]. Both tricortical and quadricortical fixation are considered to be screws.
(2) Reported mean, standard deviation (SD), range, and number of subjects in each treatments for continuous outcomes.

2.3. Exclusion criteria

Patients with compound fractures, multiple injuries, neuropathic arthropathy, bilateral injuries, fixation of absorbable screw and chronic or missed syndesmotic injuries were excluded [22]. Editorials, letters to the editor, review articles, case reports, biomechanical studies, and animal experimental studies were excluded.

2.4. Data extraction and outcomes of interest

Data from the included studies were extracted and summarized independently by two of the authors (Huang and Yang). Any disagreement was resolved by the adjudicating senior authors (Zeng and Chen).

The primary outcomes were AOFAS scores at 3, 6 and 12 months follow-up [23], tibiofibular clear space (TFCS), tibiofibular overlap (TFO), medial clear space (MCS), and postoperative complications without screw loosening.

The secondary outcomes were postoperative pain, malreduction, time to full weight-bearing, reoperation and range of motion (ROM), including dorsiflexion (DF) and plantar flexion (PF). We used the data available from all studies included in the analysis.

2.5. Quality assessment

The quality of the RCTs was assessed using the Cochrane risk of bias tool [24] and quality of the retrospective studies was assessed using the modified Newcastle–Ottawa scale [25,26]. Factors considered in this evaluation consisted of patient selection, comparability of the study groups, and number of outcomes reported. Retrospective studies were given a score of 0–9. RCTs, and observational studies achieving six or more stars were considered high-quality.

2.6. Statistical analysis

Analyses were performed using Review Manager version 5.2 (Cochrane Collaboration, Oxford, UK). Continuous and dichotomous variables were compared using the weighted mean difference (WMD) and odds ratio (OR). The 95% confidence intervals (CIs) was reported in all results. In case where the necessary information was not available, we calculated the SD from the standard error (SE) by multiplying the SE by the square root of the sample size; from the 95%CIs by dividing the CI by (2*1.96); from the IQR by dividing the width of the IQR by 1.349 (24); from the range by dividing the range by four if the sample size was 70 or less, or by six if the sample size was greater than 70 [27,28]. Statistical heterogeneity between studies was assessed using the chi-square test with significance set at $p < 0.10$ and capturing the χ^2 and I^2 statistic. A fixed-effects model was used when I^2 was less than 40%, and a random-effects model was used when I^2 was more than 40% [29,30].

Subgroup analyses were performed to compare AOFAS from 3, 6 and 12 months follow-up period. Funnel plots were performed to screen for potential publication bias. We were not able to could not perform sensitivity analyses to exclude heterogeneity.

3. Result

Nine studies, including 397 cases (196 cases for suture-button and 201 cases for screw) fulfilled the predefined inclusion criteria for the final analysis (Fig. 1). All nine publications were full-text articles [24]. Examination of the references listed for these studies and for the review articles did not yield any further studies for evaluation. Agreement between the two reviewers was 90% for study selection and 77% for quality assessment of trials.

3.1. Characteristics of eligible studies

The characteristics of included studies are shown in Table 1. Among the included studies, there were 3 small sample RCTs [13–15]; 2 prospective data collection [16,17] studies and 4 retrospective studies that used a historical series as controls [18–21]. Regarding, surgical indications, all studies investigated suture-button and screw of distal tibiofibular syndesmotic injuries. The baseline demographics of average age and gender ratio were comparable between the two groups of studies.

3.2. Methodological quality of included studies

The overall quality of included studies was moderate. True randomization was only used in three RCTs. None of the retrospective studies adopted an appropriate protocol for treatment assignment; instead, treatment allocation was usually at the discretion of the physician. Three [13,14,17] studies provided information regarding allocation concealment or the blinding method. Matching criteria between the groups were variable, and little matching information was identified from the conference

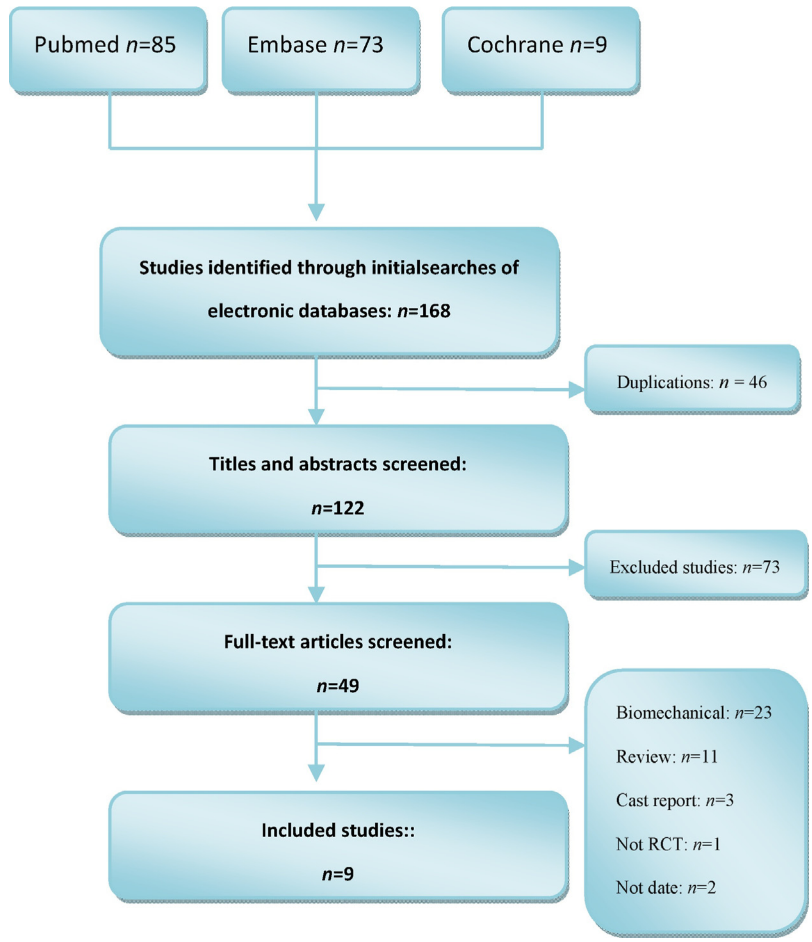

Fig. 1. Flow diagram of studies identified, included, and excluded.

abstracts. All studies indicated the length of follow-up. The average score for the quality of studies was 7.66 (of 9).

3.3. Primary outcomes

3.3.1. AOFAS scores at follow-up periods

Seven studies [13,15,17–21] reported the AOFAS scores, which were reported at postoperation [16,17], 3 [13,19,21], 6 [13,17,19], and after 12 months [13,15,17–21] of follow-up. We performed subgroup analysis according to the follow-up period using a fixed-effects model. The suture-button procedure had significantly higher AOFAS scores at 3, 6 and 12 months of follow-up compared to the screw (Fig. 2). The mean difference of AOFAS scores at postoperation and after 3, 6 and 12 months follow-up through the fixed effect model were −1.68 (95%CI, −5.49 to 2.13; P = 0.39); 7.39 (95%CI, 3.10–11.68; P = 0.0007); 3.67 (95%CI, −0.07 to 7.41; P = 0.05); 2.72 (95%CI, 0.83–4.62; P = 0.005) and the statistical heterogeneity was as follow: I^2 0%, P = 0.48; I^2 3%, P = 0.36; I^2 31%, P = 0.24; I^2 19%, P = 0.28. We conducted subgroup analysis which confirmed that the AOFAS scores with screw was lower than with suture-button (Table 2).

Table 1
Characteristics of included studies.

Study	Year	Level of evidence	Design	Patients, no.		Outcome measurement	Follow-up, *mo	Quality score
				Tightrope	SCREW			
Laflamme et al. [13]	2015	2	RCT	34	36	1,3,5,6,7,8,9,0	NA	9
Kortekangas et al. [14]	2015	1	RCT	21	22	6,8,9,0	24 month	8
Naqvi et al. [15]	2012	2	RCT	23	23	1,2,3,4,5,6,9	2.5 year (1.5–3.5)	9
Cottom et al. [16]	2009	2	RP	25	25	2,3,4,5,6,0	9.4 month	7
Ebeling et al. [17]	2009	2	RP	12	12	1,6,7,0	28 month	7
Kim et al. [18]	2016	4	R	24	24	1,3,4,5,6,8,0	14.6 month (12–18)	8
Seyhan et al. [19]	2015	4	R	15	17	1,6,7,0	14.6 month (12–50)	8
Kocadal et al. [20]	2016	3	R	26	26	1,6,0	16.7 ± 11.0 month	6
Thornes et al. [21]	2005	3	RP	16	16	1,2,6,9,0	1 year	7

R = retrospective; RP = prospective data collection; RCT = randomized controlled trail; NA = data not available.
Outcome measurement: 1 = AOFAS; 2 = time to full weightbearing; 3 = MCS; 4 = TFO; 5 = TFCS; 6 = complications; 7 = range of motion; 8 = VAS score; 9 = malreduction; 0 = reoperation.

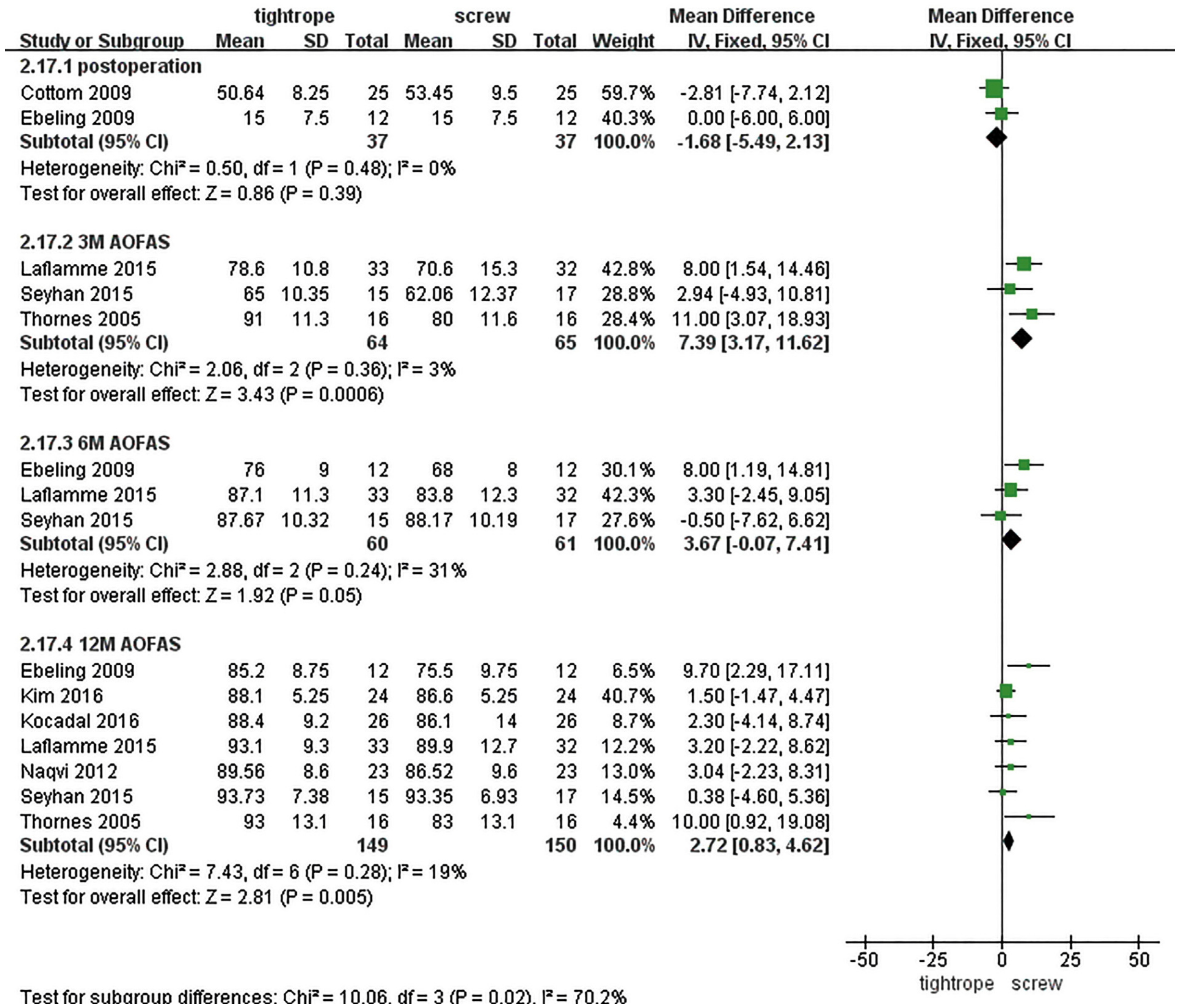

Fig. 2. Forest plot and meta-analysis of AOFAS scores of follow-up period.

Table 2
Results of meta-analysis comparison.

Outcomes of interest	Studies, no.	Tightrope	Screw	WND/OR (95%CI)	P value	Study heterogeneity			
						χ^2	df	I^2, %	P value
AOFAS									
Postop-AOFAS	2	37	37	−1.68 [−5.49,2.13]	0.39	0.50	1	0	0.48
3M AOFAS	3	64	65	7.39 [3.17,11.62]	0.0006	2.06	2	3	0.36
6M AOFAS	3	60	61	3.67 [−0.07,7.41]	0.05	2.88	2	31	0.24
12M AOFAS	7	149	150	2.72 [0.83,4.62]	0.005	7.43	6	19	0.28
Full-weight time	3	64	64	−2.78 [−5.48,−0.08]	0.04	40.94	2	95	<0.00001
TFCS	4	101	104	−0.37 [−0.95,0.21]	0.21	7.91	3	62	0.05
TFO	3	68	72	0.23 [−0.96,1.42]	0.71	4.55	2	56	0.10
MCS	4	101	104	0.08 [−0.11,0.26]	0.42	0.63	3	0	0.89
Complication	8	177	184	0.60 [0.14,2.52]	0.48	1.88	6	51	0.06
Malreduction	4	93	90	0.11 [0.03,0.53]	0.005	0.67	2	0	0.71
Reoperation	8	158	161	0.05 [0.01,0.20]	<0.00001	14.07	6	57	0.03
VAS	3	78	75	−0.27 [−0.71,0.17]	0.24	1.25	2	0	0.54
Dorsiflexion	3	60	61	−0.48 [−3.41,2.44]	0.75	8.67	2	77	0.01
Plantar flexion	3	60	61	1.03 [−6.85,8.91]	0.80	22.00	2	91	<0.0001
OMAS	2	54	51	2.49 [−2.80,7.79]	0.34	0.93	1	0	0.36

3.3.2. Radiographic measure

Radiographic measure was described in four studies [13,15,16,18] at postoperation (205 patients), and a random effect model assessing the TFCS, TFO and MCS showed no significant difference between the suture-button (Fig. 3). The coefficients were as follows: a random effect model assessing the TFCS (−0.37 (95%CI, −0.95 to 0.21; P = 0.21)), TFO (0.23 (95%CI, −0.96 to 1.42; P = 0.71)), and MCS (0.08 (95%CI, −0.11 to 0.26; P = 0.42)) showed no significant difference between the tightrope and screw groups.

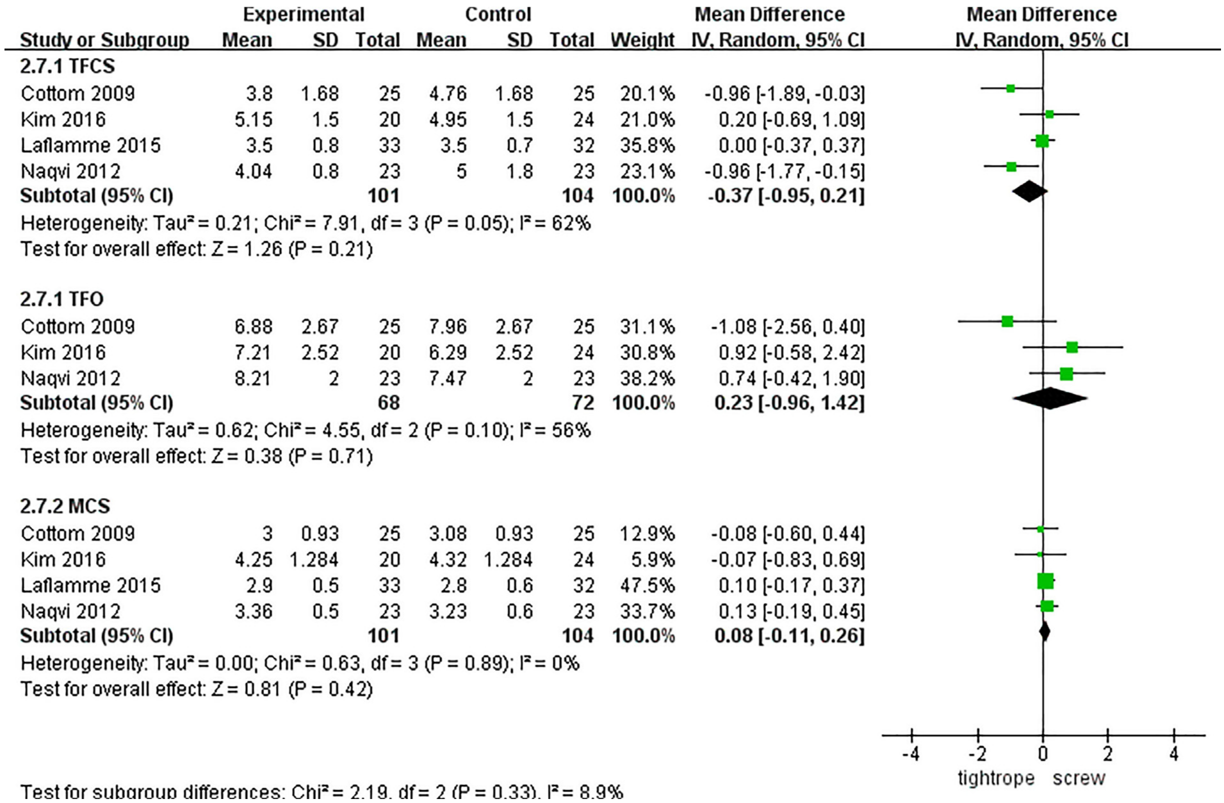

Fig. 3. Forest plot and meta-analysis of radiographic measure.

3.3.3. Complications

Eight studies [13–20] presented the incidence of irritation, infection and failure of fixation. No difference is observed in complications between suture-button and screw (OR, 0.57, 95%CI, 0.29–1.11, P = 0.10; I^2 = 34%). Subgroup analysis based on type of complications showed that the use of screws led to significantly worse failure of fixation (OR, 0.12; 95%CI, 0.03–0.44; P = 0.002; I^2 = 0%). Nevertheless, no significant difference was found in infection and irritation in sub-group analysis (Fig. 4).

3.4. Secondary outcomes

3.4.1. Malreduction

Malreduction was reported in four [13–15,21] studies, showing that the rates of overall malreduction in the suture-button group were significantly lower (Fig. 5) than in the screw group (OR, 0.11; 95%CI, 0.03–0.53; P = 0.005; I^2 = 0%).

3.4.2. Range of motion

ROM, including dorsiflexion and plantar flexion, at 6 and 12 months of follow-up, was reported by three studies [13,17,19]. No significant difference was observed between the suture-button and screw groups at 6 and 12 months of follow-up in a random-effects model [0.70 (95%CI, −0.41 to 1.81; P = 0.22); 0.49 (95%CI, −6.07 to 7.04; P = 0.88); −0.44 (95%CI, −3.53 to 2.66; P = 0.78); 1.07 (95%CI, −7.01 to 9.14; P = 0.80)] with the statistical heterogeneity as follows: I^2 0%, P = 0.45; I^2 83%, P = 0.003; I^2 77%, P = 0.01; I^2 90%, P < 0.0001.

3.4.3. Full-weight time

Three studies [15,16,21] investigated the differences of full-weight time between the suture-button group and the screw group [−2.78 (95%CI, −5.48 to −0.08; P = 0.04; I^2 95%, P < 0.00001)] which mean a shorter time of full-weight in suture-button.

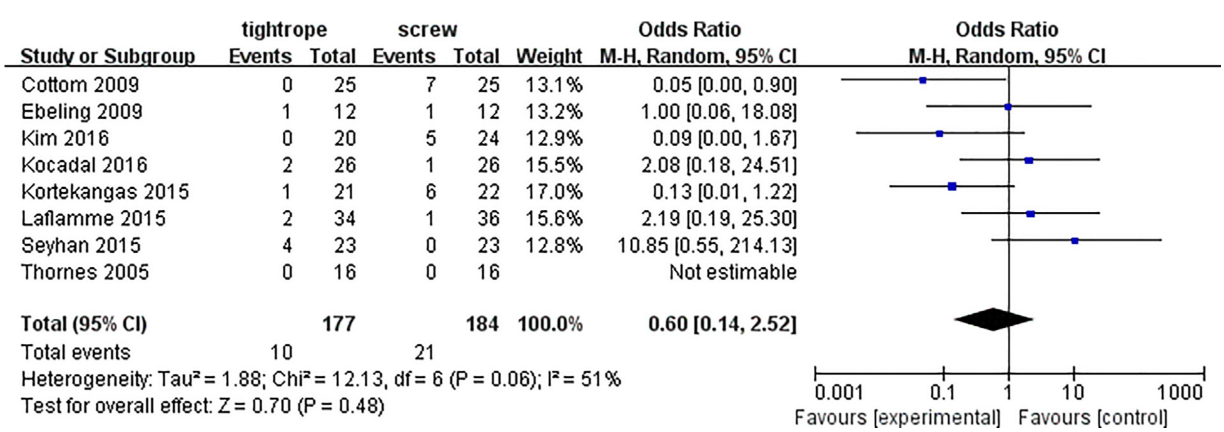

Fig. 4. Forest plot and meta-analysis of complications.

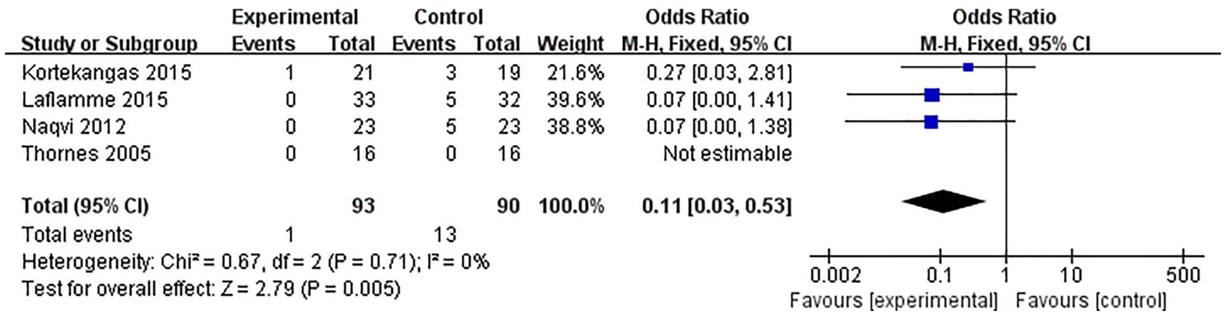

Fig. 5. Forest plot and meta-analysis of malreducion.

3.4.4. Reoperation

Eight studies [13,14,16–21] showed that reoperation rate was significantly higher in screw patients than that in suture-button (OR 0.07; 95%CI, 0.03–0.16; $P < 0.00001$; $I^2 = 18\%$)

3.4.5. Sensitivity analysis and publication bias

Eight studies [13–20,30] of high quality were used in the sensitivity analysis. Only outcomes that were included in more than three studies were included in the sensitivity analysis. There was no change in the significance of any of the outcomes. Fig. 6 shows a funnel plot of the studies included in this meta-analysis that reported AOFAS score. All studies lie inside the 95% CIs, with an even distribution around the vertical, indicating no obvious publication bias

4. Discussion

This meta-analysis of 3 RCTs and 5 retrospective studies, including 397 patients, comparing the efficacy of suture-button and screw procedures showed that suture-button was the better option with significantly greater AOFAS score, lower reoperation rates and shorter time to full weight-bearing. We observed no significant differences in TFO, TFCS, MCS, complications, dorsiflexion or plantar flexion.

Several studies have revealed [31,32] patients who opted for the suture-button had the same effect as those who opted for the screw, and one review [5] reported the similar AOFAS between two groups. References used in this article preferred AOFAS than Olerud–Molander (OMS) score (7 out of 9). A strong relationship between function items and self-reported pain has been reported in the scale of marks, and different measuring techniques and inquiry of different examiners may lead to high risk of expectation bias [33]. This approach also failed to show if the patient filled out the self-reported items directly or indirectly. This finding can reduce the validity and reliability of an AOFAS score. OMS shows no significant difference between two groups. An implication of this phenomenon is the possibility that the outcome of ankle between suture-button and screw are essentially identical.

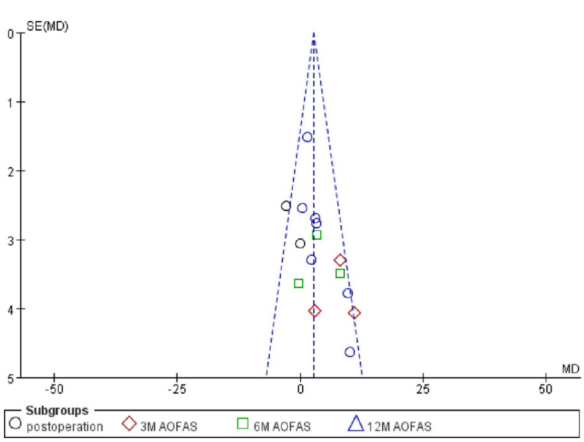

Fig. 6. Funnel plots illustrating meta-analysis of AOFAS scores of follow-up period. SE = standard error; OR = odds ratio.

Screw and suture-button showed no difference in complications. We analyzed the incidence of infection, skin irritation, knot prominence, soft tissue disruption and breakage of the screw. The malreduction analysis must be performed independently because researchers consider malreduction to be a poor indicator, rather than a complication. The analysis indicates that these complications are not at all specific to the suture-button but also occur in the use of syndesmotic screws [34–36]. A retrospective review of 102 cases by Storey et al. [37] reported 8 patients with osteomyelitis, aseptic osteolysis, failed stabilization of the syndesmosis. A recent systematic review [34] demonstrated the complications of the suture-button procedure, which include skin irritation and infection. Peterson et al. [7] suggest a low complication of infection except for irritation by using a knotless suture button fixation device called ZipTight. Hodgson and Thomas [38] recommended a new surgical technique for avoiding suture knot prominence by passing the Arthrex TightRope suture under the fibula and buried so that the knot is not prominent as knotless. Naqvi et al. [39] reported a slightly modified surgical method, embedding the knot at the lateral side, by using the slightly modified surgical technique no tightrope device had to be removed. We have analyzed subgroups of complications (failure and infection) that yielded several different results when compared with the original analysis. The suture-button had a significant advantage over screws in failure of fixation but not in infection and irritation of fixation. Wound breakdown, infection and skin irritation with the use of suture-button fixation have been reported in several studies [4,39,40]. Hong et al. suggest skin irritation could occur on account of a prominent lateral knot. The button with uninterrupted abrasion and micro-motion in the bone tunnel would subsequently cause corrosion and enlargement of the tibiofibula tunnel [39]. It is possible that if a screw breaks and is corrected this could improve the outcome without the need of screw removal

There were no significant differences between the two group in TFCS, TFO, and MCS. The mean TFCS, TFO, MCS of the syndesmosis between suture-button and screw were 4.02 mm, 7.42 mm, 3.30 mm and 4.47 mm, 7.24 mm, 3.31 mm. Open literature sources [16,41–43] identified the syndesmosis with diastasis on an anteroposterior radiograph by an increased TFCS more than 6 mm, a reduced TFO less than 6 mm, and an increased MCS more than 4 mm. In our analysis, both groups fall within the criteria mentioned above which means syndesmosis obtained reduction. The pooled analysis of radiological measurements showed that suture-button is as strong as static fixation. Between-study heterogeneity was significant for TFCS and TFO, which may not require moving at 90° of dorsiflexion.

The suture-button has a lower rate of hardware removal in our statistics. As mentioned in the literature review [44], screws do not have to be removed routinely. This finding indicates that the rate of screw reoperation and its cost are similar to the costs of suture-button. This outcome is contrary to that of Neary et al. [45], who found suture-button is the more cost-effective option.

The data showed suture-button procedures led to a lower rate of malreduction than screws. Leeds and Ehrlich [46] found adequate reduction of the syndesmosis is related to subjective and objective results, as well as any late instability of the syndesmosis and osteoarthritis. The static displacement of the ditch of the tibiofibula, which can prevent perfectly recovering, is the most likely explanation. The absence of correlation between the quality of the reduction and the clinical results indicates that dynamic fixation can make a dynamic adaptation to the reduction of syndesmosis. It should be noted that neither the syndesmotic screw nor the suture-button is a reduction tool. However, a screw can maintain a malreduction whereas a suture-button may accommodate one.

Wang et al. [8], in a similar analysis, suggested that TFC, complication, dorsiflexion and plantarflexion have significant distinctions. However, these parameters are not different in our study. Most likely, disagreement in the exclusion criteria in Wang's analysis and the deficiency of the latest relative published literatures is which leads to these inconsistent results.

The present meta-analysis has several limitations. First, the length of follow-up period of included studies varied. In this instance, bias was inescapable on account of inconsistency of the follow-up of AOFAS periods. Second, patients in the screw group were treated not only with four cortices but also three cortices combined with a 3.5-mm or 4.5-mm quadricortical screw. We could not perform sensitivity analysis to exclude this heterogeneity. Because the number of included studies was not sufficiently large to use this method, we did not conduct subgroup analysis, except on the AOFAS scores and complications. Due to a lack of a larger number of studies and larger samples, more high-quality trials with large samples and longer follow-up periods are proposed.

5. Conclusions

The results of this investigation show that both screw and suture-button generally occur in similar circumstances with their own unique flaws. Therefore, we have argued that a screw is recommended due to easier operation and exhibiting the same effects as the suture-button. While this study did not confirm a preference for suture-button, it did partially substantiate the security and early full weight bearing of the suture-button. This analysis will benefit from updating with larger sample data and rigorously designed RCTs.

Conflict of interest

The authors declare that they have no conflicts of interest concerning this article.

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