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Review

Comparison of suture button fixation and syndesmotic screw fixation in the treatment of distal tibiofibular syndesmosis injury: A systematic review and meta-analysis

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ABSTRACT

Purpose: This systematic review and meta-analysis was performed to investigate the outcomes of syndesmotic screw fixation versus suture button fixation in the treatment of distal tibiofibular syndesmosis injury from the current literature.

Methods: The electronic literature database of PubMed, Embase, and Cochrane library were searched in August 2018. The data on medial clear space, tibiofibular clear space, tibiofibular overlap, American Orthopaedic Foot and Ankle Society (AOFAS) scores and complications (including wound infection, local irritation or discomfort, screw loosening and screw breakage) were extracted. Stata 14.0 software was used for our meta-analysis.

Results: A total of 11 studies including 5 randomized controlled trials (RCTs) and 6 cohort studies met our inclusion criteria. This meta-analysis showed that there was no significant difference between the two groups regarding medial clear space (P = 0.54), tibiofibular clear space (P = 0.23) and tibiofibular overlap (P = 0.88) postoperatively. However, the present meta-analysis demonstrated that the suture button fixation group had significantly higher AOFAS scores than the syndesmotic screw fixation group at 3rd, 6th, 12th and 24th months postoperatively (P = 0.001, P = 0.006, P = 0.000 and P = 0.049 respectively). Besides, the time to full weight bearing in the suture button fixation group was significantly earlier than that in the syndesmotic screw fixation group (P = 0.000). As for the complications, the suture button fixation group had a lower rate of post-operative complication (screw loosening and screw breakage) compared with the syndesmotic screw fixation group (P = 0.048 and P = 0.000 respectively).

Conclusion: Our meta-analysis suggested that suture button fixation could achieve significant higher AOFAS scores with a lower rate of postoperative complications and earlier time to full weight bearing in distal tibiofibular syndesmosis injury. More RCTs are required for further research.

1. Introduction

Ankle fractures are one of the most common fractures treated by orthopaedic surgeons, often requiring surgical treatment to restore anatomic congruity of the ankle mortise to provide stable load transmission through the talocrural joint, and to ease rehabilitation and minimize posttraumatic osteoarthritis [1]. Syndesmotic injuries arise in approximately 13% of all patients with ankle fractures which are commonly seen in pronation and external rotation injuries, and in approximately 20% of ankle fractures requiring operative fixation [2]. The syndesmosis stabilizes the ankle mortise by maintaining the tibiofibular relationship. As persistent ankle pain, function disability and early osteoarthritis are potential problems related to misdiagnosed or inadequate treatment of syndesmotic injuries [3,4], it is necessary to acquire accurate and maintain syndesmotic reduction when treating ankle fractures with concomitant syndesmotic injuries.

Various syndesmotic fixation techniques have been introduced over recent decades. Trans-syndesmotic screw fixation was the most commonly used method and considered as the gold-standard in treatment of syndesmotic injury. However, some significant issues should be taken

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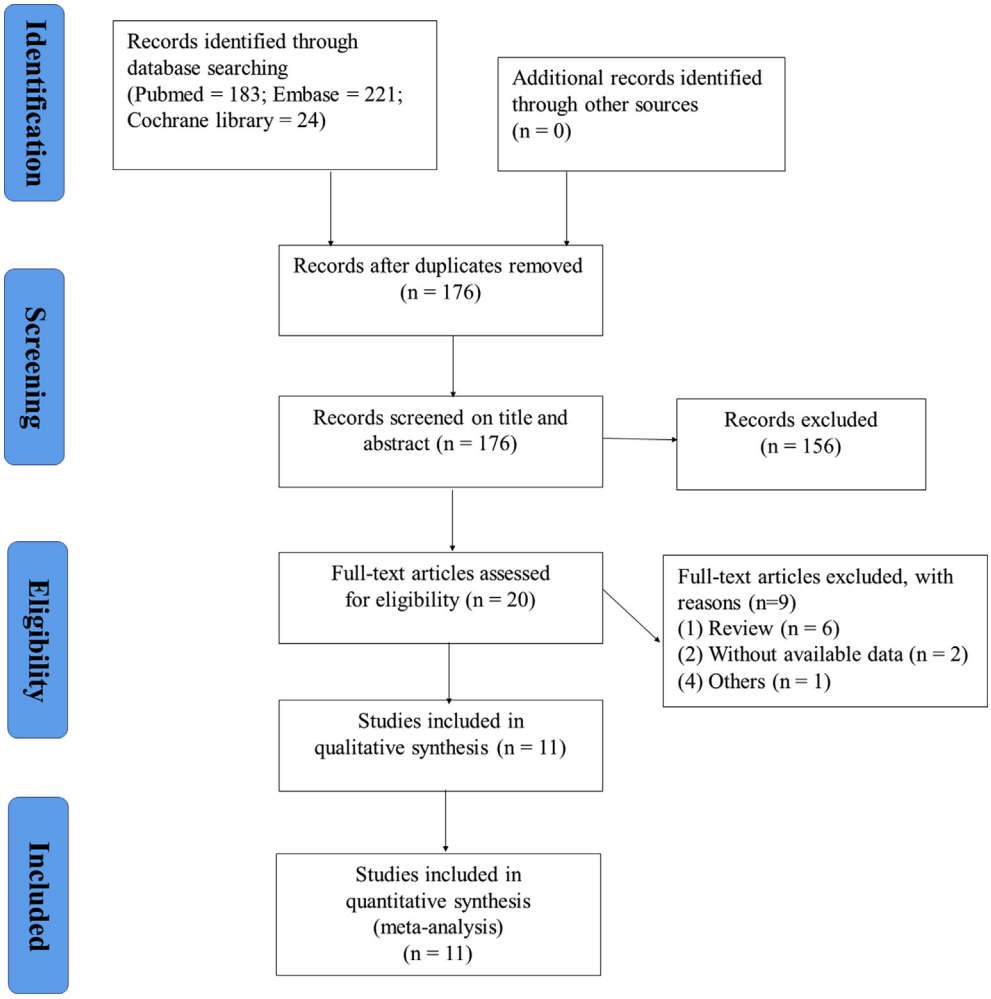

Fig. 1. Flowchart of study selection.

into account, such as screw loosening, breakage, discomfort, reoperation, and loss of reduction due to early implant removal [5–7]. More recently, the suture button fixation device, especially the TightRope, has aroused the attention of many orthopedists. This device has been reported with some potential advantages, such as allowing physiological movement while retaining the required reduction, less risk of implant removal and recurrent syndesmotic diastasis, and earlier rehabilitation [8–10]. Biomechanical investigations have demonstrated that the strength of the TightRope device is comparable to a tricortical 3.5 mm syndesmotic screw [11,12]. Despite all this, optimal surgical management is still a subject of debate in the literature [13].

Recently, several clinical trials have evaluated the effectiveness of syndesmotic screw fixation versus suture button fixation in surgical treatment of syndesmotic injuries. However, the results in these studies are inconsistent and there was no meta-analysis conducted to test which fixation method is better in the surgical treatment of syndesmotic injuries. Therefore, we conducted a systematic review and meta-analysis of published randomized controlled trials (RCTs) and cohort studies to explore the outcomes of syndesmotic screw fixation versus suture button fixation for distal tibiofibular syndesmosis injury by comparing their clinical results. The outcomes included radiographic parameters (medial clear space, tibiofibular clear space and tibiofibular overlap), functional outcomes, and complications (wound infection, local irritation or discomfort, screw loosening and screw breakage).

2. Methods

This systematic review and meta-analysis has been reported in line with PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) and AMSTAR (Assessing the methodological quality of systematic reviews) Guidelines [14]. No primary personal data were collected; therefore no additional ethical approval was required to be obtained.

2.1. Search strategy

The electronic databases of PubMed, Embase and Cochrane library were searched from the inception of the database to August 2018, without language restriction. Two independent researchers conducted literature searches using the search strategy of “tibiofibular syndesmosis” or “distal tibiofibular syndesmosis” and “screw” or “syndesmotic screw” and “TightRope” or “suture button” or “endobutton”. In addition, the reference lists of previously published randomized trials, review articles, and meta-analyses were manually searched for additional eligible studies. Related articles and reference lists were searched to avoid original miss.

2.2. Inclusion and exclusion criteria

We identified published reports that met the following inclusion criteria: (1) randomized and/or non-randomized controlled clinical studies; (2) skeletally mature patients (older than 18 years); (3)

Table 1
The characteristics of the included studies.

Study	Country	Study design	Cases (SG/CG)	Age (years)	Gender (M:F)	Suture button type	Cortical screw type	Follow-up term (months)
Andersen 2018 [1]	Norway	RCT	48/49	46/43	34:14/30:19	One TightRope	One 4.5 mm screw (4 cortices)	24
Kortekangas 2015 [8]	Finland	RCT	21/19	46.0/43.5	13:8/14:8	One TightRope	One 3.5 mm screw (3 cortices)	36 months in SG 37 months in CG
Laflamme 2015 [9]	Canada	Multicenter RCT	34/36	40.1/39.3	25:9/26:10	One TightRope	One 3.5 mm screw (4 cortices)	12
Coetzee 2009 [17]	USA	RCT	12/12	35/38	8:4/9:3	All but one had two TightRopes	Two 4.0 mm, 4.5 mm or 6.5 mm screws (4 cortices)	27.6
Cottom 2009 [13]	USA	RCT	25/25	34.7/36.7	14:11/19:6	21 cases with one suture endobutton 4 cases with two suture endobuttons	12 cases with one screw 13 cases with two screws (diameter and depth was not given)	10.8 months in SG 8.2 months in CG
Naqvi 2012 [18]	Ireland	Cohort study	23/23	42/40	17:6/16:7	16 cases with one TightRope 7 cases with two TightRopes	20 cases with one screw 3 cases with two screws (3.5 mm or 4.5 mm, 4 cortices)	30
Kocadal 2016 [5]	Turkey	Cohort study	26/26	43.3/44.8	16:10/17:9	One ZipTight	One 3.5 mm screw (4 cortices)	24
Seyhan 2015 [19]	Turkey	Cohort study	15/17	33.2/32.0	13:2/14:3	One TightRope	One 4.5 mm screw (4 cortices)	14.6
Kim 2016 [3]	Korea	Cohort study	20/24	51.3/40.5	14:6/18:6	One TightRope	One 3.5 mm screw (3 cortices)	13.4 months in SG 14.6 months in CG
Lou 2016 [20]	China	Cohort study	12/26	38.7/37.9	7:5/16:10	One endobutton	One 4.0 mm screw (3 cortices)	15.8 months in SG 14.2 months in CG
Zhang 2017 [21]	China	Cohort study	21/25	42.3/40.6	8:13/13:12	One TightRope	One 3.5 mm screw (3 cortices)	14

SG: suture button group; CG: cortical screw group; M/F: male/female; RCT: randomized controlled trial.

comparison of the outcomes of suture-button fixation and traditionally screw fixation in the treatment of distal tibiofibular syndesmosis injury. The exclusion criteria were: (1) abstracts, case reports, letters, editorials, conference articles; (2) repeated studies and data.

2.3. Selection of literature

We used the PRISMA flow diagram to select the included studies. The results of literature search were imported into the software Endnote X7. Two authors independently assessed the potentially eligible studies. Firstly, the titles and abstracts were screened to exclude the duplicated and apparently irrelevant ones or those that do not meet our inclusion criteria. Then, the remaining potential studies were full-text downloaded and reviewed. Any disagreement between the above two authors was sent and discussed with a third independent author.

2.4. Data extraction

Two reviewers independently extracted data, and the third reviewer checked the consistency between them. A standard form was used; the extracted items included the following: (1) the general study information, for example, the authors, publishing date, country, study design, case number, age, gender, suture button type, cortical screw type and follow-up term. (2) radiographic parameters, including medial clear space, tibiofibular clear space and tibiofibular overlap. (3) clinical outcomes including the time to full weight bearing and the American Orthopaedic Foot and Ankle Society (AOFAS) hindfoot scores. (4) complications, including wound infection, local irritation or discomfort, screw loosening and screw breakage. For continuous outcomes, we extracted the mean and standard deviation (SD) and the participant number was extracted. For dichotomous outcomes, we extracted the total numbers and the numbers of events of both the groups. The data in other forms were recalculated when possible to enable pooled analysis. Disagreements between two researchers were resolved by discussion. Whenever necessary, we contacted the authors of the studies for missing data and additional information.

2.5. Quality assessment of included studies

Two authors independently performed methodological quality and risk of bias assessment of the included RCTs using the Cochrane collaboration's tool [15]. The Cochrane tool assesses the following items: randomization, allocation concealment, blinding of participants, blinding of outcome assessment, incomplete outcome data, selective outcome reporting and other bias for each individual item, classifies studies into low, unclear, and high risk of bias. The methodological quality of the included retrospective cohort studies was assessed according to the Newcastle–Ottawa Scale (NOS) [16]. The NOS uses a star system which ranges from zero to nine stars. We determined studies that received a score of more than 6 stars to be high-quality.

2.6. Statistical analysis

The data were collected and input into the STATA software (version 12.0; StataCorp, College Station, TX) for meta-analysis. A random-effects model was applied when heterogeneity was detected or the statistical heterogeneity was high ($P < 0.05$ or $I^2 > 50\%$) and then further subgroup study and meta-regression analysis were performed to detect the origin of heterogeneity. Otherwise, a fixed-effects model was used ($P \geq 0.05$ or $I^2 \leq 50\%$). To test the strength and stability of the pooled results, we performed a sensitivity analysis by omitting the individual studies one by one. Moreover, the effect of publication bias was investigated by the Begg's test and Egger's test. Relative risk (RR) was calculated for dichotomous outcomes, and standard mean difference (SMD) was calculated for continuous outcomes.

Table 2
Risk of bias assessment of the RCTs.

Study	Randomization	Allocation concealment	Blinding of participants	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias
Andersen 2018 [1]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk
Kortekangas 2015 [8]	Low risk	Low risk	High risk	Unclear risk	Low risk	Low risk	Low risk
Laflamme 2015 [9]	Low risk	Low risk	High risk	Low risk	Low risk	Low risk	Low risk
Coetzee 2009 [17]	Low risk	Unclear risk	Low risk	Low risk	Low risk	Low risk	Unclear risk
Cottom 2009 [13]	Low risk	Low risk	Low risk	Low risk	Unclear risk	Low risk	Low risk

3. Results

3.1. Included studies

A total of 544 potential records were identified through PubMed (n = 183), Embase (n = 221), and Cochrane library (n = 24). After removal of duplicates, 156 articles were screened for relevance on the basis of the title and abstract. Of the 20 articles that were possibly eligible for inclusion, 9 were excluded for reasons of "the papers were review or without available data" and some other reasons (details are showed in Fig. 1**).** The remaining 11 studies (5 RCTs [1,8,9,13,17] and 6 cohort studies [3,5,18–21]) were included in this meta-analysis.

3.2. Characteristics and quality assessment of the eligible studies

The characteristics of all the 11 included studies are summarized and shown in Table 1. They were from 8 different countries (2 from China, 2 from Turkey, 2 from USA, 1 from Norway, 1 from Finland, 1 from Canada, 1 from Ireland and 1 from Korea) and all of them were published between 2009 and 2018. A total of 257 participants in the suture button (SB) group and 282 in the cortical screw (CS) group were included in this meta-analysis. The risk of bias assessment of RCTs is presented in Table 2. The methodological quality of the 6 cohort trials assessed with the NOS are illustrated in Table 3. A total of 2 studies scored 7 stars, 2 studies scored 8 stars whereas 2 studies scored 9 stars, indicating that all the 6 included cohort studies were of high quality.

3.3. Radiographic outcomes

3.3.1. Medial clear space

Four studies reported the medial clear space postoperatively [3,13,18,20]. No significant heterogeneity was found in the pooled outcomes, so a fixed-effects model was utilized in our study (χ^2 = 3.48, df = 3, I^2 = 13.7%, P = 0.32). As shown in Fig. 2, the pooled results showed no significant difference between the two groups (SMD = 0.10; 95% CI = −0.21 to 0.40; P = 0.54).

3.3.2. Tibiofibular clear space

Five studies stated the tibiofibular clear space postoperatively [3,13,18,20,21]. Based on the five studies providing available data, the pooled results showed significant heterogeneity (χ^2 = 47.8, df = 4, I^2 = 91.6%, P = 0.001), and therefore, a random-effects model was used. The available data demonstrated that the tibiofibular clear space postoperatively was not significantly different between the two groups (SMD = −0.17; 95% CI = −0.46 to 0.11; P = 0.23, Fig. 3). The causes of heterogeneity in the results were explored by subgroup analysis and meta-regression. Subgroup analyses stratified by age, study type, country and suture button type were conducted to investigate the difference between the SB and CS group (Table 4). The subgroup analyse of age showed that no significant difference was observed in either the low age group (< 40, SMD = −0.30; 95% CI = −3.41 to 2.82; P = 0.85) or the high age group (≥40, SMD = −0.04; 95% CI = −0.70 to 0.62; P = 0.91). Meanwhile, the subgroup analyse of the study type indicated that the tibiofibular clear space postoperatively was significantly wider in the CS group than that in the SB group in the RCT group (SMD = −1.89.; 95% CI = −2.55 to 1.21; P = 0.000). However, there was no statistically significant difference between the two groups in the cohort study group (SMD = 0.27.; 95% CI = −0.49 to 1.03; P = 0.48). Besides, subgroup analyse of country showed that no significant difference was found in either the China group (SMD = 0.83; 95% CI = −0.01 to 1.68; P = 0.054) or the non-China group (SMD = −0.80; 95% CI = −1.92 to 0.32; P = 0.16). Also, the subgroup analyse of the suture button type suggested that there was no obvious difference in either the TightRope group (SMD = −0.04; 95% CI = −0.70 to 0.62; P = 0.91) or the endobutton group (SMD = −0.30; 95% CI = −3.41 to 2.82; P = 0.85). In addition, the meta-regression analyses for the publication year, age of patients and sample size were performed to analyze the potential sources of inter-study heterogeneity (Fig. 4). Overall, the publication year (β = 0.32; P = 0.029; R^2 = 87.4%) and sample size (β = −0.25; P = 0.041; R^2 = 79.6%) might be the major sources of heterogeneity for the tibiofibular clear space postoperatively.

3.3.3. Tibiofibular overlap

There were five studies reporting the tibiofibular overlap postoperatively [3,13,18,20,21]. A fixed-effects model was applied because no significant heterogeneity was found between the studies (χ^2 = 5.44, df = 4, I^2 = 26.5%, P = 0.25). The results indicated that there was no statistically significant difference regarding the tibiofibular overlap postoperatively between the two groups (SMD = 0.02; 95% CI = −0.25 to 0.29; P = 0.88, Fig. 5).

3.4. Time to full weight bearing

Three studies [13,18,21] described the time to full weight bearing. The pooled results showed no significant heterogeneity (χ^2 = 0.10, df = 2, I^2 = 0%, P = 0.95), and therefore, a fixed-effects model was used. The available data demonstrated that the time to full weight bearing in the SB group was significantly earlier than that in the CS group (SMD = −0.72; 95% CI = −1.06 to −0.38; P = 0.000, Fig. 6).

3.5. AOFAS score

3.5.1. AOFAS score at 3rd months postoperatively

The results of a pooled statistical analysis of three studies [9,19,21] are shown in Fig. 7 and indicate that there was no statistically significantly heterogeneity (χ^2 = 1.13, df = 2, I^2 = 0%, P = 0.57). The results revealed that the AOFAS score at 3rd months postoperatively was significantly higher in the SB group than that in the CS group (SMD = 0.57; 95% CI = 0.23 to 0.91; P = 0.001, Fig. 7).

3.5.2. AOFAS score at 6th months postoperatively

Five studies reported the AOFAS score at 6th months postoperatively [1,9,17,19,21]. No significant heterogeneity was found in the pooled outcomes, so a fixed-effects model was utilized in our study (χ^2 = 5.90, df = 4, I^2 = 32.2%, P = 0.21). As shown in Fig. 8, the pooled results showed that the AOFAS score at 6th months postoperatively of the SB group was significantly higher than that in the CS group (SMD = 0.35; 95% CI = 0.10 to 0.59; P = 0.006, Fig. 8).

Table 3
Quality assessment according to the Newcastle-Ottawa scale.

Study	Selection				Comparability	Outcome			Total score
	Exposed cohort	Nonexposed cohort	Ascertainment of exposure	Outcome of interest		Assessment of outcome	Length of follow-up	Adequacy of follow-up	
Naqvi 2012 [18]	*	*	*	*	**	*	*	*	9
Kocadal 2016 [5]	*	*	*	*	*	*	*	*	8
Seyhan 2015 [19]	*	*	–	*	**	*	*	*	8
Kim 2016 [3]	*	*	–	–	**	*	*	*	7
Lou 2016 [20]	*	*	*	–	**	*	*	–	7
Zhang 2017 [21]	*	*	*	*	**	*	*	*	9

Risk of bias was assessed with use of the Newcastle–Ottawa Scale. "*" means a score of 1; "**" means a score of 2; the total score of this scale is 9. A higher overall score corresponds to a lower risk of bias; a total score of 5 or less indicates a high risk of bias.

3.5.3. AOFAS score at 12th months postoperatively

There were seven studies reporting the AOFAS score at 12th months postoperatively [1,3,9,17,19–21]. A fixed-effects model was applied because no significant heterogeneity was found among the studies (χ^2 = 9.92, df = 6, I^2 = 39.5%, P = 0.13). The results indicated that the AOFAS score at 12th months postoperatively of the SB group was obviously higher than that in the CS group (SMD = 0.44; 95% CI = 0.22 to 0.66; P = 0.000, Fig. 9).

3.5.4. AOFAS score at 24th months postoperatively

Four studies [1,5,17,18] described the AOFAS score at 24th months postoperatively. However, we found that there was a significant heterogeneity between the two groups (χ^2 = 10.84, df = 3, I^2 = 72.3%, P = 0.013). Therefore, we used a random-effects model and the results suggested that the AOFAS score at 24th months postoperatively of the SB group was markedly higher than that in the CS group (SMD = 0.55; 95% CI = 0.003 to 1.10; P = 0.049, Fig. 10).

3.6. Complications

Complications including wound infection, local irritation or discomfort, screw loosening and screw breakage were reported. Meta-analysis showed that there was a significant difference between the two groups (RR = 0.48, 95% CI = 0.31 to 0.76, P = 0.001, Fig. 11). However, the heterogeneity among the studies was very low (χ^2 = 23.60, df = 16, I^2 = 32.2%, P = 0.10).

3.6.1. Wound infection

Four articles [1,5,8,17] provided the relevant data. The summarized estimate of effect size did not show a statistically significant difference between the compared groups (RR = 1.84, 95% CI = 0.51 to 6.60, P = 0.35, Fig. 11A). At the same time, no significant statistical heterogeneity was present (χ^2 = 0.61, df = 3, I^2 = 0%, P = 0.89).

3.6.2. Local irritation or discomfort

Data extracted from four studies [1,5,8,19] substantiated that no statistically significant difference was found between the two groups (RR = 1.45, 95% CI = 0.62 to 3.39 P = 0.49, Fig. 11B), with an absence of statistical heterogeneity (χ^2 = 3.71, df = 3, I^2 = 19.2%, P = 0.29).

3.6.3. Screw loosening

Two studies [1,8] provided data regarding screw loosening. The pooled estimate of information showed that the CS group had a significantly high rate of screw loosening than the SB group (RR = 0.13, 95% CI = 0.02 to 0.98, P = 0.048, Fig. 11C), and statistical heterogeneity was not present (χ^2 = 0.16, df = 1, I^2 = 0%, P = 0.69).

3.6.4. Screw breakage

Data regarding the incidence of screw breakage was reported in seven studies [1,3,5,8,9,17,20]. The pooled data suggested that the rate of screw breakage was observably higher in the CS group than the SB group (RR = 0.12, 95% CI = 0.04 to 0.34, P = 0.000, Fig. 11D), with an absence of statistical heterogeneity (χ^2 = 3.39, df = 6, I^2 = 0%, P = 0.76).

3.7. Publication bias and sensitivity analysis

Begg's funnel plot and Egger's test (Fig. 12A–F) were used to assess the potential publication bias of the medial clear space, tibiofibular overlap and tibiofibular clear space postoperatively for the studies included in this meta-analysis. The symmetrical shape of the funnel plots and the P values from the Begg's and Egger's tests indicated that there was no significant publication bias for the medial clear space, tibiofibular overlap and tibiofibular clear space postoperatively (P = 0.806 and P = 0.826, P = 0.308 and P = 0.141, P = 0.806 and P = 0.445,

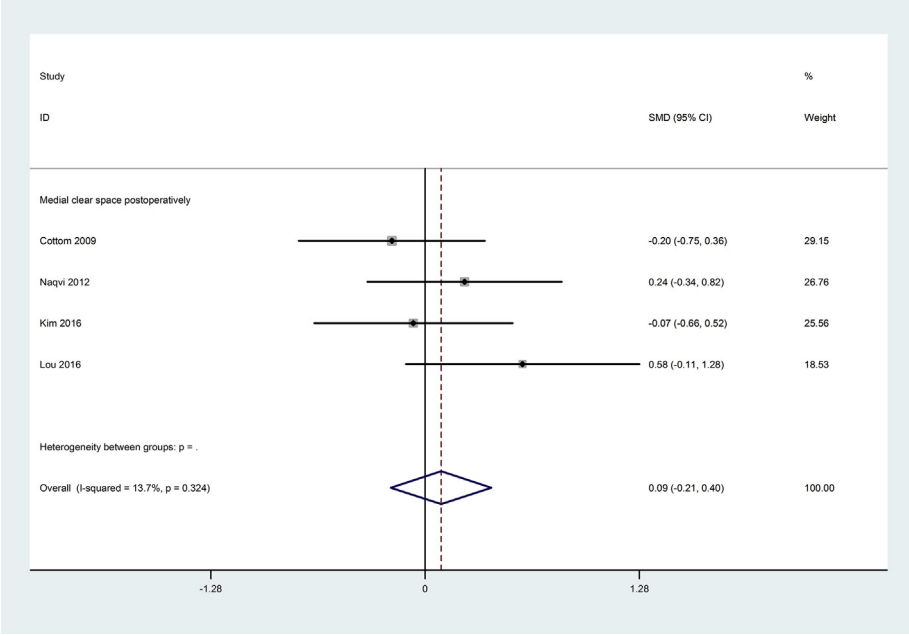

Fig. 2. Forest plot showing medial clear space postoperatively.

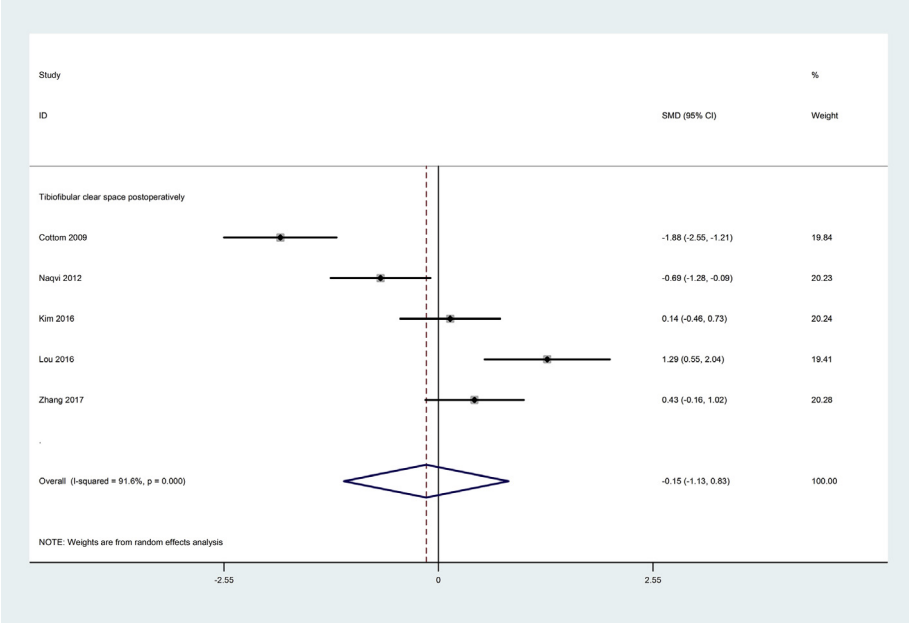

Fig. 3. Forest plot showing tibiofibular clear space postoperatively.

respectively).

To determine the influence of each of the studies on the pooled SMDs for medial clear space, tibiofibular overlap and tibiofibular clear space postoperatively and to verify the robustness of our results, sensitivity analysis was performed by omitting one study at a time and calculating the pooled SMDs for the remaining studies. The results of the sensitivity analysis indicated that no significant effect on pooled SMDs was observed after excluding any single study, suggesting that the results of this meta-analysis were relatively robust (Fig. 13A–C).

4. Discussion

Syndesmotic injuries are commonly encountered clinical conditions since they occur in isolation or associated with fibular fractures [22,23]. Recently, many controversies have emerged in various aspects of syndesmotic fixation [24]. The current gold standard to treat syndesmotic injuries is syndesmotic screw fixation. However, suture button technique has raised more interest over the last decade. To our knowledge, no high-quality meta-analysis has been reported to analyse a high level clinical evidence in syndesmotic screw fixation versus suture button fixation for distal tibiofibular syndesmosis injury. The present study summed up high-quality studies after strict screening to find reliable outcomes.

One of the shortcomings of syndesmotic screw fixation is the need for screw removal. However, the need for conventional syndesmotic screw removal and the time to screws removal are still controversial. A second operation for implant removal could lead to infections, with an increased cost to the patient, missed work days, or other complications [25,26]. Routine removal of the syndesmosis screws has been reported with the additional cost for a second procedure and the potential of

Table 4
Subgroup analysis for tibiofibular clear space postoperatively.

Stratifed analysis	Number of study	Cases (SG/CG)	I^2(%)	Heterogeneity (P)	SMD	95% CI	Z test (P)
Age (years)							
≥40	3	64/72	72.9	0.025	−0.039	−0.695 to 0.618	0.908
< 40	2	37/51	97.4	0.000	−0.298	−3.412 to 2.815	0.851
Study type							
RCT	1	25/25	–	–	−1.882	−2.553 to 1.212	0.000
Cohort study	4	76/98	82.8	0.001	0.273	−0.483 to 1.028	0.479
Country							
China	2	33/51	68.6	0.074	0.830	−0.014 to 1.675	0.054
Non-China	3	66/70	89.8	0.000	−0.802	−1.920 to 0.317	0.160
Suture button type							
TightRope	3	64/72	72.9	0.025	−0.039	−0.695 to 0.618	0.908
Endobutton	2	37/51	97.4	0.000	−0.298	−3.412 to 2.815	0.851

SG: suture button group; CG: cortical screw group; RCT: randomized controlled trial.

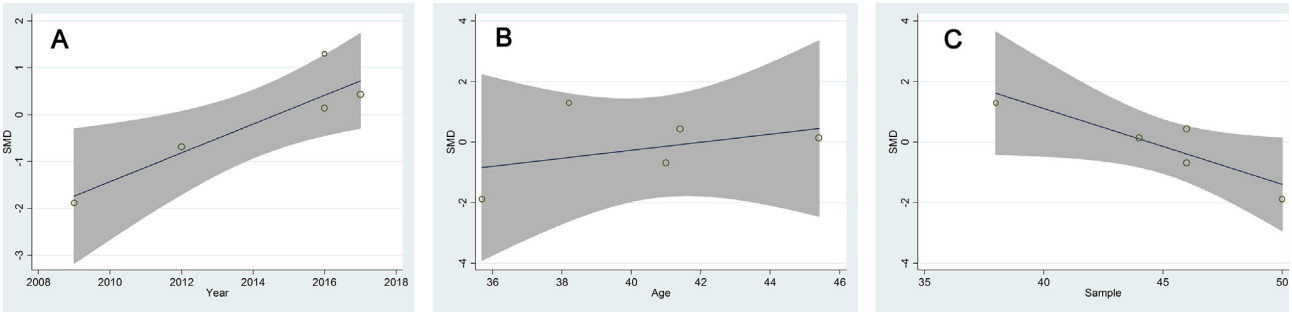

Fig. 4. Meta-regression analysis of tibiofibular clear space postoperatively for publication year, age of patients and sample size.

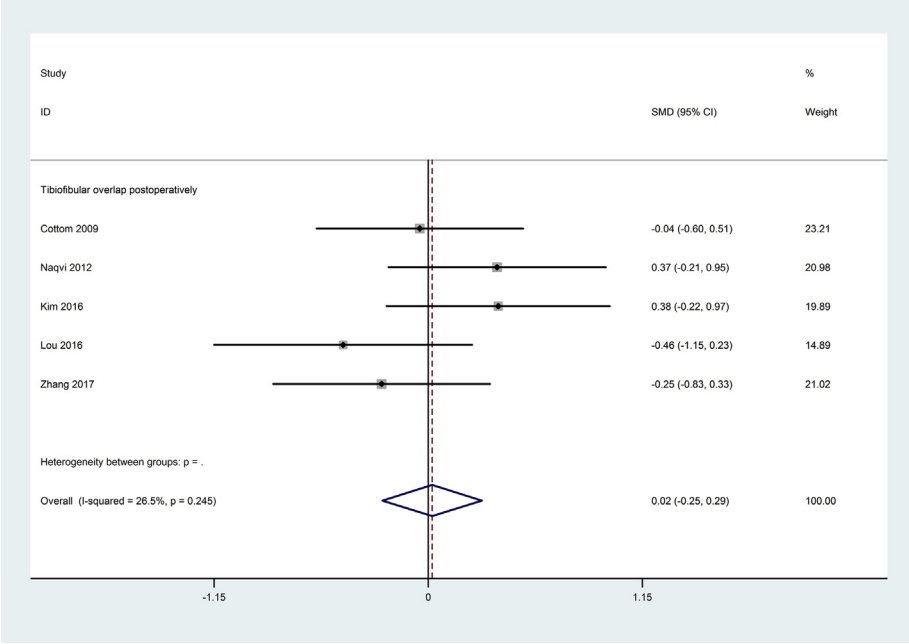

Fig. 5. Forest plot showing tibiofibular overlap postoperatively.

complications [26,27]. Besides, a previous study has demonstrated that early screw removal before ligamentous healing is accompanied with the risk of developing recurrent syndesmotic diastasis [28]. In a previously published review, wound infection was observed in 9.2% of the cases and recurrent syndesmotic diastasis in 6.6% after removal of syndesmosis screws [28]. A recent publication demonstrated no favorable outcome when electively removing syndesmosis screws compared to leaving the screws in place [29]. Despite local symptoms may develop if the screw is not removed and remains unbroken [30], routine removal of the syndesmosis screw or not is still debatable, suggesting the need for additional high-quality studies to compare routine removal and removal on indication. Consequently, the lack of screws when using the suture button technique, is theoretically accompanied with no need of implant removal, less risk of hardware pain and quicker mobility as there is no risk of screw breakage. However, the removal of the suture button device was described in several studies with varying percentages which range from 0% to 12% in the studies included in this meta-analysis. The main reason of implant removal was implant irritation.

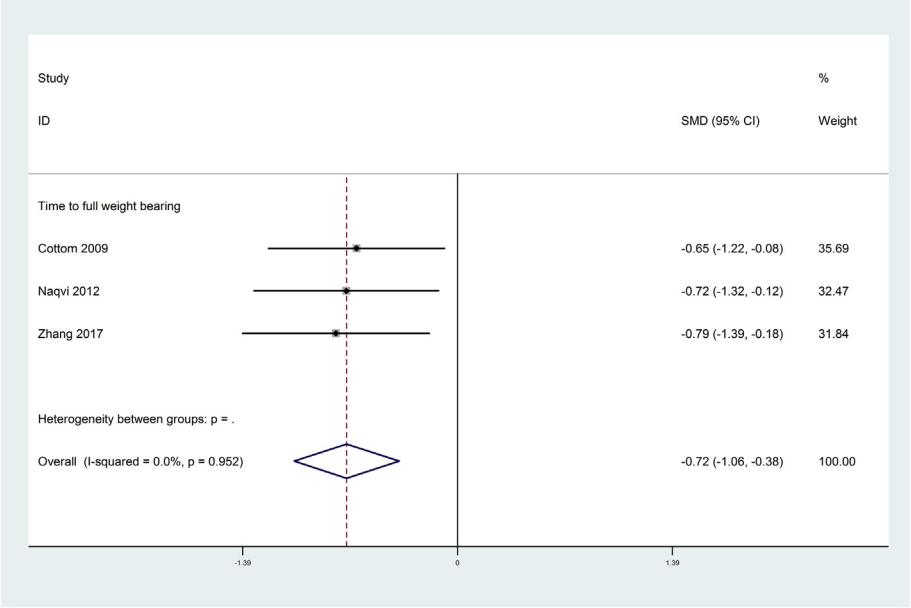

Fig. 6. Forest plot showing the time to full weight bearing.

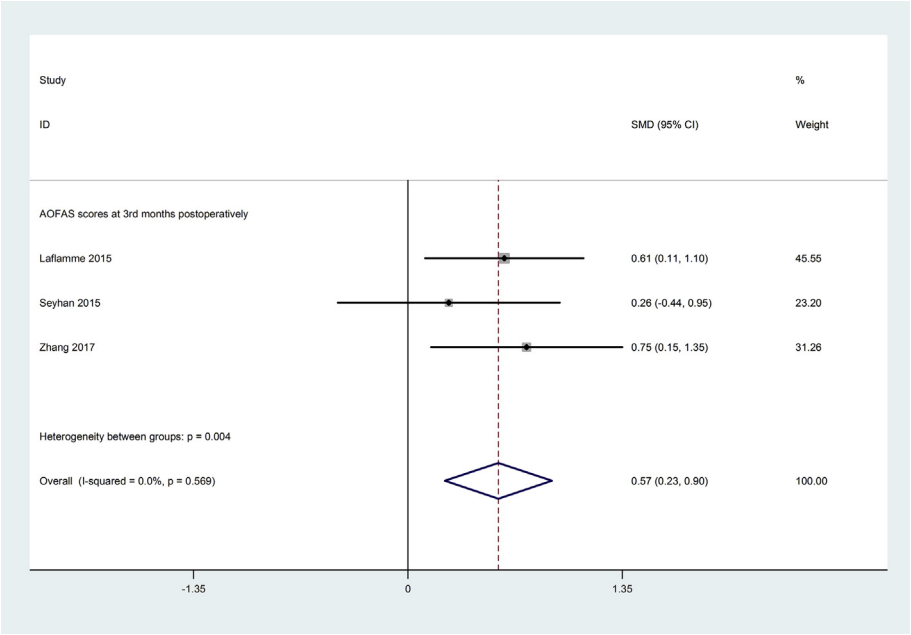

Fig. 7. Forest plot showing AOFAS scores at 3rd months postoperatively.

Every publication in this meta-analysis, when reporting on device removal, showed a lower removal rate in the suture button group compared to the syndesmotic screw group. One study even described a significant lower reoperation rate in the TightRope group compared to the syndesmotic screw group (6% vs. 34%, P = 0.006) [9]. Naqvi et al. [31] demonstrated that after a slight modification (embedding of the knot at the lateral side) of the surgical technique in 31 of the 49 patients, resulted in no removal of the TightRope device.

The dynamic nature of the suture button device theoretically could allow some degree of physiologic micromovement of the syndesmosis, leading to earlier return to full weight-bearing and better objective range of motion measurements. Nevertheless, screw fixation does not allow normal motion of the syndesmosis during healing because the screw may break or loose. Thornes et al. [32] noted that patients in the suture button group were kept on no weight bearing for a significantly shorter mean time than patients in the syndesmotic screw group (4.1 weeks versus 6.3 weeks, P = 0.01), with no patients in the suture button group required implant removal. This was supported by our meta-analysis demonstrating that the time to full weight bearing in the suture button group was significantly earlier than that in the cortical screw group (P = 0.000). Degroot et al. [33] reported an average time to full weight bearing of 5.7 weeks using TightRope, with no signs of implant failure or residual displacement at a follow-up of 20 months. Cottom et al. and Thornes et al. both demonstrated that fast full weight-bearing could bring accelerated rehabilitation [13,32]. In this meta-analysis, we found that the AOFAS scores at the 3rd, 6th, 12th and 24th months postoperatively were significantly higher in the suture button group than that in the cortical screw group (P = 0.001, P = 0.006, P = 0.000 and P = 0.049 respectively), which may attribute to the earlier time to full weight bearing in the suture button group.

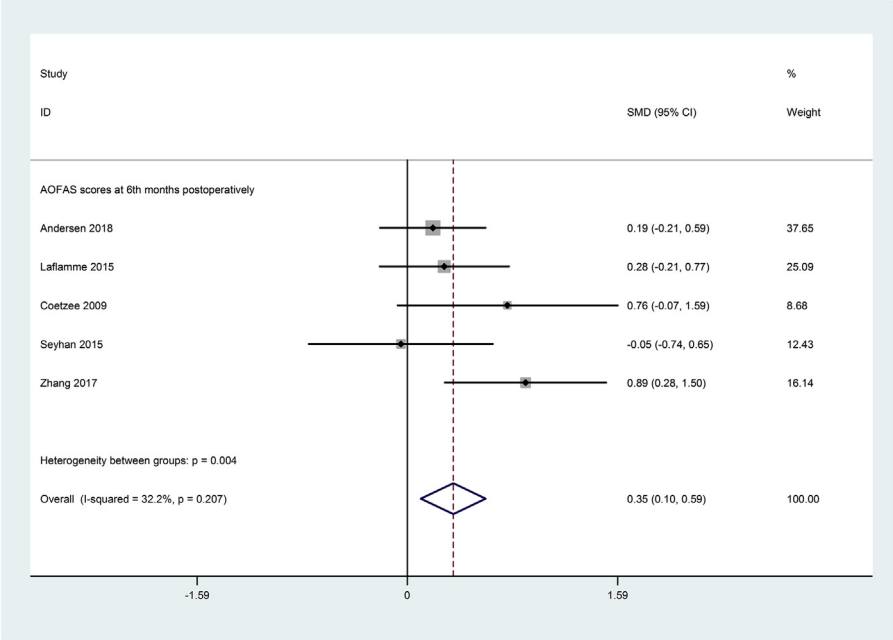

Fig. 8. Forest plot showing AOFAS scores at 6th months postoperatively.

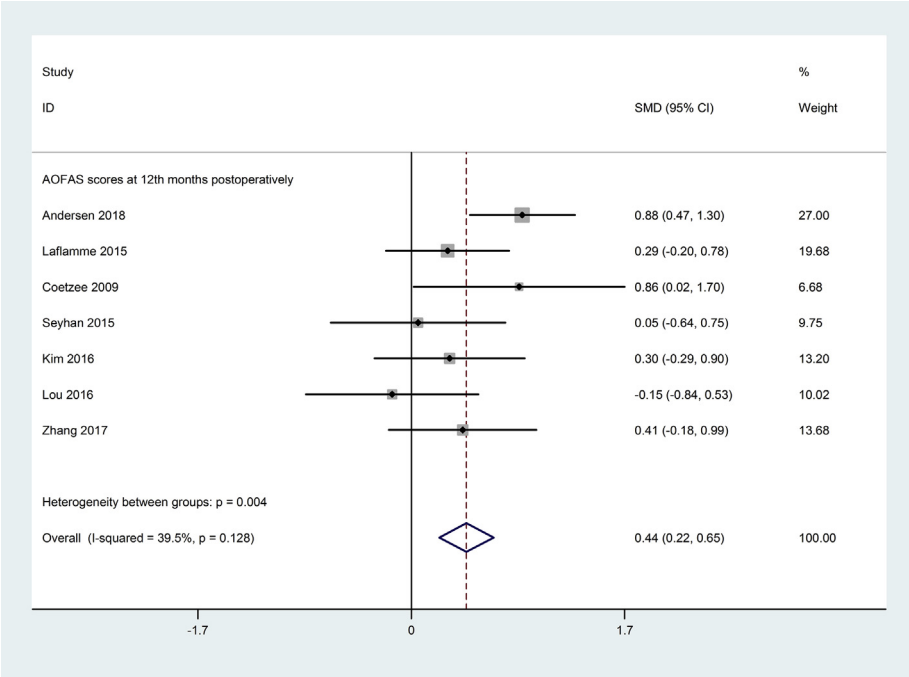

Fig. 9. Forest plot showing AOFAS scores at 12th months postoperatively.

Interestingly, some included studies reported that patients in the dynamic fixation group seemed to present with less pain and discomfort which may also contribute to earlier full weight bearing [9,17].

The main complications reported in the included studies were wound infection, local irritation or discomfort, screw loosening and screw breakage. In our meta-analysis, the suture button fixation group showed a significantly lower rate of post-operative complications than the screw fixation group (P = 0.001). Regarding the suture button fixation group, some literature suggested with modifications in the surgical procedure, such as a posterior short knot and/or reaming the posterior aspect of fibula, were useful to reduce the incidence rates of infection, irritation and discomfort [31,34]. The rates of screw loosening and screw breakage were observably higher in the screw fixation group than the suture button fixation group (P = 0.048 and P = 0.000 respectively), which led to a higher rate of re-operation, thus causing not only a higher risk of complications but also more costs. Fantry et al. [35] described 3 patients with the TightRope fixation for syndesmotic instability who developed deep infection. They considered that braided sutures within the suture button devices could provide an environment advantageous to the development of infection across the syndesmotic fixation tract. The sign of suture button migration or osteolysis of the TightRope tract should prompt an infectious workup and the need of implant removal. When there is concern for infection, it is essential to remove both the metallic buttons and the entirety of the

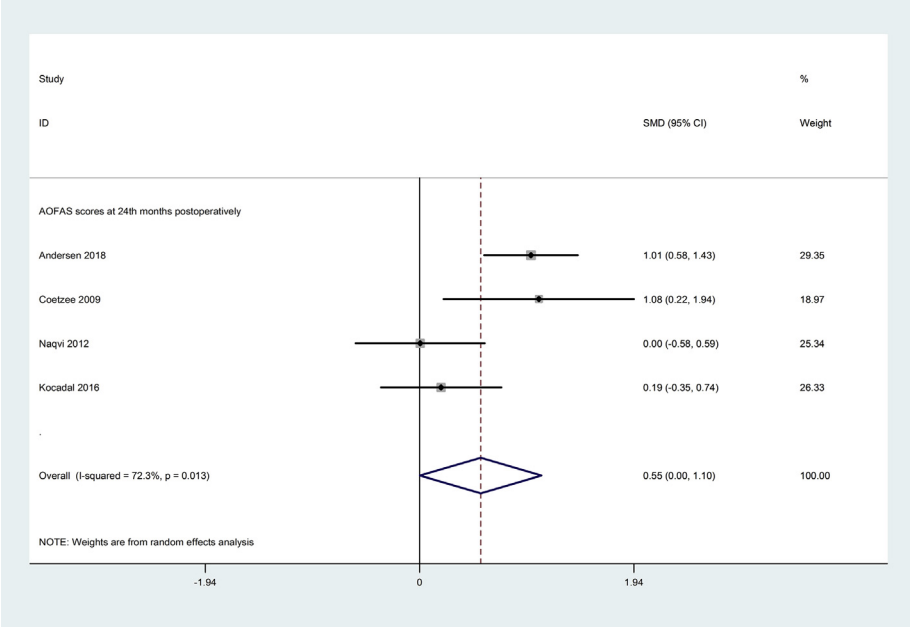

Fig. 10. Forest plot showing AOFAS scores at 24th months postoperatively.

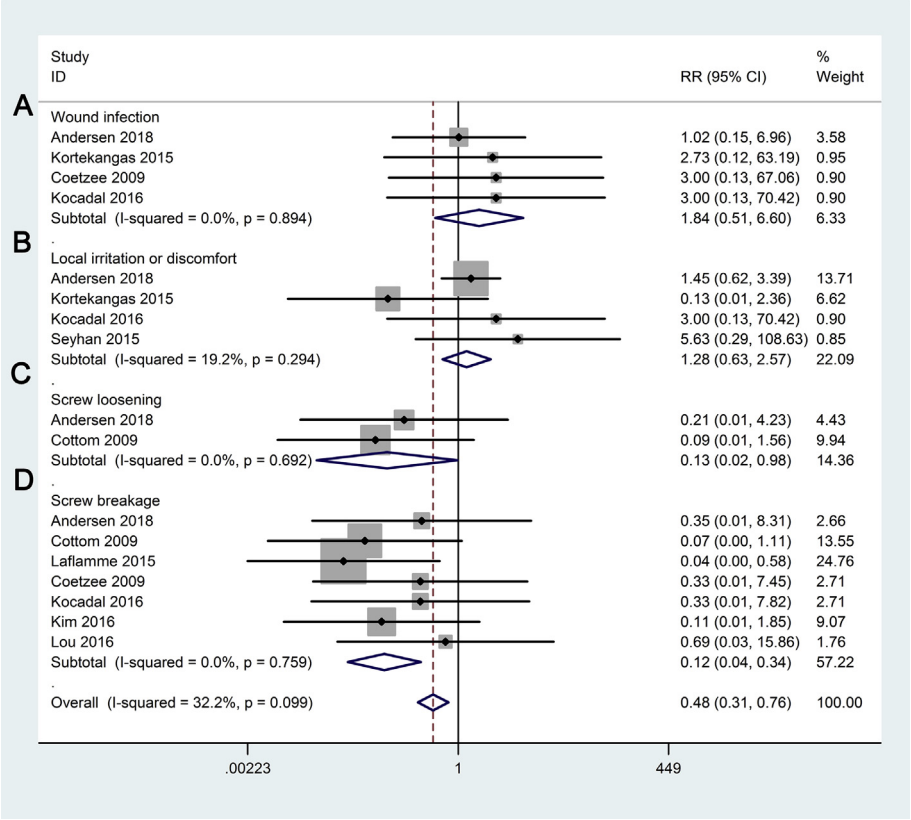

Fig. 11. Forest plot showing complications wound infection (A), local irritation or discomfort (B), screw loosening (C) and screw breakage (D).

sutures to prevent further infection.

The strengths of this meta-analysis include the clear definition of the research question to reduce bias in the selection of the studies, adherence to an explicit research protocol that was developed prior to the analysis, the comprehensive literature search, consensus between the two reviewers with the entry data elements, and a quality control review of all results. Most of our included studies in this meta-analysis are RCTs, which therefore overcomes the shortcomings of recall or selection bias in non-randomized studies. The methodological quality of the included cohort studies is high (a total of 2 studies scored 7 stars, 2 studies scored 8 stars whereas 2 studies scored 9 stars) according to the NOS. No publication bias was found in our meta-analysis and sensitivity analysis indicating that the results of this meta-analysis are relatively robust.

Nonetheless, some limitations in the present meta-analysis should be recognized. (1) Only 11 articles with small sample sizes were

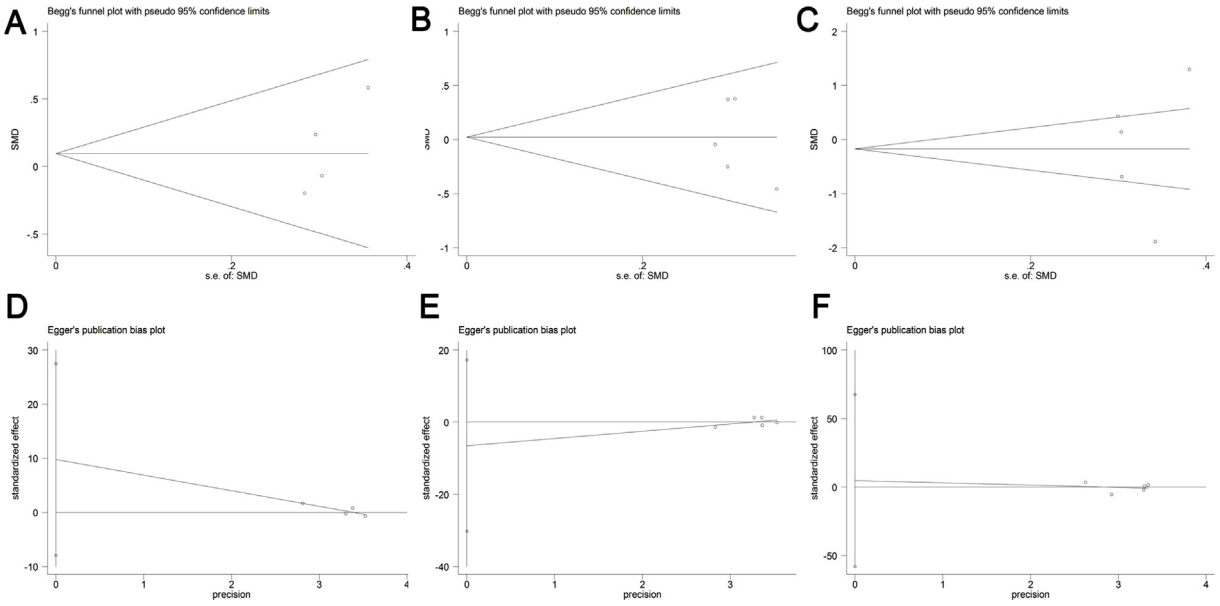

Fig. 12. Begg's funnel plot (A–C) and Egger's test (D–F) of medial clear space, tibiofibular overlap and tibiofibular clear space postoperatively.

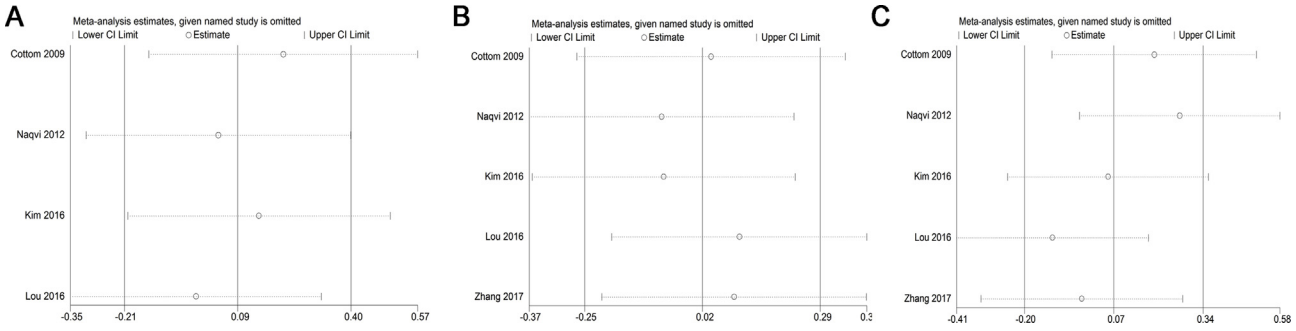

Fig. 13. Sensitivity analysis for medial clear space, tibiofibular overlap and tibiofibular clear space postoperatively.

included in the study, and six of the included studies were cohort studies, which might lower the evidence level. (2) The duration of the follow-up of the included studies was variable. (3) The foot functional score is an important parameter. But the type of foot functional score varied, which may generate heterogeneity. We suggest that larger sample sizes and multicentric high-quality randomized controlled trials could be carried out to evaluate the outcomes of syndesmotic screw fixation versus suture button fixation for distal tibiofibular syndesmosis injury in the future. Despite these limitations, this meta-analysis provides evidence that suture button fixation could achieve significant higher AOFAS scores with a lower rate of postoperative complications and earlier time to full weight bearing.

5. Conclusion

In conclusion, suture button fixation for distal tibiofibular syndesmosis injury might be superior to syndesmotic screw fixation with better functional scores. Meanwhile, suture button fixation had a lower rate of post-operative complication and earlier return to work. Taking the heterogenicity and small sample sizes into consideration, more high-quality RCTs are required in demonstrating the benefits of suture button fixation in the treatment of distal tibiofibular syndesmosis injury.

Ethical approval

All analyses were based on previous published studies; thus, no ethical approval is required.

Sources of funding

None.

Author contribution

Wenhao Zheng designed the study and Hua Chen wrote this manuscript. Linzhen Xie and Huanguang Xie searched database and reviewed studies. Wenhao Zheng and Chunhui Chen collected and analyzed data. All of the authors have read and approved the final manuscript.

Conflicts of interest

None.

Research registry number

The Unique Identifying Number (UIN) from the Research Registry of the study is reviewregistry603

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Wenhao Zheng

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijsu.2018.11.007.

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