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Early Versus Delayed Mobilization Post-Operative Protocols for Primary Lateral Ankle Ligament Reconstruction: A Systematic Review and Meta-Analysis

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ABSTRACT

Introduction. Lateral ankle instability represents a common orthopaedic diagnosis. Nonoperative treatment through focused physical therapy provides satisfactory results in most patients. However, some patients experience persistent chronic lateral ankle instability despite appropriate nonoperative treatment. These patients may require stabilization, which can include primary lateral ligament reconstruction with a graft to restore ankle stability. Optimal post-operative rehabilitation of lateral ankle ligament reconstruction remains unknown, as surgeons vary in how long they immobilize their patients post-operatively. The aim of this review was to provide insight into early mobilization (EM) versus delayed mobilization (DM) post-operative protocols in patients undergoing primary lateral ankle ligament reconstructions to determine if an optimal evidence-based post-operative rehabilitation protocol exists in the literature.

Methods. Following PRIMSA criteria, a systematic review/meta-analysis using the PubMed/Ovid Medline database was performed (10/11/1947 - 1/28/2020). Manuscripts that were duplicates, non-lateral ligament repair, biomechanical, and non-English language were excluded. Protocols were reviewed and divided into two categories: early mobilization (within three weeks of surgery) and delayed mobilization (after three weeks of surgery). Functional outcome scores (American Orthopedic Foot and Ankle Society Score (AOFAS), Karlsson scores), radiographic measurements (anterior drawer, talar tilt), and complications were evaluated using weighted mean differences (pre- and post-operative scores) and mixed-effect models.

Results. After our search, twelve out of 1,574 studies met the criteria for the final analysis, representing 399 patients undergoing lateral ankle reconstruction. Using weighted mean differences the DM group showed superior AOFAS functional scores compared to the EM group (28.0 (5.5) vs. 26.3 (0.0), respectively; $p < 0.001$), although sample size was small. Conversely, no significant differences were found for Karlsson functional score ($p = 0.246$). With regards to radiographic outcome, no significant differences were observed; anterior drawer was $p = 0.244$ and talar tilt was $p = 0.937$. A meta-analysis using mixed-effects models confirmed these results, although heterogeneity was high.

Conclusions. While there are some conflicting results, the findings indicated the timing of post-operative mobilization made no difference in functional outcomes or post-operative stability for patients undergoing lateral ankle ligament reconstruction. Because heterogeneity was high, future studies are needed to evaluate these protocols in less diverse patient groups and/or more consistent techniques for lateral ankle ligament reconstruction. ***Kans J Med 2021;14:141-148***

INTRODUCTION

Lateral ankle instability represents a common orthopaedic injury that can be treated conservatively with good results.[1] However, when lateral ligamentous instability is severe or persists after nonoperative management, surgical management may be indicated. The Brostrom-Gould procedure is the gold standard for repair of lateral ligamentous injuries of the ankle.[2,3] However, in instances where the Brostrom procedure fails, there is insufficient residual anterior talofibular or calcaneofibular ligaments, large athletes or patients exhibit generalized ligamentous laxity, and reconstruction may be indicated.[4,5] Anatomic reconstruction with a graft has shown to be biomechanically similar to the native lateral ligamentous complex and has led to satisfactory outcomes with regards to function and patient satisfaction.[6,7]

However, lateral ankle ligament reconstruction is not without complications. Patients may suffer from graft site morbidity, pain, stiffness, muscle disuse atrophy, or graft failure. Several of these complications may be minimized by optimal post-operative rehabilitation protocols. Many surgeons chose to immobilize patients following their surgery to protect the reconstruction and avoid graft failure. Unfortunately, with prolonged immobilization, rates of stiffness and atrophy are likely to increase.[8,9]

There have been studies investigating outcomes after reconstruction that have allowed early range of motion and studies that have allowed late range of motion. However, there are no randomized studies that have compared early range of motion to late range of motion in the same study. Therefore, the optimal post-operative rehabilitation protocol remains unknown.

The aim of this review was to provide insight into early and delayed mobilization protocols in patients undergoing lateral ankle ligament reconstruction with a graft. We hypothesized that early mobilization post-operative rehabilitation protocols would have equivalent outcomes compared to delayed mobilization post-operative rehabilitation protocols without an increase in complications.

METHODS

Search Strategy and Study Selection. This study followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[10] Since this study was a systematic review/meta-analysis of published studies, institutional review board approval was not required. A systematic literature review/meta-analysis was conducted on May 6, 2020 using the PubMed/Ovid MEDLINE database; dates of publication were limited to 10/11/1947 through 1/28/2020. The main keywords "lateral ankle reconstruction" and "lateral ankle ligament reconstruction" were used in the electronic search. Two inves-

tigators performed a separate, manual study selection from this list to exclude repetitions and to select those specifically related to the discussed item. In case of any discrepancies in article selection between the two investigators, a third investigator was involved as the tie-breaking vote. Only studies published in the English language were included in this study. The reference lists of all the articles selected were screened for additional articles.

Eligibility Criteria. Clinical trials that included the following criteria were considered eligible: published in the English language; patients undergoing primary lateral ankle reconstruction; a follow-up of at least one year; reported measured outcomes (American Orthopedic Foot and Ankle Society Score (AOFAS), Karlsson score, and total complications), along with post-operative rehabilitation protocols. Exclusion criteria were studies involving the following procedures: lateral ankle ligament repair, suture tape augmentation (internal brace fixation), revision ligament repair or reconstruction; concomitant talar chondral or osteochondral repair or reconstructive procedures; concomitant peroneal tendon procedures (peroneal tendon debridement, tendon repair); concomitant superior peroneal retinaculum repair; concomitant treatment of hindfoot or forefoot pathology (calcaneal osteotomy for cavovarus reconstruction, subtalar arthrodesis); and/or syndesmosis repair or ankle fracture open reduction and internal fixation (ORIF).

Data Extraction and Quality Appraisal. Post-operative protocols in each article were reviewed and divided into two categories: early mobilization (EM), defined as allowing range-of-motion therapy and/or weight-bearing within three weeks of date of surgery, and delayed mobilization (DM), defined as permitted ankle range of motion after three weeks from date of surgery. Talar tilt, anterior drawer, functional outcome scores (AOFAS, Karlsson scores), and total complications of both populations were recorded. Assessment of methodological quality was conducted by two investigators utilizing the Cochrane Collaboration tool.[11] As before, a third investigator was enlisted to arbitrate disagreements.

Statistical Analysis. Descriptive statistics were conducted using aggregate data from all studies. Categorical data were summarized with frequencies and percentages, and continuous variables with means and standard deviations. Statistical tests were weighted for sample size. To compare early versus delayed mobilization treatment, Levene's test, t-test, and 95% confidence intervals of differences were conducted (equal variances were not assumed in all cases). Analyses were conducted in IBM™ SPSS™ Statistics, version 26, using two-sided tests with an alpha level of 0.05. Because multiple tests were conducted, Bonferroni correction was used to indicate the level of significance: 0.05/13 tests = 0.0038.

Meta-analyses were conducted in RStudio®, using R version 4.0.1, following Harrer, Cuijpers, Furukawa, and Ebert, 2019.[12] Mixed-effects models (random-effects within subgroups and fixed-effects between subgroups) were utilized. The meta-analytical method included the inverse variance method, Sidik-Jonkman estimator for tau^2, Hartung-Knapp adjustment, and Heges's g (bias corrected standardized mean difference). These methods were chosen because the number of studies were few and heterogeneity may be problematic. For each model, mobility measures (delayed vs. early) were compared.

A total of four models were developed: two for the functional measure (AOFAS and Karlsson scores) and two for the radiographic measure (anterior drawer and talar tilt). In addition, a sensitivity analysis was conducted for anterior drawer because mean values differed substantially for the Lee et al. 2018 study.[13]

Results from the quality bias analysis can be found in Figure 6. From our literature review, only one paper evaluated for both EM and DM in their study; however, this was only level III evidence.[14] Thus, the majority of studies included in our analysis were case series, which may skew our study results due to risk of overall bias.

RESULTS

Study Selection. The initial PubMed/Ovid MEDLINE database search identified 1,580 articles; other sources identified 264 (Figure 1). Based on a review of the abstracts, duplicates were removed, 773 articles were excluded for non-lateral ligament repair, and 538 were either non-human studies or not in English. A total of 263 articles were screened using the full-text and 251 were excluded. The result was 12 articles to be analyzed. Of these, two studies utilized early mobilization for their post-op rehabilitation protocol[14,15] and 11 studies utilized delayed mobilization.[8,9,13,14,16-22] One study utilized both early and delayed mobilization.[14]

Study Characteristics. Table 1 shows the demographic characteristics of the 12 studies that met the inclusion criteria. A total of 399 patients had undergone primary lateral ligament reconstruction with at least a one-year follow-up. The DM group included 362 patients; 219 males and 123 females. The EM group included 37 (9%) patients; 23 males and 14 females. Of those categorized as DM, two studies were grouped into two separate categories (Lee et al.[13] and Xu et al.[19]). One study (Miyamoto et al.[14]) evaluated both EM and DM post-operative protocols. Thus, the total number of studies shown for DM was 11 and 2 for EM.

Participants were categorized as either athletes or general population (Table 2). Note that athletes tended to be younger than the general population for both DM and EM, although the sample size was smaller for those classified as athletes, and four studies did not report the type of patient.

Table 3 shows a comparison of pre- and post-surgical outcomes by mobility timing. Averages were weighted by the sample size. Significant differences were observed for age; participants tended to be older for DM compared to EM (29.2 (3.6) vs. 27.1 (0.8), respectively; $p < 0.001$). Regarding differences between pre- and post-operation scores, only AOFAS was significant: mean DM was 28.0 (5.5) vs. mean EM of 26.3 (0.0); $p < 0.001$. However, only one study (Wang et al.[15]) was observed for early mobility and the sample size was small, $n = 19$.

Not shown in the tables are studies by reconstruction technique or complications. All but one study[8] reported using allograft or autograft or compared both. There were 159 patients (five studies) with allograft and 202 patients (seven studies) with autograft reconstruction.

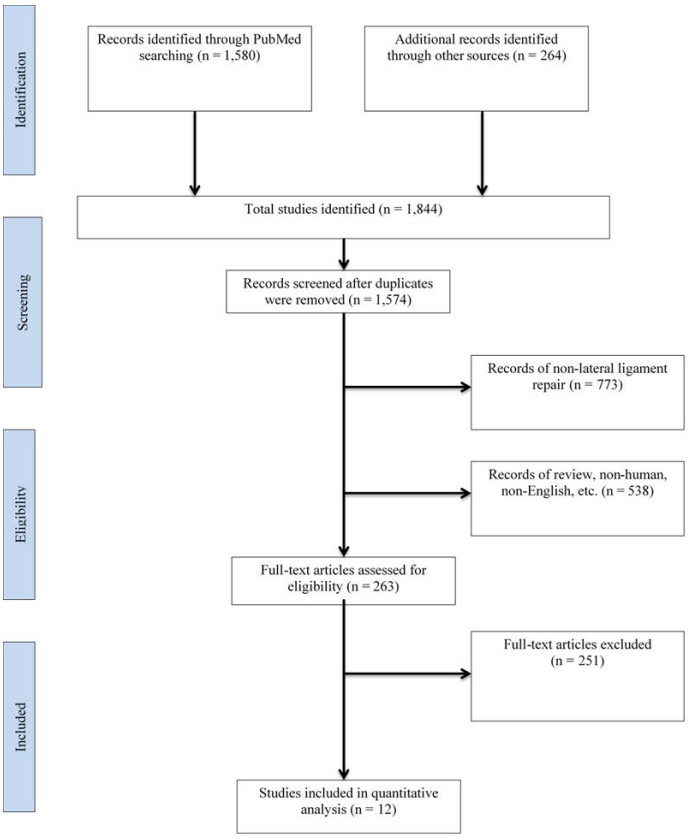

Figure 1. Detailed flowchart of the literature search using PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) criteria.

Table 1. Studies by mobility timing.

Author	Year	n	Males	Females	Age range	Level of evidence	Range of follow-up (months)	Average follow-up (months)
Delayed mobility								
Giannini et al.[8]	2014	38	25	13		IV	24-96	60
Lee et al.[13]	2018							
Non-Smokers		47	30	17	16-59		12-68	18.8
Smokers		23	20	3	19-41		12-33	17.3
Miyamoto et al.[14]*	2014	15	10	5	18-43	III	24	24
Nakata et al.[9]	2000	20	n/a	n/a	15-31	IV	37.2-120	50.4
Park et al.[16]	2016	30	23	7	17-54	IV	12-33	20
Sammarco et al.[17]	1999	30	17	13	12-47	IV	24-64	44
Sun et al.[21]	2019	32	18	14	18-43		24-35	28
Ventura et al.[22]	2020	20	12	8	29.2 ± 9.8		180	180
Wang et al.[18]	2013	25	14	11	17-62	IV	12-56	32.3
Xu et al.[19]	2014							
Autograft		32	19	13		III	26.8-40.2	33.5
Allograft		36	22	14		III	21.8-35.2	28.5
Youn et al.[20]	2012	14	9	5	20-53	IV	12-40	18.1
Total delayed mobility	*N = 11*	*362*	*219*	*123*				
Early mobility								
Miyamoto et al.[14]	2014	18	13	5	21-40	III	24	24
Wang et al.[15]	2017	19	10	9	19-41	IV	12-40	18.1
Total early mobility	*N = 2**	*37*	*23*	*14*				

*Miyamoto et al.[14] contained both delayed and early mobility, thus it is listed in both categories.

Table 2. Participant demographics by mobility timing.

Mobility timing	Sample size		Males		Females		Average age
	n = 277	100.0%	n = 162	45.5%	n = 95	34.3%	
Delayed mobility*	240	86.6	139	47.0	81	27.4	28.3
Athletes	53		35		18		26.4
General population	187		104		63		29.2
Early mobility	37	13.3	23	8.3	14	5.1	27.2
Athletes	18		13		5		26.4
General population	19		10		9		27.9

*Four studies from the delayed mobility group (a total of 122 participants) did not report the sample by type.

Table 3. Comparison of pre- and post-surgical outcomes by mobility timing.

Description	Delayed mobility				Early mobility				
	N	n	$mean_w$	SD	N	n	$mean_w$	SD	p**
Average age	11*	362	29.2	3.6	2*	37	27.1	0.8	< 0.001
Functional outcome									
AOFAS Function Score difference	7	283	28.0	5.5	1	19	26.3	n/a	'--
Pre-operation scores			64.5	5.2			64.0	n/a	'--
Post-operation scores			92.5	2.1			90.3	n/a	'--
Karlsson Function Score difference	6	181	32.7	4.1	2	37	34.0	6.3	0.246
Pre-operation scores			58.1	4.7			57.3	6.7	0.490
Post-operation scores			90.8	3.3			91.3	0.4	0.071
Radiographic outcome									
Anterior drawer difference	8	226	4.9	2.9	2	37	5.1	0.7	0.244
Pre-operation scores			17.0	9.8			9.3	0.6	< 0.001
Post-operation scores			12.1	11.6			4.1	0.2	< 0.001
Talar tilt difference	9	294	9.8	1.7	2	37	9.8	3.5	0.937
Pre-operation scores			13.7	1.6			14.0	3.5	0.646
Post-operation scores			3.9	1.1			4.2	0.1	< 0.001

N = number of studies; n = number of participants; $mean_w$ = Weighted means based on number of participants per study.
*Of those categorized as delayed mobility, two studies were grouped into two separate categories (Lee et al.[13] and Xu et al.[19]); one study, Miyamoto et al.[14], contained both delayed and early mobility, thus it is listed in both categories.
**Results from two-sided t-test for equality of means, equal variances not assumed.

Overall complication rates between study groups were significantly different with a complication rate of 1.7% (4/240) in the DM group versus 0.0% (0/37) in the EM. Park et al.[16] reported one complication and Sammarco et al.[17] reported three. In the DM group, three patients had painful hardware that required repeat surgery for removal, and one had sensory nerve damage.

Meta-Analysis Using Random and Mixed-Effects Models: Functional Outcomes. Results of the meta-analysis for the functional outcomes are shown in Figures 2 and 3. Figure 2a shows a random-effects model for AOFAS scores from eight studies[8,13,15,16,18,19,21,22] totaling 302 patients. Of these, 283 patients were in the DM group and 19 patients in EM. Both groups saw improvements in scores after the operation, with a standardized mean difference (SMD) of 3.56 (95% CI (2.56, 4.57); $p < 0.01$), although, heterogeneity was high, (I^2 = 91% (85%, 95%)), indicating that these groups may not be comparable. A subgroup analysis to compare DM with EM using a mixed-effects model showed significant differences between groups in favor of delayed mobilization, (SMD = 2.71, 95% CI (2.12, 3.30); $p < 0.01$). However, high heterogeneity was present, and only one study was included in the EM group (Figure 2b).

Results for Karlsson scores are shown in Figures 3a and 3b. Similarly, the random-effects model showed improvements to scores for these seven studies[13-16,20-22] totaling 218 patients (SMD = 3.52, 95% CI (2.82, 4.23)). Although the mixed-effects model to compare DM and EM was not significant and heterogeneity was high (I^2 = 75% (51%, 87%); p = 0.86).

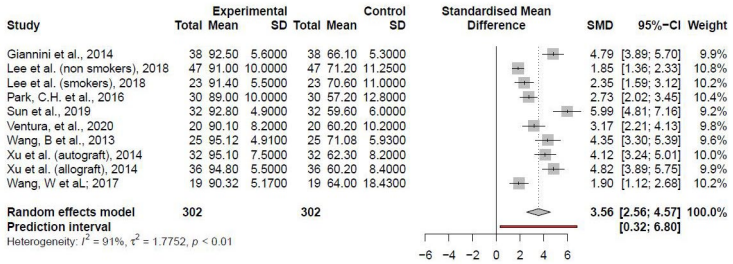

Figure 2a. Functional measure: AOFAS Random-effects model.

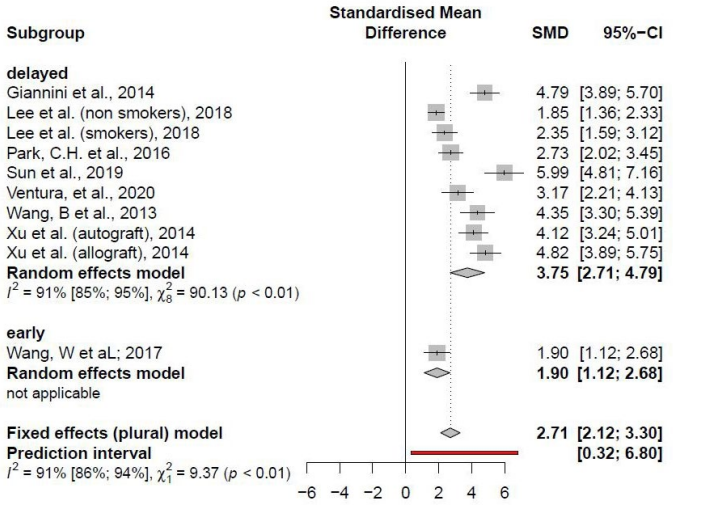

Figure 2b. Functional measure: AOFAS Mixed-effects model delayed vs. early mobilization.
Experimental = post-operational scores; Control = pre-operational scores

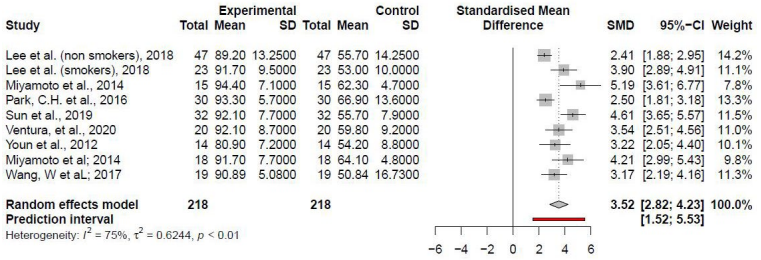

Figure 3a. Functional measure: Karlsson Scores Random-effects model.

Meta-Analysis Using Random and Mixed-Effects Models: Radiographic Outcomes. Results for radiographic outcomes are shown in Figures 4 and 5. Anterior drawer is shown in Figures 4a and 4b, which included 263 patients from nine studies; SMD = -2.35, indicating improved scores from pre- to post-operations. However, group comparisons were not significant, and heterogeneity was high. A second sensitivity analysis was conducted for anterior drawer measures because the scores from Lee et al.[13] were marked higher than all other studies, thus it was removed. Results from this analysis are shown in Figures 4c and 4d. The analysis showed no significant findings and heterogeneity was only slightly reduced from I^2 = 94% to 90% in the random effects model. Results from Talar tilt scores are shown in Figures 5a and 5b. No significant findings were observed.

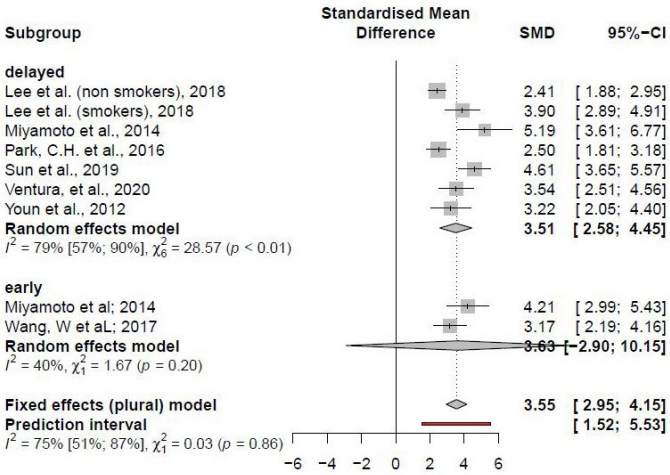

Figure 3b. Figure 3b. Functional measure: Karlsson Scores Mixed-effects model delayed vs. early mobilization.
Experimental = post-operational scores; Control = pre-operational scores
Note: inappropriately wide confidence intervals observed in the early random effects model may be a spurious finding, possibly due to the Hartung-Knapp-Sidik-Jonkman approach, as this produces wider confidence intervals. Although, Higgins and Thompson[23] argued it makes no sense to compare two or more subgroups in a meta-analysis with smaller than 10 studies, as spurious results may occur.

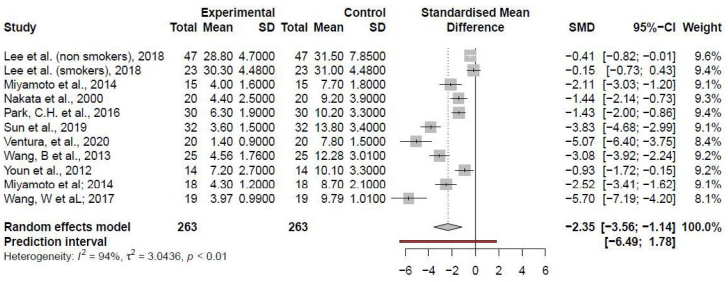

Figure 4a. Radiographic measure: Anterior drawer Random-effects model.

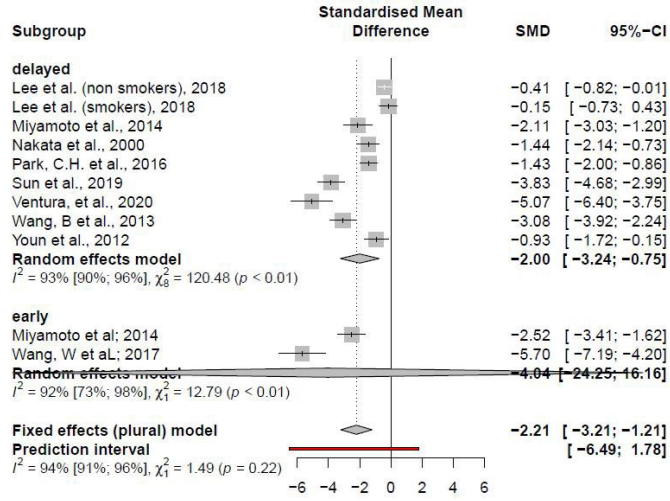

Figure 4b. Radiographic measure: Anterior drawer Mixed-effects model delayed vs. early mobilization.
Experimental = post-operational scores; Control = pre-operational scores
See note in Figure 3b regarding spurious findings for confidence intervals with small studies.

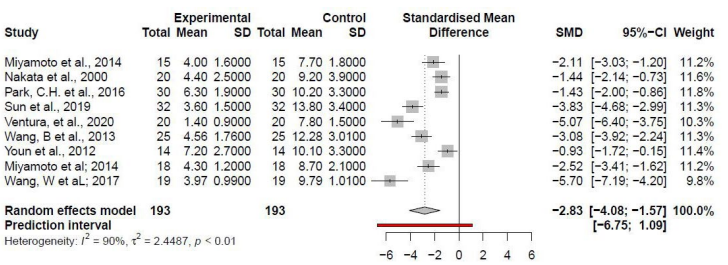

Figure 4c. Radiographic measure: Anterior drawer Random-effects sensitivity model.

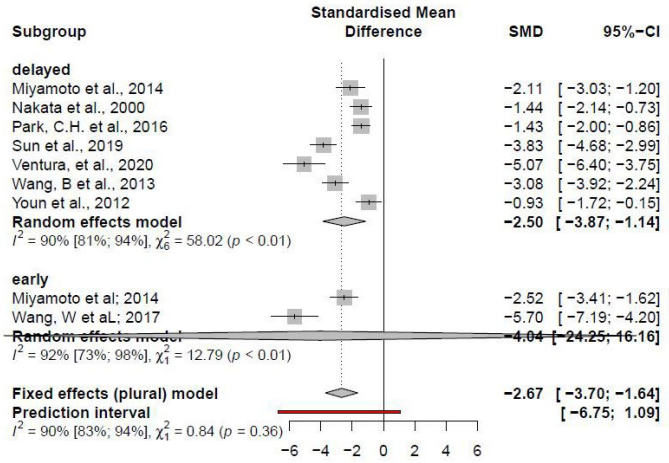

Figure 4d. Radiographic measure: Anterior drawer Mixed-effects sensitivity model delayed vs. early mobilization.
Experimental = post-operational scores; Control = pre-operational scores
See note in Figure 3b regarding spurious findings for confidence intervals with small studies.

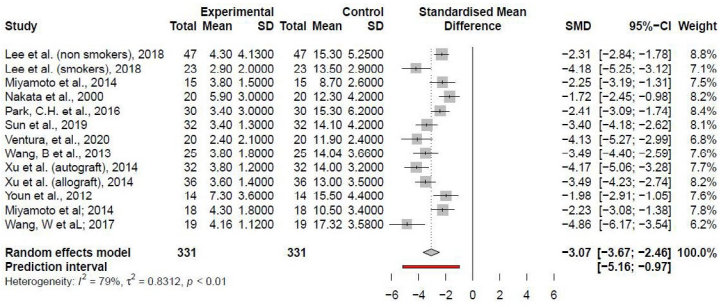

Figure 5a. Radiographic measure: Talar tilt Random-effects model.

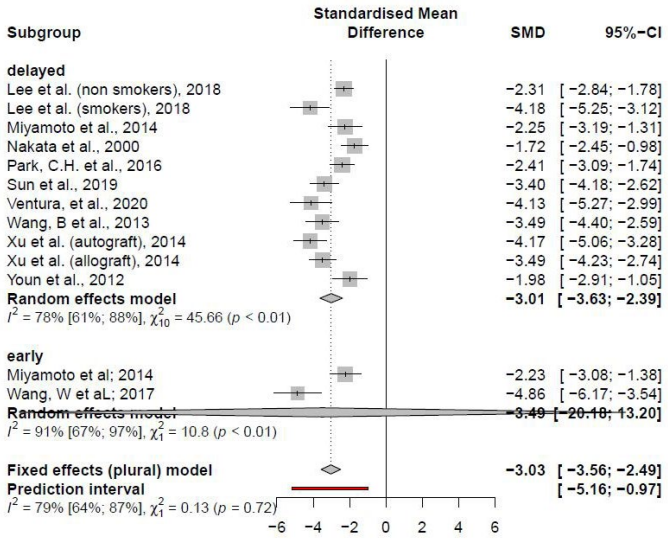

Figure 5b. Radiographic measure: Talar tilt Mixed-effects model delayed vs. early mobilization.
Experimental = post-operational scores; Control = pre-operational scores
See note in Figure 3b regarding spurious findings for confidence intervals with small studies.

DISCUSSION

Overall, our analysis demonstrated that lateral ankle reconstruction can provide significant improvements in functional and radiographic outcomes, regardless of rehabilitation protocols. While no significant differences were found between DM and EM groups for any radiographic outcomes, nor for Karlsson functional scores, a statistically significant greater improvement was observed for AOFAS functional scores, in favor of delayed mobilization. Although, it should be noted the sample size of the EM group was small with only one study.

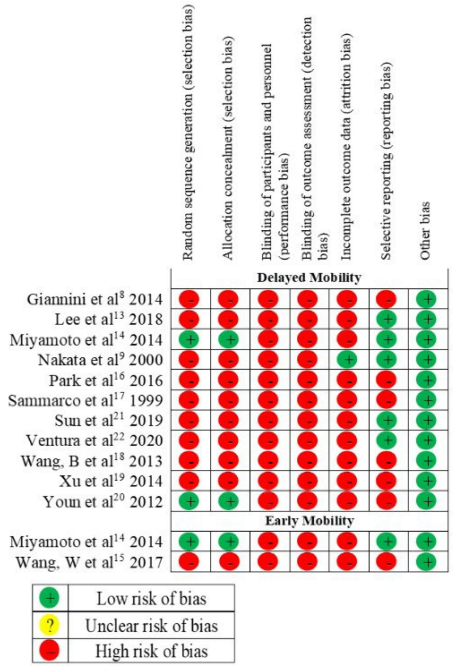

Figure 6. Quantitative bias analysis results for this study.

Results from the meta-analysis showed substantial heterogeneity present in all random and fixed effects models. This may be because study samples were small (some analysis had less than 10 studies) and were underpowered.[23] Furthermore, it is unclear if this difference in AOFAS is clinically significant. Our results demonstrated that EM post-operative protocols may not compromise post-operative instability, with no difference found between EM and DM in terms of both radiographic measures. However, our results also displayed that patients treated with DM may have a higher complication rate compared to the EM group.

The type of patient who undergoes a lateral ankle ligament reconstruction may be one that benefits from DM protocols. Typically, reconstruction is recommended in patients who have longstanding instability and insufficient soft tissue to perform repair or have physical demands that make repair unsuitable. In this type of patient, it would make sense that a period of prolonged immobilization would benefit the patient and give their soft tissues additional time to stabilize. However, our results illustrated that EM did not compromise post-operative stability in terms of both anterior drawer and Talar tilt test. Thus, these results may demonstrate that the use of reconstruction with graft may allow patients to mobilize sooner. It would be beneficial to see if this would correlate into returning to sport or work sooner in patients who are treated with EM. More studies are needed to evaluate this benefit in both graft versus other treatment options such as lateral ligament primary repair.

These findings did not corroborate with the Miyamoto el al.[14] study fully, which directly compared EM versus DM and found no difference in functional outcomes. Our study found a significantly higher change in AOFAS scores in the DM group, but no significant difference in Karlsson scores. Additionally, that study found that patients undergoing EM returned to athletic activity five weeks sooner than patients undergoing

DM. There may be multiple reasons for this, as Miyamoto el al.[14] was the lone study to use a gracilis autograft with an interference screw construct. The authors' goal of this construct was to determine if immediate range of motion could be accommodated. In other EM studies, the aim of the study was not one of length of recovery with a specific technique, but rather to demonstrate a given novel technique was not inferior to established techniques.[15,17]

Three out of the four complications encountered in our analysis were due to painful hardware and these occurred in the DM group.[15,16] Traditionally, it has been thought that delayed mobility can prevent complications. Yet, our analysis showed that all four complications encountered were in the DM group. However, it is not certain that these complications arose due to the timing of post-operative mobilization; rather, they could be due to surgical repair techniques. No studies reported recurrent post-operative ankle instability.

There are several limitations to our study. One was that differences in functional outcomes and ankle stability were not examined by the type of reconstruction. In our analysis, four studies used autografts, three used allografts, and two used a mix of auto and allografts to reconstruct the lateral ligament complex of the ankle. It is possible that differences in reconstruction technique affected outcomes greater than rehabilitation protocols. Also, as stated above, there were a larger number of studies in the DM group compared to the EM group, resulting in a higher number of patients in the DM group. Also, as illustrated by our quantitative analysis, our results were at a high risk from bias due to the lower level of evidence of our studies. Only one paper compared DM and EM; however, this was not a randomized control study design. Another limitation was that our study assumed that protocols were similar in the EM and DM groups. However, there was variability within both groups as to how early (or delayed) each protocol began mobilization. To our knowledge, there are no meta-analyses that compare reconstruction techniques and could provide the basis for future studies. This study suggested that EM post-operative protocols may not compromise patient's function or stability post-operatively. However, future meta-analysis should consider conducting meta-regression to more thoroughly evaluate this. Regardless, further studies are needed to evaluate specific post-operative protocols in patients undergoing lateral ankle ligament reconstruction to help physicians determine how to appropriately treat their patients.

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