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Rigid Dressings for Lower Limb Amputees: a Systematic Review and Meta-analysis

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Abstract

Purpose of Review To systematically investigate the efficacy and safety of rigid dressings for postoperative management in lower limb amputees.

Recent Findings There has been ongoing debate regarding the effectiveness of various postoperative management methods, including rigid and soft dressing, for individuals with lower limb amputations. Previous meta-analyses focused on specific outcomes and included only randomized controlled trials (RCTs) and quasi-RCTs. This study adds non-randomized studies of intervention (NRSI) to supplement existing evidence and provides a comprehensive analysis of efficacy and adverse events outcomes.

Summary The significant results that favor the use of the rigid dressings included a reduction in the time to wound healing, time to prosthetic fitting, stump volume, and post-operative pain, as well as a lower incidence of adverse events of revision and joint contracture. However, caution is needed in interpreting these results due to the high risk of bias among the included studies.

Keywords Rigid dressing · Removable rigid dressing · Rehabilitation · Amputation · Meta-analysis

Introduction

Lower limb amputation can be caused by trauma or various diseases such as peripheral vascular disease, diabetes, malignancy, or congenital deficiencies. In 2017, an estimated 35.3 million people worldwide had lower limb amputation due to traumatic causes [1], and the global annual incidence of diabetes-related major lower limb amputations during the 2010–2020 period was estimated to be 95 cases per 100,000 people with diabetes [2]. Following lower limb amputation, mortality rates were substantial. The overall mortality rate was 47.9%, 61.3%, 70.6%, and 62.2% at 1-, 2-, 3-, and 5-year follow-up, respectively [3].

The desired outcomes of postoperative management following lower limb amputation include successful wound healing, pain control, edema control, protection of residual limb from further trauma, maintaining and improving the range of motion and strength, and preparation for prosthetic fitting [4, 5]. To achieve these goals, various types of dressings have been used, including local wound dressings and outer dressings [6]. The outer or postoperative dressings are mainly applied to deliver the compression and protection of the residual limb, which are classified as soft dressing (SD), semi-rigid dressing (SRD), and rigid dressing (RD). RD is further subcategories into non-removable rigid dressing and removable rigid dressing (RRD).

SD, such as elastic bandages, crepe bandages, Ace wraps, shrinker socks, or other elastic materials, has been traditionally used as postoperative dressing due to their low cost and availability. However, fine motor skills are required for proper bandaging techniques to control and reshape the residual limb, and improperly tight application of SD can result in compromised distal blood flow [7], which may delay residual limb maturation.

With the advent of RD, considerable emphasis was placed on the application of hard exterior materials, such as plaster cast or plastic dressing. RD has been considered for compression and protection of residual limbs from external

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trauma. However, non-removable rigid dressings can hinder surgical wounds and residual limb observation, leading to delayed detection of complications like wound dehiscence or infection. To overcome this limitation, RRD was developed [8]. However, producing RD is costly and requires specialized skills.

Some wound-encasement alternatives for postoperative interventions have been developed to obtain the advantages of RD. Two alternatives, Unna paste and the air splint, are referred to as SRD. Unna paste consists of gauze impregnated with zinc oxide ointment, gelatin, and glycerin and is supported with an elastic wrap [9]. This bandage acts as a liner which is soft but inextensible. The air splint is a plastic pneumatic bag inflated to an optimal pressure [10–12].

Immediate postoperative prosthesis (IPOP) is a type of dressing that incorporates a prosthesis into the postoperative care plan. IPOP consists of an RD or SRD attached with an extension of a pylon and foot assembly, allowing the amputee to early ambulate with this temporary prosthesis.

The effectiveness of different postoperative management approaches, such as RD versus SD, in lower limb amputees has been a subject of debate. Two systematic reviews and meta-analyses have been conducted on this topic. Churilov et al. [13•] focused on the time to first prosthetic casting or fitting as the primary outcome, while Kwah et al. [14••] investigated various outcomes, including wound healing, time to prosthetic prescription, physical function, length of hospital stay, stump volume reduction, and adverse events. To reduce potential biases, only randomized controlled trials (RCTs) and quasi-RCTs were included in the meta-analysis, resulting in only 9 studies being analyzed [14••]. This systematic review and meta-analysis were conducted by adding non-randomized studies of intervention (NRSI) to supplement existing randomized trial evidence for determining the efficacy and especially the adverse effects which are long-term or rare outcomes of the postoperative dressings in lower limb amputees.

Methods

This systematic review with meta-analysis was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement. The review protocol was prospectively registered on the International Prospective Register of Systematic Reviews (PROSPERO) under the registration number CRD42023408645.

Search Strategy

A systematic search of electronic databases including PubMed, Ovid MEDLINE, Ovid Embase, Scopus, and Cochrane Central Register of Controlled Trials (CENTRAL) was conducted to identify articles published between the database's inception and February 2023. The search terms used were "removable rigid dressing" OR "rigid dressing" OR "postoperative dressing" AND "amput*" OR "transtibial" OR "prosthe*". Unpublished and ongoing trials were identified through Clinical Trial Registries using the international clinical trials registry platform (ICTRP) and ClinicalTrials.gov. Gray literature was identified through Google Scholar, CADTH Gray Matters, GreySource, Gray Literature Report, and WorldCat.gov. In addition, citation tracking and reference lists of the included studies and relevant systematic reviews were searched to identify further studies.

Eligibility Criteria

Two reviewers (NK and CS) independently screened titles, abstracts, and full texts and then extracted data from eligible studies. The criteria for inclusion were as follows: (1) a study comparing the efficacy of RD (including non-removable rigid dressing, RRD, IPOP, and SRD) with SD comparator in lower limb (transtibial or transfemoral) amputees; (2) reported outcomes of efficacy: (i) wound healing, (ii) edema control and volume reduction, and (iii) time to prosthetic fitting/stump maturation or outcomes of safety: (i) local adverse events (such as wound infection, wound breakdown, joint contracture, and re-amputation or revision, etc.), (ii) systemic adverse events (death and falls); and (3) study designs of the RCT, quasi-RCT, or NRSI. The criteria for exclusion were as follows: (1) the article was either a case report, review, study protocol, or ongoing study; (2) the studies were published in languages other than English; and (3) full text was not available.

Selection Process

The Covidence systematic review software [15] was employed to screen titles and abstracts that met the study criteria. Any duplicate articles were identified and removed. Eligible articles were selected based on their compliance with the inclusion and exclusion criteria. If the full text of a relevant article was not accessible, contact was made with the corresponding author, and the study was excluded if no response. In cases where there were disagreements between the two reviewers, the third reviewer (TV) intervened to resolve the issue, and the reasons for the exclusion of studies were documented.

Data Extraction

The data was extracted by one reviewer and verified by a second reviewer. Any disagreements were resolved by consensus with the third reviewer. The extracted data included trial details, study design, number of patients, participant characteristics, type of dressings used, and measured outcomes.

To facilitate synthesis and analysis of the data, the median and range values presented in the original article were converted into mean and standard deviation [16]. Any missing standard deviation of baseline changes was imputed using estimated correlation coefficient values [17]. The unit of measurement for time-to-event outcomes was adjusted to days. The assessment times for stump volume and pain reduction varied in different studies [18–21]. To maintain consistency in the analysis, we restricted the data collection for stump volume to the 4 to 6-week time frame, while pain reduction was evaluated at the 6-week interval.

Risk of Bias and Quality Assessment

One reviewer assessed the risk of bias using the revised Cochrane Collaboration Risk of Bias tool (RoB2) [22] for RCTs and the Risk of Bias tool for non-randomized studies of interventions (ROBINS-I) [23] for quasi-RCTs and observational studies. The risk of bias of each domain and overall bias were classified as low, some concerns, high risk in RoB2, and low, moderate, serious, critical, or no information of risk in ROBINS-I. The decisions were verified by a second reviewer. The risk-of-bias plots were created using the risk-of-bias visualization (Robvis) tool [24]. Additionally, to assess publication bias when applicable, a funnel plot diagram was used.

Statistical Method

The Review Manager (RevMan) 5.4 software was utilized for data analysis. The mean difference (MD) with a 95% confidence interval was used for continuous data, except for volume reduction, which was converted to a standard mean difference (SMD) to account for measurement method differences. For categorical data, the risk ratio with a 95% confidence interval was used. A random-effects model was applied, and statistical significance was defined as a p value of < 0.05. The I^2 statistic was utilized to evaluate data heterogeneity, with low heterogeneity defined as 25–50%, moderate heterogeneity as 50–75%, and high heterogeneity as greater than 75%. Subgroup analyses were performed based on study type (RCT, quasi-RCT, and NRSI) and intervention type (IPOP and non-IPOP) to assess the time to prosthetic fitting outcome.

Results

Study Selection

The search of databases and registers yielded 738 records after removal of duplicates. Following the screening of titles and abstracts, 33 manuscripts were selected for full-text review. After a thorough review process, 25 studies were deemed eligible for inclusion. Four articles were excluded due to their unavailability in full text [25–28], as were two ongoing studies (ClinicalTrials.gov, Identifier: NCT03948087 and NCT03593174), and two studies from which data could not be extracted [29, 30]. An additional two studies [20, 31] were identified and included in the quantitative synthesis through further searching using other methods. Overall, 27 studies [7, 8, 18–21, 31–39, 40•, 41–51] were enrolled for comprehensive review, with the flow of included studies throughout the review process being depicted in Fig. 1.

Study Characteristics and Demographics

All included studies [7, 8, 18–21, 31–39, 40•, 41–51] were published between 1971 and 2022 and consisted of 10 RCTs, 6 quasi-RCTs, and 11 NRSIs. In total, there were 964 participants in the rigid dressing group and 803 in the control group. Only three studies [20, 33, 50] included participants who had undergone transfemoral amputations rather than just transtibial amputations. Various types of rigid dressings, including non-removable RD, RRD, SRD, and IPOP, were used in the intervention group, while soft dressings or elastic bandages were applied in the control group in all studies. Table 1 displays the characteristics of the participants and outcome assessments of the included studies.

Risk of Bias Assessment

Most of the RCT studies [18, 20, 34–36, 49–51] were judged to have a high risk of bias according to the RoB2 assessment, primarily because the outcome assessor was not blinded, and the studies focused on soft outcomes such as stump maturation, wound healing, or pain. Additionally, a moderate to high number of participants were excluded from the analysis after randomization, without appropriate analysis to estimate the effect of the intervention (Fig. 2A). Only two studies, Janchai et al. [19] and Koonalinthip et al. [40•], were classified to have moderate and low risk of bias, respectively.

When assessing the risk of bias in quasi-RCTs and observational studies using ROBINS-I, one study [43] was classified to have moderate risk of bias, one study [39] as a critically high risk, and the others [7, 8, 31–33, 37, 38, 41–48] as high risk of bias. Most of the reasons causing bias in the included studies were bias in measurement outcomes and bias due to confounding factors (Fig. 2B).

Regarding publication bias, we considered only two applicable outcomes: time to prosthesis and rate of revision. The analysis revealed an asymmetric funnel plot for the outcome of time to prosthesis. However, no such asymmetry was observed in the funnel plot for the outcome of rate of revision (Figs. 3, 4 and 5).

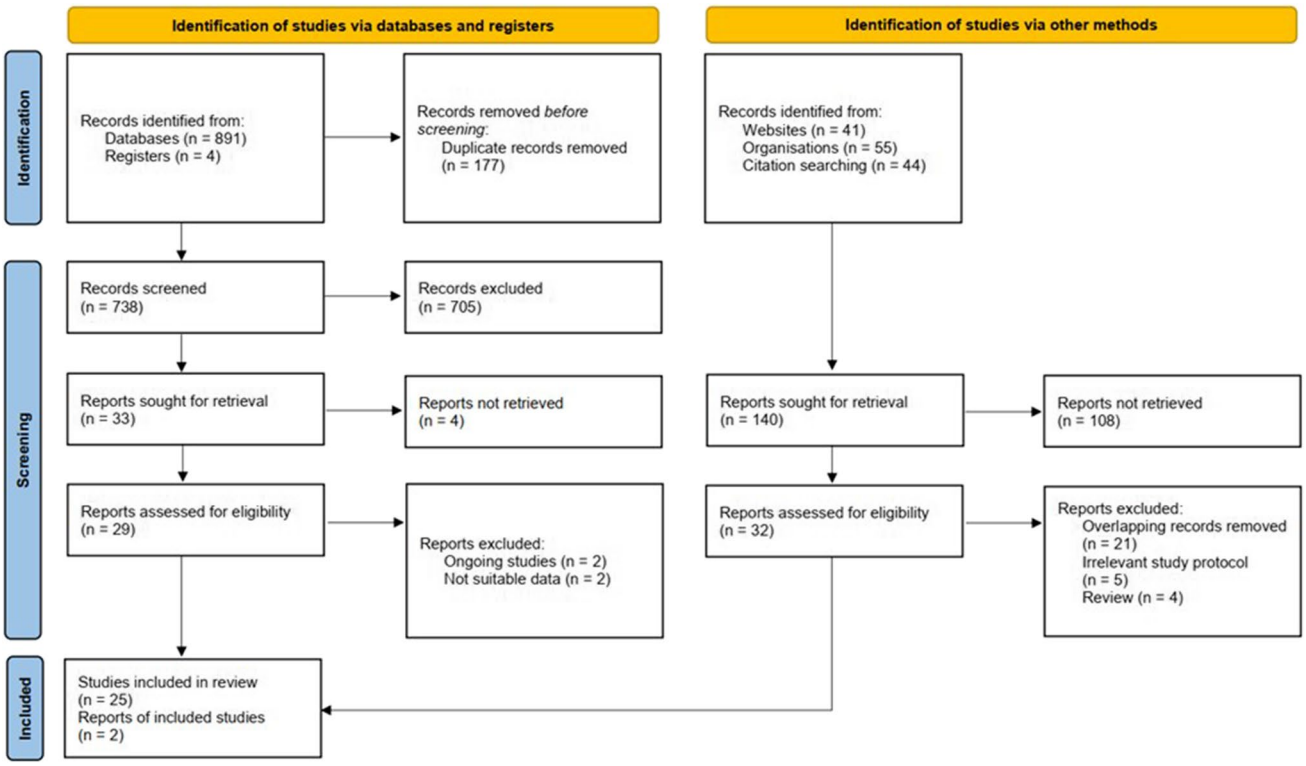


Fig. 1 Flow diagram of the included studies

Meta-analysis Outcomes

The meta-analysis results of the efficacy and adverse events of RD compared with soft dressings were shown in Table 2.

Outcomes of Efficacy

Time to Wound Healing

Four studies reported time to wound healing outcomes [8, 36, 38, 49], and one study [8] was excluded from the analysis due to insufficient data for extraction. The rigid dressing group demonstrated a shorter period of wound healing for 20.32 days than the control group (MD -20.32, 95% CI [-33.97, -6.67], $p = 0.004$, $I^2 = 0\%$, as shown in Fig. 3A).

Time to Prosthetic Fitting or Stump Maturation

The results of 18 studies [7, 18, 31–33, 36, 38, 39, 40•, 41–44, 46–48, 50, 51] regarding the time to prosthetic fitting or stump maturation were analyzed. Out of these, six studies [31, 32, 39, 42, 43, 51] did not provide sufficient data for extraction and were excluded, leaving 12 studies for data synthesis. The analysis revealed that the rigid dressing group had a mean difference of 34.5 days less for stump maturation or prosthetic fitting, but there was considerable high heterogeneity in the results (MD 34.52, 95% CI [22.58, 46.47], $p < 0.001$, $I^2 = 93\%$, as shown in Fig. 3B.1).

Subgroup analysis based on study design (RCT, quasi-RCT, and NRSI) showed that the rigid dressing group was still favored overall, and heterogeneity was reduced in the RCT subgroup (MD -7.82, 95% CI [-13.97, -1.67], $p = 0.01$, $I^2 = 23\%$, as shown in Fig. 3B.1). Moreover, the subgroup analysis based on the type of rigid dressing (IPOP and non-IPOP) showed that the IPOP group had a tendency toward a shorter time to prosthesis fitting (MD -73.96, 95% CI [-101.88, -46.04], $p < 0.001$, $I^2 = 81\%$) than the non-IPOP group (MD -14.54, 95% CI [-26.03, -3.04], $p < 0.001$, $I^2 = 93\%$, as shown in Fig. 3B.2).

Pain Reduction

Three studies mentioned pain reduction [18, 20, 45], which two [18, 20] reported in visual analog scale (VAS), and another reported in terms of narcotic prescription [45] which was excluded from the analysis. The analysis showed that participants who used rigid dressing experienced less pain than those who used soft dressing with a mean difference of 0.84 mm (MD 0.84, 95% CI [0.56, 1.13], $p < 0.001$, $I^2 = 0\%$, as shown in Fig. 3C).

Table 1 Characteristics of the included studies

Study	Year	Design	Number of participants (*n*) Intervention/control	Level of amputation	Cause of amputation	Intervention	Outcomes	
							Efficacy	**Adverse events**
Ali	2013	Retrospective cohort	37/35	TT	Dysvascular, trauma, infection	IPOP (plaster)	Prosthetic fitting	Death, fall, revision, wound complication
Alsancak	2011	Quasi-RCT	10/5	TT, TF	DM, dysvascular, tumor, osteomyelitis	IPOP (plastic), IPOP (pneumatic)	Prosthetic fitting, perimeters of the stump, prosthetic training period	Contracture, wound complication
Baker	1977	RCT	27/24	TT	Dysvascular	RD (plaster)	Wound healing, LOS, rehabilitation time	Revision
Barber	1983	RCT	35/35	TT	N/A	RD	Level of ambulation	Death
Deutsch	2005	RCT	26/24	TT	Dysvascular	RRD (fiber glass)	Wound healing, prosthetic fitting, LOS	Death, fall, revision
Fencel	2022	Retro-prospective cohort	53/42	TT	N/A	RRD (laminate)	-	Revision
Hallam	1988	Quasi-RCT	9/9	TT	Dysvascular (DM and non-DM)	IPOP (plaster) + Dunlopillo insert	Wound healing, prosthetic fitting	-
Hayes	1983	Retrospective cross sectional	10/15	TT	N/A	IPOP (plaster)	Prosthetic fitting	Fall
Hidayati	2013	RCT	12/11	TT	DM	RRD (plaster)	Pain reduction, time to stump maturation, volume reduction	-
Janchai	2008	RCT	12/14	TT	Dysvascular, infection, tumor	RRD (plaster)	Volume reduction	Fall
Koonalinthip	2020	RCT	13/12	TT	Dysvascular, infection, trauma	RRD (plaster)	Time to stump maturation	Fall, contracture, wound complication
Kothari	2017	RCT	24/20	TT, TF	Trauma, dysvascular, tumor, infection	IPOP (plaster)	Pain reduction, volume reduction	-
Ladenheim	2007	Retrospective cohort	76/28	TT	Dysvascular, DM, trauma	RRD (prefabricated)	Prosthetic fitting	-
MacLean	1994	Quasi-RCT	19/21	TT	Dysvascular	SRD (Unna)	Prosthetic fitting	Death, revision
Mooney	1971	Quasi-RCT	106/76	TT	DM	RD, IPOP (plaster)	Wound healing, prosthetic fitting	Death, revision
Moore	1972	Retrospective cohort	47/53	TT	Dysvascular	IPOP (plaster)	Wound healing, prosthetic fitting, rate of success in rehabilitation	Death, revision, wound complication
Mueller	1982	Quasi-RCT	7/8	TT	Dysvascular	RRD (plaster)	Volume reduction, secure of dressing, dressing application	-
Sarkar	2022	Retrospective cohort	54/41	TT	Dysvascular	RRD	Pain (narcotic prescription), ambulatory status	Revision

Table 1 (continued)

Study	Year	Design	Number of participants (*n*) Intervention/ control	Level of amputation	Cause of amputation	Intervention	Outcomes	
							Efficacy	**Adverse events**
Schon	2002	Retro-prospective cohort	19/23	TT	Dysvascular, DM, trauma	IPOP (pneumatic)	Prosthetic fitting	Revision, wound complication
Sumpio	2013	Retrospective cohort	91/60	TT	N/A	RD (plaster), RD (plastic)	Prosthetic fitting	-
Taylor	2008	Retrospective cohort	28/37	TT	Dysvascular, others	RRD (plaster)	Prosthetic fitting, LOS	-
van Velzen	2005	Retrospective cohort	97/52	TT	Dysvascular	IPOP (plaster)	Prosthetic fitting	Death, revision, contracture, wound complication
Vigier	1999	RCT	28/28	TT	Dysvascular	RRD (plaster)	Wound healing, time to walk, rehabilitation time	-
Wong	2000	RCT	12/9	TT, TF	Dysvascular	SRD (Unna)	Prosthetic fitting, functional status at discharge	Death
Woodburn	2004	RCT	78/76	TT	N/A	RD (plaster)	Prosthetic fitting	Death, revision, wound complication
Wu	1979	Retro-prospective cohort	19/30	TT	Dysvascular, osteomyelitis, burn, DM	RRD (plaster)	Wound healing, rehabilitation time	Revision, wound complication
Ziarati	2021	Quasi-RCT	15/15	TT	DM	IPOP (plastic)	Prosthetic fitting	-

Abbreviations: *DM*, diabetes mellitus; *IPOP*, immediate postoperative fitting of prosthesis; *LOS*, length of stay; *N/A*, not applicable; *RCT*, randomized controlled trial; *RD*, rigid dressing; *RRD*, removable rigid dressing; *SRD*, semi-rigid dressing; *TF*, transfemoral; *TT*, transtibial

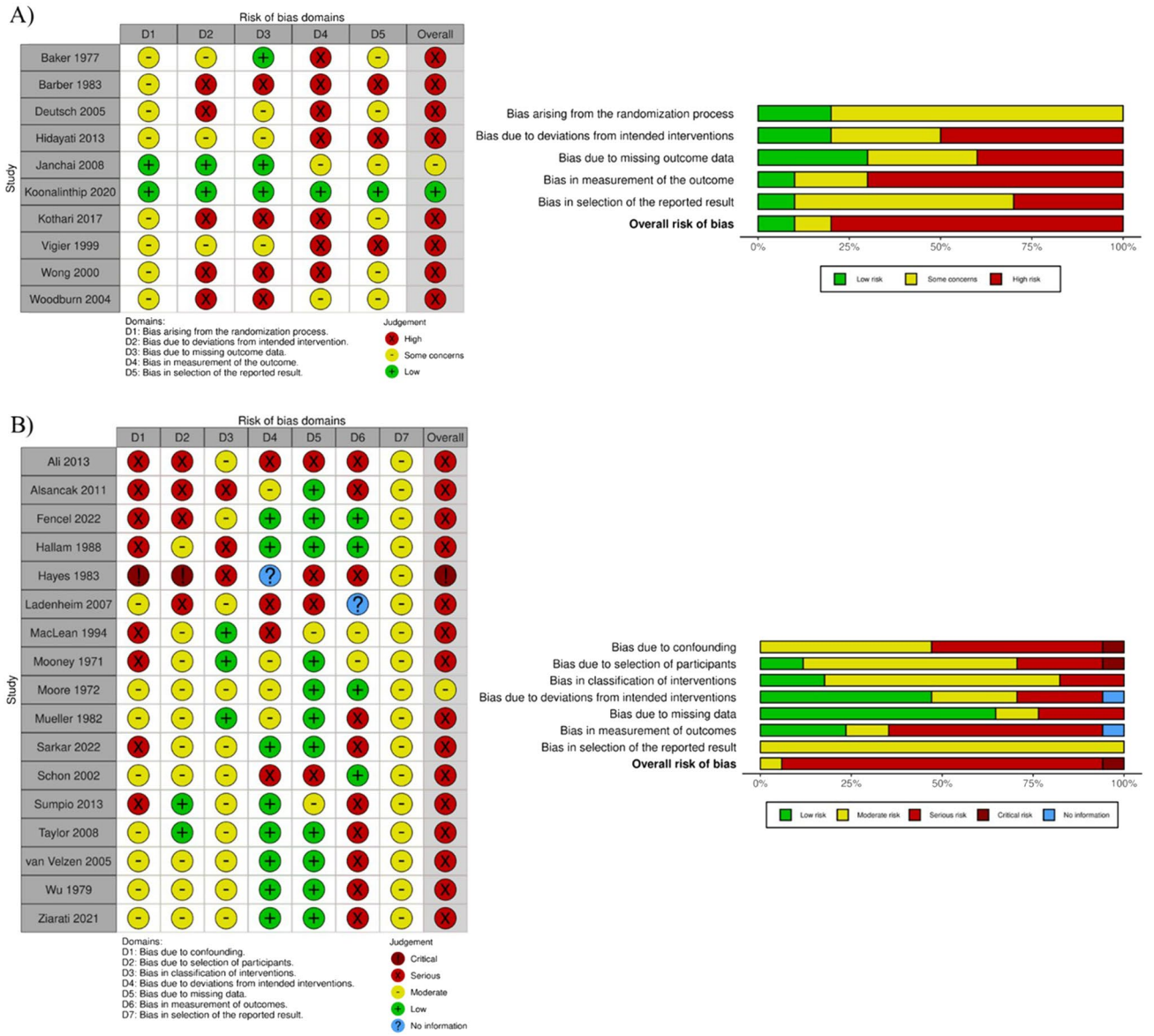


Fig. 2 Summary graph and table of the risk of bias assessment. (**A**) RoB2 tool assessing risk of bias in RCT studies. (**B**) ROBINS-I tool assessing risk of bias in NRSI including quasi-RCT and observational studies

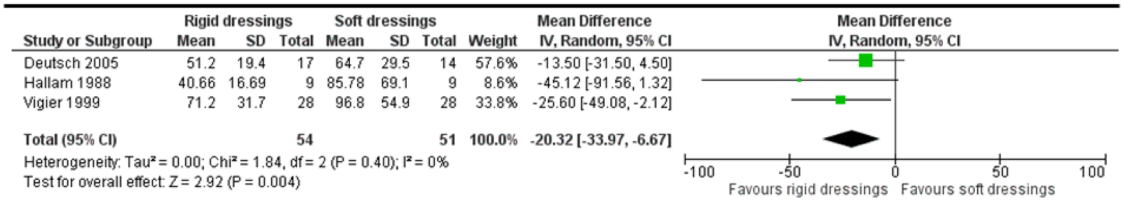
Volume Reduction

Five studies were identified that assessed the reduction of stump volume [18–21, 29]. Among these, one study [29] was excluded due to insufficient data. The results of the analysis indicated that there was no significant difference in the average stump volume reduction between the rigid and soft dressing groups (SMD 0.23; 95%CI [-0.22, 0.69], $p = 0.31$, $I^2 = 25\%$, as shown in Fig. 3D).

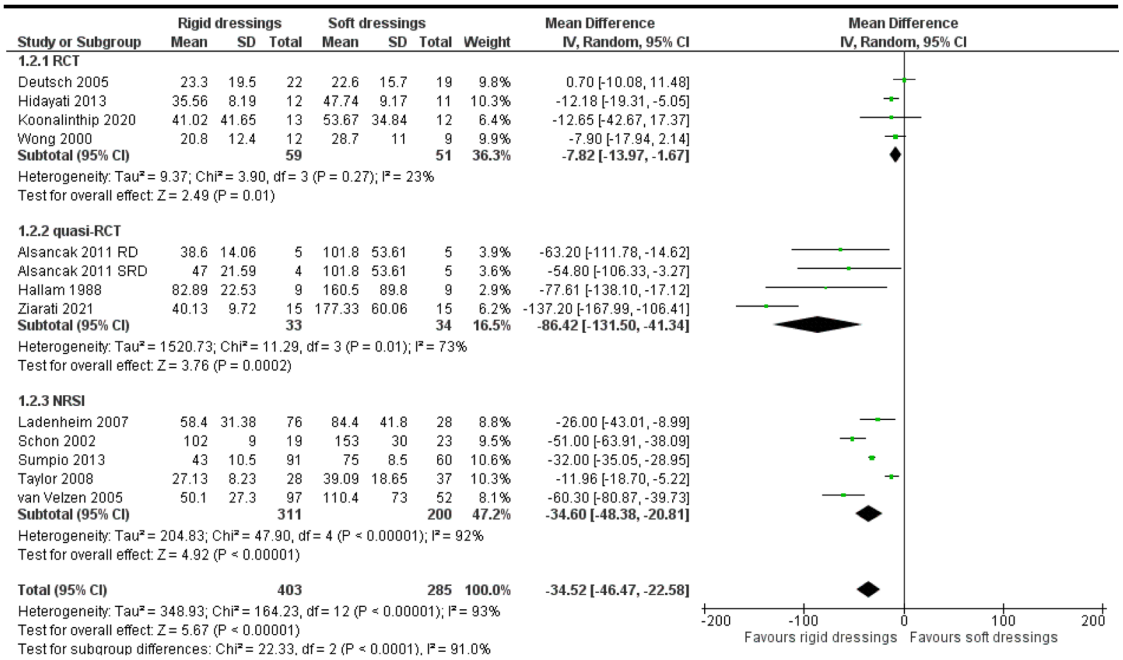
Length of Hospital Stay (Post-operative)

Four studies [30, 34, 36, 47] were included in the analysis of length of hospital stay after amputation. However, two studies [30, 34] were excluded due to incomplete data. The results showed that the rigid dressing group had a significantly shorter overall length of stay compared to the control group, with a mean difference of -6.24 days (MD -6.24, 95% CI [-11.02, -1.50], $p = 0.31$, $I^2 = 25\%$, as shown in Fig. 3E).

A)



B1)



B2)

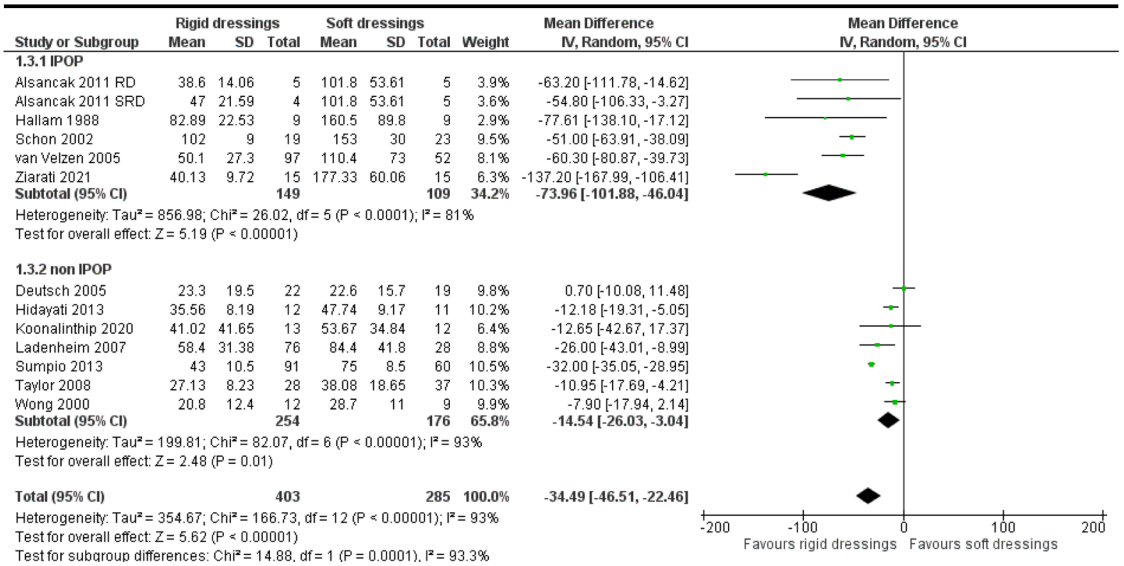
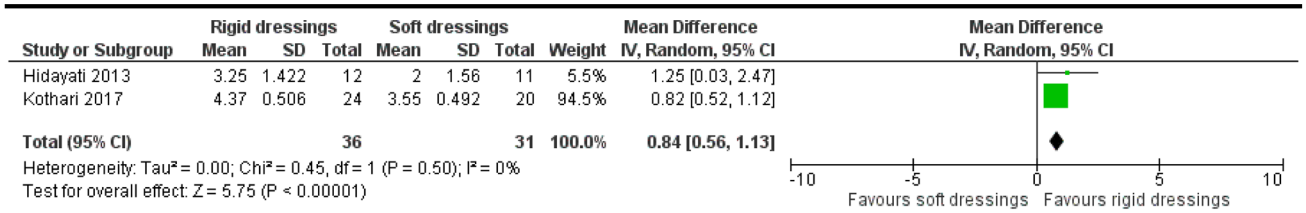
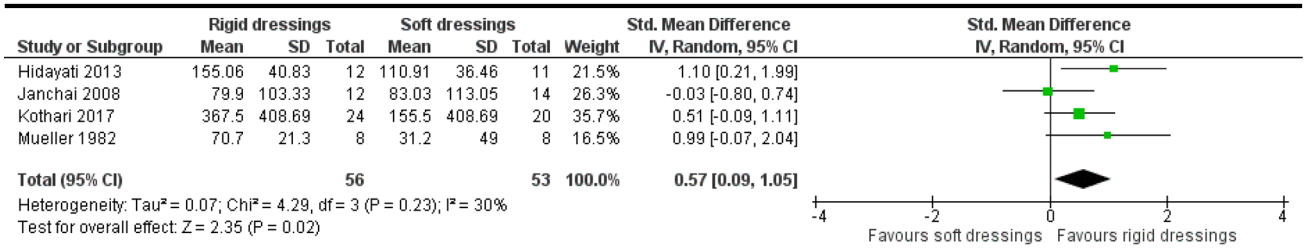


Fig. 3 The forest plots displayed the comparison of efficacy between rigid dressings and soft dressings, with outcomes including (**A**) time to wound healing, (**B.1**) time to prosthetic fitting/casting or residual limb maturation with subgroup analysis based on study design, (**B.2**) time to prosthetic fitting/casting or residual limb maturation with subgroup analysis based on type of intervention, (**C**) pain reduction, (**D**) volume reduction, and (**E**) length of stay

C)



D)



E)

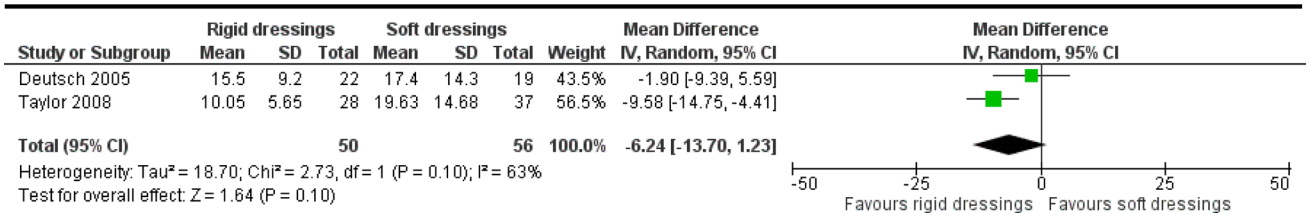


Fig. 3 (continued)

Outcomes of Adverse Events

Adverse events or complications were categorized as systemic adverse events (death and falls) and local adverse events (revision, joint contracture, and wound complications).

Death

The findings from nine studies [31, 32, 35, 36, 42, 43, 48, 50, 51] did not provide a clear indication on whether the use of rigid dressings increase the risk of death in the rigid dressings group when compared with the soft dressings group (RR 1.14, 95%CI [0.78, 1.69], $p = 0.49$, $I^2 = 0\%$, as shown in Fig. 4A).

Falls

The data from five studies [19, 32, 36, 39, 40•] showed that it is uncertain whether the use of rigid dressings increased the proportion of fall adverse events in the rigid dressings group when compared to the soft dressings group (RR 0.50, 95%CI [0.25, 1.00], $p = 0.05$, $I^2 = 0\%$, as shown in Fig. 4B).

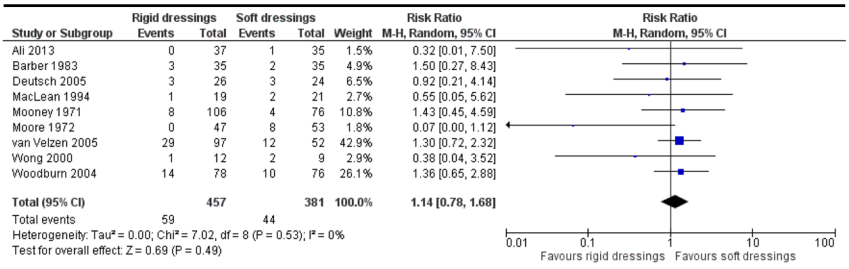
Revision or Re-amputation

The data from twelve studies [8, 31, 32, 34, 36, 37, 43, 45, 46, 48, 51] were analyzed for re-amputation and revision to further levels of amputations. The findings indicated that the use of rigid dressings led to a significant decrease in the proportion of revision in the rigid dressings group compared to the soft dressings group (RR 0.45, 95%CI [0.30, 0.68], $p < 0.001$, I^2 33%, as shown in Fig. 4C).

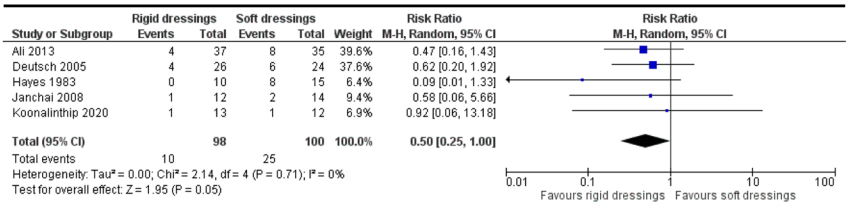
Joint Contracture

The findings from three studies [33, 40•, 48] demonstrated that the use of rigid dressings resulted in a significant reduction in the proportion of joint contracture in the rigid dressings group compared to the soft dressings group (RR 0.09, 95%CI [0.002–0.38], $p = 0.001$, $I^2 = 0\%$, as shown in Fig. 4D).

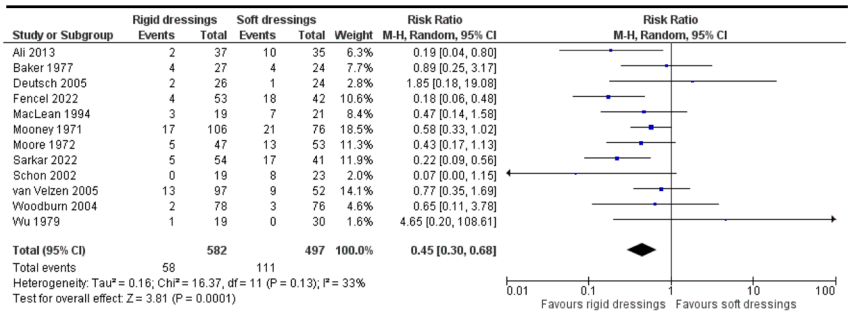
A)



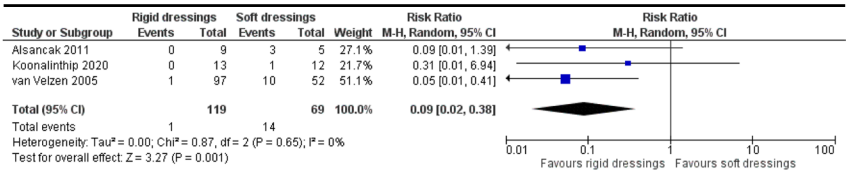
B)



C)



D)



E)

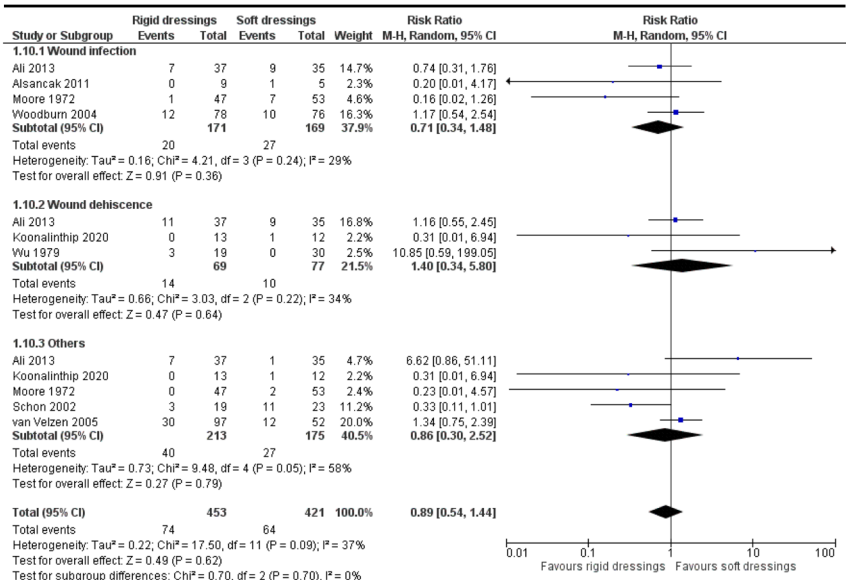


Fig. 4 The forest plots displayed the comparison of adverse events between rigid dressings and soft dressings, with outcomes including (**A**) death, (**B**) falls, (**C**) revision or re-amputation, (**D**) contracture, and (**E**) wound or skin complications

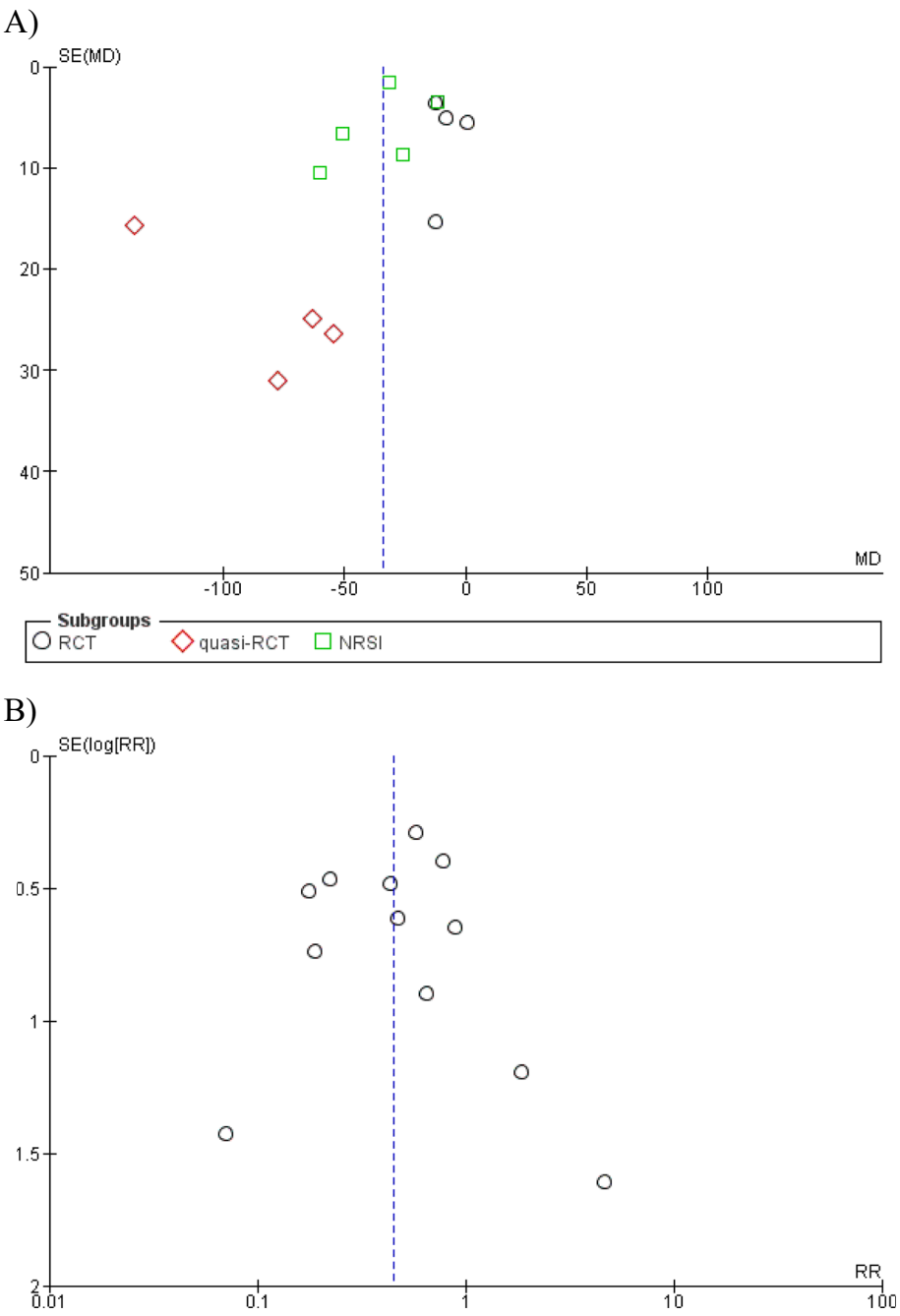


Fig. 5 The funnel plots assessing publication bias displayed the comparison of rigid dressings versus soft dressings for two outcomes: (**A**) time to prosthetic fitting and (**B**) revision

Skin or Wound Complications

The occurrence of skin or wound complications, such as wound infection, wound dehiscence, skin breakdown, skin irritation, hematoma, and pressure necrosis, was analyzed using data from eight studies [8, 32, 33, 40•, 43, 46, 48, 51]. However, the findings from these studies did not provide a clear indication on whether the use of rigid dressings increased the proportion of wound-related adverse events in the rigid dressings group when compared to the soft dressings group (RR 0.89, 95%CI [0.54, 1.44], $p = 0.49$, $I^2 = 37\%$, as shown in Fig. 4E).

Discussion

This meta-analysis synthesized the efficacy and safety of rigid dressings versus soft dressings for postoperative management in lower limb amputees, based on the RCT and NRSI studies. The findings indicated that the use of rigid

Table 2 Meta-analysis result of the efficacy and adverse events of rigid dressings compared with soft dressings

Outcomes	No. of studies	No. of participants	Mean difference (95%CI) (RD – SD)	RR (95%CI) (RD / SD)	*p* value	I^2 (%)
Efficacy						
Time to wound healing	3	105	-20.32 (-33.97, -6.67)		0.004	0
Time to prosthetic fitting	12	688	-34.52 (-46.47, -22.58)		< 0.0001	93
Pain reduction	2	67	0.84 (0.56, 1.13)		< 0.0001	0
Volume reduction	4	109	0.57 (0.09, 1.05)*		0.02	30
Length of hospital stay	2	106	-6.24 (-13.70, 1.23)		0.10	63
Adverse events						
Death	9	838		1.14 (0.78, 1.68)	0.49	0
Falls	5	198		0.50 (0.25, 1.00)	0.05	0
Revision	12	1079		0.45 (0.30, 0.68)	0.0001	33
Contracture	3	188		0.09 (0.02, 0.38)	0.001	0
Wound complications	8	874		0.89 (0.54, 1.44)	0.62	37

*standardized mean difference. Abbreviations: *RD*, rigid dressing; *SD*, soft dressing

dressings was more effective in reducing the time taken for wound healing, time taken for prosthetic fitting or stump maturation, stump volume, and post-operative pain. Additionally, it was observed that the incidence of adverse events of revision and joint contracture was lower in the rigid dressings group. However, there were no significant differences between the two dressings in terms of their efficacy in reducing length of hospital stay, or in terms of adverse events of death, falls, and wound-related complications. The significant results in favor of the rigid dressings group should be interpreted with caution, considering the high risk of bias of the included studies. The results may be affected by various biases, including bias in measurement of outcome and bias due to confounding.

To obtain the most reliable evidence on the effects of interventions, conducting a systematic review and meta-analysis of RCTs is considered the gold standard. However, the previous systematic review and meta-analysis conducted by Kwah et al. [14••] only included RCTs and quasi-RCTs, leading to the analysis of a mere 9 studies. In some instances, a lack of reporting on certain primary outcomes by the limited number of studies impeded the synthesis. Since non-randomized studies of intervention (NRSI) can provide supplementary evidence to RCTs, particularly on long-term outcomes, rare events, and adverse effects, this systematic review and meta-analysis incorporated both types of studies, yielding a total of 27 studies being analyzed. Nonetheless, NRSI is prone to confounding and several other potential biases. In this study, most quasi-RCTs and NRSIs were classified as high risk of bias assessment by ROBINS-I.

The studies included in this meta-analysis showed that dysvascular disease, diabetes, and trauma were the most common reasons for lower limb amputation, while a smaller proportion of amputees underwent the procedure due to tumors and burns. Among the participants, the majority had undergone transtibial amputation, while a small number had undergone transfemoral amputation (only 33 participants from three studies, which accounted for 1.8% of all participants). Manufacturing RDs for transfemoral amputees requires a high level of expertise to properly fit and apply. The rigid hip spica cast could restrict hip mobility and increase the risk of pressure sores over bony prominences [52]. The Dutch evidence-based guidelines for amputation and prosthetics of the lower extremity, in fact, recommend against using RDs for transfemoral amputations [53].

Successful wound healing, pain control, edema control, and preparation for prosthetic fitting are desired outcomes of postoperative management following lower limb amputation. Previous studies have examined different types of postoperative dressings and reported various outcomes to determine their effectiveness. In this meta-analysis, we synthesized outcomes, including time to wound healing, time to prosthetic fitting or stump maturation, pain reduction, volume reduction, and length of hospital stay, to determine the efficacy of RDs compared with soft dressings. The overall analysis favored RDs, except for length of hospital stay, which showed no significant difference between the two groups. Our findings are consistent with two previous meta-analyses [13•, 14••], which demonstrated a positive effect of RDs on time to wound healing and time to prosthesis fitting. However, we identified some contradictory results in three areas. First, we found a significant effect of RDs in reducing stump volume in the medium term, possibly due to our analysis including more studies than Kwah et al. [14••]. Second, we quantitatively analyzed the effect of RDs on reducing stump pain severity and post-operative length of hospital stay, whereas Kwah et al. [14••] focused on the event rate of stump pain and an average rehabilitation time.

Assuming faster wound healing and reduced likelihood of revision, the outcome of wound healing demonstrated that using RDs led to a shorter time for wound healing compared to soft dressings. This finding was corroborated by the adverse events outcome, which showed a notable decrease in the rate of revision among the group that used RDs when compared to the soft dressings group. The complications associated with the use of rigid dressing, excluding the revision rate and joint contracture, were not significantly different from those of soft dressing, which is consistent with the findings of Kwah et al. [14••]

Reducing the residual limb volume is the objective of postoperative edema control. Once the residual limb has adequately healed and its volume has reduced to a stable level, it is considered to have reached maturation, indicating that it is ready for prosthetic casting. To account for this, we combined the results from two studies [18, 40•] that assessed the time to stump maturation with the outcomes from most studies that measured the time to prosthetic fitting or casting. The analysis demonstrated a notable reduction in stump volume for the RD group when compared to the soft dressing group. The finding was also consistent with the group who used RD had a shorter time to stump maturation or time to prosthetic fitting. Similarly, Churilov et al. [13•] reported similar results, with a shorter time to prosthetic fitting observed in the RD group. However, both studies exhibited considerable heterogeneity in the results. In our study, the significant heterogeneity was reduced in the RCT group through subgroup analysis based on study design. Another subgroup analysis was carried out to assess the effectiveness of IPOP versus non-IPOP among the RD groups. The outcomes revealed that IPOP subgroups tended to have a shorter time to prosthesis fitting than non-IPOP subgroups. Early ambulation in the postoperative phase prevents complications related to immobilization, as indicated by the reduced proportion of joint contracture adverse events in the RD group.

Limitations and Future Research

The present meta-analysis had several limitations that should be considered when interpreting the results. First, we observed high heterogeneity in the analysis of the outcome of time to prosthesis, which could affect the validity and generalizability of the findings. To address this issue, we performed a subgroup analysis based on study design, which was able to reduce the heterogeneity to a low level only in the RCT subgroup, but not in the overall or other subgroups. However, residual heterogeneity may still exist due to other unmeasured factors. Second, most of the studies included in the meta-analysis were judged as having a high risk of bias, which could affect the internal validity of the results. Some of the biases may have arisen from the inclusion of non-randomized studies, which are more prone to bias than randomized controlled trials. Third, we detected publication bias in the outcome of time to prosthetic fitting, as indicated by the asymmetry of the funnel plot. This suggests that studies reporting shorter time to prosthetic fitting may be more likely to be published, which could inflate the effect size estimates and affect the overall conclusions of the meta-analysis. Finally, a small proportion of the participants in the included studies had transfemoral amputations, which may limit the generalizability of the results to this subgroup of patients. Therefore, caution should be exercised when applying the findings to this population.

Subsequent studies ought to prioritize high-quality randomized controlled trials that implement effective blinding methods and measurement of outcomes. Furthermore, they should delve deeper into investigating the potential benefits of utilizing rehabilitation interventions in patients undergoing transfemoral amputations.

Conclusions

In conclusion, the results of this meta-analysis suggest that rigid dressing (RD) may be a more effective postoperative management method for lower limb amputees compared to soft dressing. The use of RD was associated with a significant reduction in pain, reduction in stump volume, shorter time to wound healing, shorter time to prosthetic fitting, and fewer local adverse events. Additionally, the inclusion of non-randomized studies of intervention (NRSI) provides additional evidence to supplement prior meta-analyses of randomized controlled trials (RCTs). However, there is a need for caution in interpreting the results due to the high risk of bias in the included studies.

Data Availability The data that support the findings of this study are available on request from the corresponding author.

Declarations

Conflict of Interest The authors declare no competing interests.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any if the authors.

References

Papers of particular interest, published recently, have been highlighted as:
• Of importance
•• Of major importance

1. McDonald CL, Westcott-McCoy S, Weaver MR, Haagsma J, Kartin D. Global prevalence of traumatic non-fatal limb

amputation. Prosthet Orthot Int. 2021;45(2):105–14. https://doi.org/10.1177/0309364620972258.
2. Ezzatvar Y, García-Hermoso A. Global estimates of diabetes-related amputations incidence in 2010–2020: a systematic review and meta-analysis. Diabetes Res Clin Pract. 2023;195:110194. https://doi.org/10.1016/j.diabres.2022.110194.
3. Stern JR, Wong CK, Yerovinkina M, Spindler SJ, See AS, Panjaki S, et al. A meta-analysis of long-term mortality and associated risk factors following lower extremity amputation. Ann Vasc Surg. 2017;42:322–7. https://doi.org/10.1016/j.avsg.2016.12.015.
4. Webster JB. Lower limb amputation care across the active duty military and veteran populations. Phys Med Rehabil Clin N Am. 2019;30(1):89–109. https://doi.org/10.1016/j.pmr.2018.08.008.
5. Lovegreen W, Murphy DP, Stevens PM, Seo YI, Webster J. Lower limb amputation and gait. Braddom's Phys Med Rehab. 2021.
6. Kwasniewski M, Mitchel D. Post amputation skin and wound care. Phys Med Rehabil Clin N Am. 2022;33(4):857–70. https://doi.org/10.1016/j.pmr.2022.06.010.
7. Sumpio B, Shine SR, Mahler D, Sumpio BE. A comparison of immediate postoperative rigid and soft dressings for below-knee amputations. Ann Vasc Surg. 2013;27(6):774–80. https://doi.org/10.1016/j.avsg.2013.03.007.
8. Wu Y, Keagy RD, Krick HJ, Stratigos JS, Betts HB. An innovative removable rigid dressing technique for below-the-knee amputation. J Bone Joint Surg Am. 1979;61(5):724–9.
9. Ghiulamila RI. Semirigid dressing for postoperative fitting of below-knee prosthesis. Arch Phys Med Rehabil. 1972;53(4):186–90.
10. Kerstein MD. Utilization of an air splint after below-knee amputation. Am J Phys Med. 1974;53(3):119–26.
11. Little JM. The use of air splints as immediate prostheses after below-knee amputation for vascular insufficiency. Med J Aust. 1970;2(19):870–2. https://doi.org/10.5694/j.1326-5377.1970.tb63234.x.
12. Sher MH. The air splint. An alternative to the immediate postoperative prosthesis. Arch Surg. 1974;108(5):746–7. https://doi.org/10.1001/archsurg.1974.01350290108022.
13.• Churilov I, Churilov L, Murphy D. Do rigid dressings reduce the time from amputation to prosthetic fitting? A systematic review and meta-analysis. Ann Vasc Surg. 2014;28(7):1801–8. https://doi.org/10.1016/j.avsg.2014.05.002. **This study was the first systematic review and meta-analysis of studies that compare time from amputation to prosthetic casting or fitting in transtibial amputees, which the results were the patients who are fitted with rigid dressings commence prosthetic management sooner than those managed with soft dressings.**
14.•• Kwah LK, Webb MT, Goh L, Harvey LA. Rigid dressings versus soft dressings for transtibial amputations. Cochrane Database Syst Rev. 2019;6(6):Cd012427. https://doi.org/10.1002/14651858.CD012427.pub2. **This study was the lastest systematic review and meta-analysis of RCTs and quasi-RCTs with the conclusion of uncertain of the benefits and harms of rigid dressings compared with soft dressings for people undergoing transtibial amputation due to limited and very low-certainty evidence.**
15. Covidence systematic review software. Melbourne, Australia: Veritas Health Innovation.
16. McGrath S, Zhao X, Steele R, Thombs BD, Benedetti A, Levis B, et al. Estimating the sample mean and standard deviation from commonly reported quantiles in meta-analysis. Stat Methods Med Res. 2020;29(9):2520–37. https://doi.org/10.1177/0962280219889080.
17. Higgins JPT TJ, Chandler J, Cumpston M, Li T, Page MJ, Welch VA. Cochrane Handbook for Systematic Reviews of Interventions. Cochrane. 2022.
18. Hidayati ER, Ilyas E, Murdana IN, Tarigan TJ, Werdhani RA. Efficacy of removable rigid dressing after transtibial amputation in diabetes mellitus patients. Med J Indones. 2013;22(1):16–21.
19. Janchai S, Boonhong J, Tiamprasit J. Comparison of removable rigid dressing and elastic bandage in reducing the residual limb volume of below knee amputees. J Med Assoc Thail = Chotmaihet thangphaet. 2008;91(9):1441–6.
20. Kothari S, Sharma R, Sabnis U. Comparison of a simple and cheap immediate postoperative prosthesis with soft dressing in lower limb amputations. J Evid Based Med Healthc. 2017;4:2184–7. https://doi.org/10.18410/jebmh/2017/428.
21. Mueller MJ. Comparison of removable rigid dressings and elastic bandages in preprosthetic management of patients with below-knee amputations. Phys Ther. 1982;62(10):1438–41. https://doi.org/10.1093/ptj/62.10.1438.
22. Sterne JAC, Savović J, Page MJ, Elbers RG, Blencowe NS, Boutron I, et al. RoB 2: a revised tool for assessing risk of bias in randomised trials. Bmj. 2019;366:l4898. https://doi.org/10.1136/bmj.l4898.
23. Sterne JA, Hernán MA, Reeves BC, Savović J, Berkman ND, Viswanathan M, et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. Bmj. 2016;355:i4919. https://doi.org/10.1136/bmj.i4919.
24. McGuinness LA, Higgins JPT. Risk-of-bias VISualization (robvis): An R package and Shiny web app for visualizing risk-of-bias assessments. Res Synth Methods. 2020;n/a(n/a). https://doi.org/10.1002/jrsm.1411.
25. Cohen S, Goldman L, Salzman E, Glotzer D. The deleterious effect of immediate postoperative prothesis in below-knee amputation for ischemic disease. Surgery. 1975;76:992–1001.
26. Kane TJ 3rd, Pollak EW. The rigid versus soft postoperative dressing controversy: a controlled study in vascular below-knee amputees. Am Surg. 1980;46(4):244–7.
27. Nicholas GG, DeMuth WE Jr. Evaluation of use of the rigid dressing in amputation of the lower extremity. Surg Gynecol Obstet. 1976;143(3):398–400.
28. Öğce F, Dramali A. Examination of the elastic bandage - rigid dressing effect for prevention of the stump oedema. SENDROM. 2003;15:117–9.
29. Golbranson FL, Wirta RW, Kuncir EJ, Lieber RL, Oishi C. Volume changes occurring in postoperative below-knee residual limbs. J Rehabil Res Dev. 1988;25(2):11–8.
30. Pinzur MS, Littooy F, Osterman H, Wafer D. Early post-surgical prosthetic limb fitting in dysvascular below-knee amputees with a pre-fabricated temporary limb. Orthopedics. 1988;11(7):1051–3. https://doi.org/10.3928/0147-7447-19880701-08.
31. Mooney V, Harvey JP Jr, McBride E, Snelson R. Comparison of postoperative stump management: plaster vs. soft dressings. J Bone Joint Surg Am. 1971;53(2):241–9.
32. Ali MM, Loretz L, Shea A, Poorvu E, Robinson WP, Schanzer A, et al. A contemporary comparative analysis of immediate postoperative prosthesis placement following below-knee amputation. Ann Vasc Surg. 2013;27(8):1146–53. https://doi.org/10.1016/j.avsg.2012.10.031.
33. Alsancak S, Köse SK, Altınkaynak H. Effect of elastic bandaging and prosthesis on the decrease in stump volume. Acta Orthop Traumatol Turc. 2011;45(1):14–22. https://doi.org/10.3944/aott.2011.2365.
34. Baker WH, Barnes RW, Shurr DG. The healing of below-knee amputations: a comparison of soft and plaster dressing. Am J Surg. 1977;133(6):716–8. https://doi.org/10.1016/0002-9610(77)90162-3.

35. Barber GG, McPhail NV, Scobie TK, Brennan MC, Ellis CC. A prospective study of lower limb amputations. Can J Surg J Can de Chir. 1983;26(4):339–41.
36. Deutsch A, English RD, Vermeer TC, Murray PS, Condous M. Removable rigid dressings versus soft dressings: a randomized, controlled study with dysvascular, trans-tibial amputees. Prosthet Orthot Int. 2005;29(2):193–200. https://doi.org/10.1080/03093640500224295.
37. Fencel R, Fitzpatrick S, Dunlap E, Nagarsheth K. Utilizing of removable rigid dressing to decrease below the knee amputations to above the knee amputations conversion rates. Am Surg. 2022;31348221101482. https://doi.org/10.1177/00031348221101482
38. Hallam FM, Jull GA. Evaluation of a temporary prosthetic insert in the rehabilitation of elderly ischaemic below-knee amputees: a pilot study. Aust J Physiother. 1988;34(3):133–8. https://doi.org/10.1016/s0004-9514(14)60605-x.
39. Hayes J, Bostick B, Williams M, Evans WE. Immediate fit prosthesis. In: Campbell RM, editor. Control Aspects of Prosthetics and Orthotics. Pergamon; 1983. p. 145–8.
40.• Koonalinthip N, Sukthongsa A, Janchai S. Comparison of removable rigid dressing and elastic bandage for residual limb maturation in transtibial amputees: a randomized controlled trial. Arch Phys Med Rehabil. 2020;101(10):1683–8. https://doi.org/10.1016/j.apmr.2020.05.009. **This study was a well-conducted RCT which be judged as a low risk of bias. The findings reveal that the use of removable rigid dressings had a significantly shorter period to residual limb maturation when compared with the soft dressings.**
41. Ladenheim E, Oberti-Smith K, Tablada G. Results of managing transtibial amputations with a prefabricated polyethylene rigid removable dressing. JPO J Prosthetics Orthot. 2007;19(1):2–4. https://doi.org/10.1097/JPO.0b013e31802d42c2.
42. MacLean N, Fick GH. The effect of semirigid dressings on below-knee amputations. Phys Ther. 1994;74(7):668–73. https://doi.org/10.1093/ptj/74.7.668.
43. Moore WS, Hall AD, Lim RC Jr. Below the knee amputation for ischemic gangrene. Comparative results of conventional operation and immediate postoperative fitting technic. Am J Surg. 1972;124(2):127–34. https://doi.org/10.1016/0002-9610(72)90003-7.
44. Mousavi Ziarati SM, Hedayatrad K, Nazari A, KalantarMotamed MR, Asadollahi DB. Comparison of personal independence between soft dressing and immediate postoperative prosthesis method in older diabetic amputees. J Rehab Sci Res. 2021;8(2):57–61.
45. Sarkar A, Fencel R, Dunlap E, Fitzpatrick S, Nagarsheth K. Utility of removable rigid dressings in decreasing discharge narcotic use and improving ambulation following below-knee amputation. Ann Vasc Surg. 2022. https://doi.org/10.1016/j.avsg.2022.11.003.
46. Schon LC, Short KW, Soupiou O, Noll K, Rheinstein J. Benefits of early prosthetic management of transtibial amputees: a prospective clinical study of a prefabricated prosthesis. Foot Ankle Int. 2002;23(6):509–14. https://doi.org/10.1177/107110070202300607.
47. Taylor L, Cavenett S, Stepien JM, Crotty M. Removable rigid dressings: a retrospective case-note audit to determine the validity of post-amputation application. Prosthet Orthot Int. 2008;32(2):223–30. https://doi.org/10.1080/03093640802016795.
48. van Velzen AD, Nederhand MJ, Emmelot CH, Ijzerman MJ. Early treatment of trans-tibial amputees: retrospective analysis of early fitting and elastic bandaging. Prosthet Orthot Int. 2005;29(1):3–12. https://doi.org/10.1080/17461550500069588.
49. Vigier S, Casillas J-M, Dulieu V, Rouhier-Marcer I, D'Athis P, Didier J-P. Healing of open stump wounds after vascular below-knee amputation: plaster cast socket with silicone sleeve versus elastic compression. Arch Phys Med Rehabil. 1999;80(10):1327–30. https://doi.org/10.1016/S0003-9993(99)90038-2.
50. Wong CK, Edelstein JE. Unna and elastic postoperative dressings: comparison of their effects on function of adults with amputation and vascular disease. Arch Phys Med Rehabil. 2000;81(9):1191–8. https://doi.org/10.1053/apmr.2000.3780.
51. Woodburn KR, Sockalingham S, Gilmore H, Condie ME, Ruckley CV. A randomised trial of rigid stump dressing following trans-tibial amputation for peripheral arterial insufficiency. Prosthet Orthot Int. 2004;28(1):22–7. https://doi.org/10.3109/03093640409167921.
52. Krajbich JI, Pinzur MS, Potter LBK, Stevens PM. Atlas of amputations & limb deficiencies. 4th ed.: AAOS; 2018.
53. Geertzen J, van der Linde H, Rosenbrand K, Conradi M, Deckers J, Koning J, et al. Dutch evidence-based guidelines for amputation and prosthetics of the lower extremity: amputation surgery and postoperative management. Part 1. Prosthetics Orthot Int. 2015;39(5):351–60. https://doi.org/10.1177/0309364614541460.