

CADTH Health Technology Review

Removable Rigid Dressings for the Post- Operative Management of Leg Amputations

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Abbreviations

AGREE II	Appraisal of Guidelines for Research and Evaluation II
AMSTAR 2	MeaSurement Tool to Assess systematic Reviews 2
DoD	Department of Defense
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
LLA	lower limb amputation
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	randomized controlled trial
RRD	removable rigid dressing
SR	systematic review
VA	Veteran Affairs
VRA	Netherlands Society of Physical and Rehabilitation Medicine

Key Messages

- Two systematic reviews and 1 randomized controlled trial provided evidence on the clinical effectiveness and safety of removable rigid dressings compared to soft dressings.
- Overall, there was limited evidence suggesting that removable rigid dressings had beneficial or neutral effects compared to soft dressings, and both types of dressings were associated with few adverse events.
- Limitations that may reduce the certainty of the evidence include small sample sizes, lack of randomization in non-randomized studies, lack of blinding, and selective reporting.
- Three evidence-based guidelines based on low-quality evidence were identified that provided recommendations related to removable rigid dressings. The Australian, Dutch, and US guidelines recommend the rigid dressings for transtibial amputations, although Australian and Dutch guidelines specified removable rigid dressings. The Dutch guideline recommends against the use of rigid dressings for transfemoral amputations.
- No evidence was identified on the cost-effectiveness of removable rigid dressings compared to alternative dressings.

Context and Policy Issues

People may require a lower limb amputation (LLA) for a variety of causes, including non-traumatic conditions, such as diabetes peripheral vascular disease, and congenital deficiencies, or traumatic cases, such as injuries.¹ LLAs may be minor, defined as at the ankle, foot, or toe; or major, which includes through-knee, below-knee (transtibial) and above-knee (transfemoral) amputation.² Estimates of LLA vary by type, as well as by country, time frame, and other factors. Worldwide, estimates range from 1.5 to 9,600 per 100,000 people, with higher incidence among people with diabetes.³ The incidence of LLA per 100,000 individuals is estimated to be 24 in the US, and 26 in the UK.^{3,4} A Canadian retrospective study using data from 2006 to 2012 reported that the incidence of LLA per 100,000 was 22.9 overall; 7.1 for transtibial amputations, and 5 for transfemoral amputations, which had declined slightly from about 6 per 100,000.⁵ Although the incidence of major LLAs in Canada has been stable or slightly declining over time,^{2,5} as populations age and the number of people with diabetes and/or peripheral artery disease increase, the number of people who will undergo major LLA may also increase. Understanding how to best provide care following an LLA can help to achieve optimal long-term health outcomes.⁶

Post-surgery management aims to provide a clean healing environment, reduce swelling and pain, protect the limb from external trauma, reduce incidence of knee flexion contractions, reduce hospital length of stay, reduce time to casting for a prosthesis, and allow for quicker return to daily living activities.⁶ One aspect of post-surgery management is the choice of dressing used. Dressings used following LLAs include soft dressings, non-removable rigid dressings, and removable rigid dressings (RRDs); each with different features, advantages, and disadvantages.⁶ Soft dressings are relatively low-cost, easy to apply, and allow for the wound to be checked if needed.^{1,6} However, they are associated with greater risk of injury from external trauma and increased risk of knee flexion contractures.⁶ They also have a tendency to fall off more easily, and could place uneven pressures on the residual limb, if not applied correctly, which may inhibit healing.⁶ In contrast, rigid dressings can provide more protection to the limb from external trauma; however, they are more difficult to apply.^{6,7} The use of

non-removable rigid dressings has decreased in clinical practice due to inaccessible wound site for inspection, and a high risk of wound dehiscence (splitting or re-opening of the surgical incision) for people with ischemic disease.⁶ An RRD is a type of rigid dressing that can also be easily removed to provide access to the wound site if needed without requiring a new cast be made after the inspection; however, they may also have a higher risk of knee flexion contractures compared to non-removable rigid dressings.^{1,6} The choice of dressing used seems to vary between sites, based on factors such as training and local practice patterns.⁶

The objective of this report is to identify and summarize current evidence regarding the clinical effectiveness, cost-effectiveness, and recommendations from evidence-based guidelines of RRDs versus alternative dressings for the post-operative management of people who underwent leg amputation.

Research Questions

1. What is the clinical effectiveness of removable rigid dressings versus alternative dressings for the post-operative management of people who underwent leg amputation?
2. What is the cost-effectiveness of removable rigid dressings versus alternative dressings for the post-operative management of people who underwent leg amputation?
3. What are the evidence-based guidelines regarding the use of removable rigid dressings for the post-operative management of people who underwent leg amputation?

Methods

Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including MEDLINE, the Cochrane Database of Systematic Reviews, the International HTA Database, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search strategy comprised controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were lower extremity amputation and dressings. No filters were applied to limit the retrieval by study type. The search was completed on May 6, 2022 and limited to English-language documents published since January 1, 2012.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in [Table 1](#).

Table 1: Selection Criteria

Criteria	Description
Population	People with leg amputations (transtibial or transfemoral)
Intervention	Removable rigid dressings
Comparator	Q1 to Q2: Alternative dressings (e.g., non-removable rigid dressings, soft dressings, stump shrinkers, compression bandages) Q3: Not applicable
Outcomes	Q1: Clinical effectiveness (e.g., healing time, length of time from amputation to prosthetic fitting, residual limb size, quality of life, pain, comfort, swelling, safety [e.g., rates of adverse events]) Q2: Cost-effectiveness (e.g., cost per quality-adjusted life-year gained) Q3: Recommendations regarding best practices (e.g., appropriate patient populations, cleaning, and maintenance protocols)
Study designs	Health technology assessments, systematic reviews, randomized controlled trials, non-randomized studies, economic evaluations, evidence-based guidelines

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in [Table 1](#), they were duplicate publications, or were published before 2012.

Critical Appraisal of Individual Studies

The included publications were critically appraised by 1 reviewer using the following tools as a guide: A Measurement Tool to Assess systematic Reviews 2 (AMSTAR 2)⁸ for systematic reviews, the Downs and Black checklist⁹ for randomized and non-randomized studies, and the Appraisal of Guidelines for Research and Evaluation (AGREE) II instrument¹⁰ for guidelines. Summary scores were not calculated for the included studies; rather, the strengths and limitations of each included publication were described narratively.

Summary of Evidence

Quantity of Research Available

A total of 170 citations were identified in the literature search. Following screening of titles and abstracts, 157 citations were excluded and 13 potentially relevant reports from the electronic search were retrieved for full-text review. Two potentially relevant publications were retrieved from the grey literature search for full-text review. Of these potentially relevant articles, 9 publications were excluded for various reasons, and 6 publications met the inclusion criteria and were included in this report. These comprised 2 systematic reviews (SRs) with meta-analyses, 1 randomized controlled trial (RCT), and 3 evidence-based guidelines. [Appendix 1](#) presents the PRISMA¹¹ flow chart of the study selection. Additional references of potential interest are provided in [Appendix 6](#).

Summary of Study Characteristics

Two SRs with meta-analyses^{1,12} 1 RCT,¹³ and 3 evidence-based guidelines¹⁴⁻¹⁶ were included in this report. Both SRs^{1,12} had broader inclusion criteria for the intervention than this review, comparing rigid dressings (including RRDs). However, both focused on transtibial amputations and had narrower comparator criteria limited to soft dressings.^{1,12} Where meta-analyses included studies not relevant to this report, only data from the individual studies were reported. Only the primary clinical studies that met the inclusion criteria are presented in this report. There was some overlap in the studies included in the SRs, and the degree of overlap is summarized in [Appendix 5](#).

Two of the guidelines^{15,16} also addressed broader inclusion criteria, providing guidance related to amputation of lower extremities in general. One guideline¹⁴ was specific to RRDs. Only the recommendations related to the usage of RRDs are presented in this report. The literature search used by the Agency for Clinical Innovation's guideline¹⁴ was reported in a separate document,¹⁷ used to supplement the information about the guideline in this report.

Additional details regarding the characteristics of included publications are provided in [Appendix 2](#).

Study Design

Both SRs^{1,12} conducted meta-analyses and searched multiple databases, and at least 1 clinical trial registry. The number of relevant primary studies ranged from 1 to 4 RCTs and 1 to 3 non-randomized studies.^{1,12} The latest literature search dates were between December 2013¹² and December 2018.¹

The included RCT was a single-centre, single-blinded study using data from 2017 to 2018.¹³ The patients were randomized using block-of-4 randomization, and were not blinded. However, the assessor measuring outcomes was blinded to patients' group assignment. The investigators performed a sample size calculation and used an intention-to-treat approach to analyze data.¹³

All 3 included evidence-based guidelines used systematic literature searches of multiple databases.¹⁴⁻¹⁶ All noted that the quality of evidence was low, and thus the recommendations were weak in strength or based on expert opinion.¹⁴⁻¹⁶

The guideline by the Agency for Clinical Innovation¹⁴ used different quality assessment tools for different types of studies (AMSTAR for SRs, a modified version of Downs and Black for primary clinical studies, and a tool adapted from the STROBE statement for practitioner survey studies). Aside from assessing evidence quality, they did not provide a guideline development methodology.

The guideline by the US Department of Veteran Affairs (VA) and Department of Defense (DoD)¹⁵ was an update to a previously published guideline. The VA and DoD guideline used the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) methodology to assess the quality of the literature and consulted with a focus group of people with LLA to provide patient perspectives. Experts gathered at a meeting to develop and update recommendations, and the draft guideline was reviewed by experts from inside and outside the federal sector.

The guideline by Geertzen et al.¹⁶ was developed by the Netherlands Society of Physical and Rehabilitation Medicine (VRA) and used evidence-based guideline development forms

to assess the quality of identified literature. Details about the guideline development methodology were not provided, though they stated that in addition to the scientific evidence, they also considered patient preferences, availability of special techniques or expertise, organizational aspects, social consequences, and costs when developing the recommendations.

Country of Origin

The SRs were conducted by authors from Singapore¹ and Australia.^{1,12} The primary studies of the SRs that were relevant to this report were from Australia, France, Thailand, the Netherlands, and the US.^{1,12} The included RCT¹³ was conducted in Thailand.

The evidence-based guidelines were developed by the New South Wales (Australia) government's Agency for Clinical Innovation,¹⁴ the US's VA and DoD,¹⁵ and the Netherlands Society of Physical and Rehabilitation Medicine.¹⁶ The VA and DoD guideline¹⁵ states that its intended population of interest are adults eligible for care within the VA and DoD health care delivery systems. The other 2 guidelines^{14,16} do not specify which country they are meant to be applied to; however, it is likely they are intended for use in the countries in which they were developed.

Patient Population

Both SRs^{1,12} included people who had undergone transtibial amputations; 1 SR¹ stated that if studies included transtibial and transfemoral amputations, it was included if at least 75% of patients had transtibial amputation. The relevant RCTs in the SRs had sample sizes between 23 and 56, while the relevant non-randomized studies had between 15 and 104.^{1,12} One SR¹ did not have age restrictions, and reported details for the individual studies, where for the relevant studies, the mean age ranged from approximately 57 to 73 years, and the proportion of male patients ranged from 42% to 80%. The other SR¹² was restricted to adults and did not report demographic details for the individual studies.

The RCT¹³ was restricted to adults (defined as patients 18 years or older). From the sample of 25, including 5 people who dropped out, the mean age was 53.65 years, and 64% of patients were men. Patients in the intervention group did not differ significantly from the patients in the control group on age, sex, cause of amputation, duration after amputation, or baseline residual limb volume.

The evidence check for the Australian guideline¹⁴ considered amputations generally, though their review question specific to post-operative dressings focused on LLAs. The VA and DoD,¹⁵ and Dutch guidelines¹⁶ provide recommendations for individuals with LLAs. For the recommendations regarding the type of dressing, the Australian,¹⁴ VA, and DoD¹⁵ guidelines provide guidance for people with transtibial amputation, while the Dutch guideline¹⁶ provides recommendations following transtibial and transfemoral amputation.

Interventions and Comparators

Both SRs^{1,12} compared rigid dressings to soft dressings; but not all their primary studies focused on RRDs. One SR¹ included 9 studies, 5 of which compared RRDs to soft dressings; the other SR¹² included 6 studies, 4 of which compared RRDs to soft dressings. The RCT¹³ compared RRDs to elastic bandages, which is a type of soft dressing.

The follow-up time varied across studies, possibly due to the use of time-to-event assessment approach, for which follow-up ended once an outcome was achieved. One SR¹ reported the

follow-up time for individual studies, with durations of up to 8 weeks for the studies relevant to this report. The other SR¹² did not report follow-up time for individual studies. In the RCT, the follow-up time was over 2 months for some patients.¹³ In this report, short-term is defined as up to 1 month, while medium-term is defined as 1 to 3 months.

Recommendations that specified RRDs were included in 2 guidelines.^{14,16} One guideline¹⁵ provided a recommendation for rigid or semi-rigid dressings, without specifying removable or non-removable; however, they referred to RRDs in the evidence discussion, which may indicate their recommendation includes RRDs.

Outcomes

Both SRs^{1,12} reported clinical effectiveness and safety outcomes. The clinical outcomes reported in the SRs included changes in swelling (measured in cm³),¹ time to wound healing,¹ time to no pain,¹ time to walking,¹ length of hospital stay,¹ time to prosthetic fitting or casting,¹² and complications or adverse effects (proportion of events per group).^{1,12} Where available, the SR by Kwah et al.¹ grouped the outcomes as short- or medium-term; they also presented a range of complications, including those related to the skin (i.e., wound infections or breakdown, stump revisions, further amputations, pressure areas) and not skin-related (i.e., deaths, chest infections, medical complications, falls, pain). The other SR¹² reported 2 types of skin-related complications (i.e., progression to transfemoral amputation, and wound infection).

The RCT¹³ also reported on clinical effectiveness and safety outcomes. Their primary outcome was time to residual limb maturation, which the authors defined as the time when the volume of the residual limb had stabilized (i.e., not changed more than 10% since the last assessment), soft tissue atrophy had occurred, and the residual limb had developed into a cylindrical shape. Their secondary outcomes included complications (recorded by medical record or patient self-report) and patient satisfaction (using a 5-point Likert scale, where a higher score indicated greater satisfaction).

The 3 included evidence-based guidelines considered efficacy outcomes (e.g., wound healing, time to prosthetic fitting, changes in functional status),¹⁴⁻¹⁶ and 2 guidelines considered safety-related outcomes (e.g., falls, complications).^{14,15}

Summary of Critical Appraisal

An overview of the critical appraisal of included publications is presented in the following section. Additional details regarding the strengths and limitations of included publications are provided in [Appendix 3](#) for the SRs ([Table 5](#)), primary clinical study ([Table 6](#)), and guidelines ([Table 7](#)).

Systematic Reviews

Both SRs^{1,12} clearly stated their research question and inclusion criteria. The primary studies included in the SRs^{1,12} were identified from searches in multiple databases and at least 1 trial registry, performed within 24 months of the review's completion. One SR¹ published the methods in advance; the other SR¹² did not report if a protocol had been published before the review being conducted. Thus, for 1 SR¹² it is unclear if there were any significant protocol deviations which may impact the interpretation of their findings. One SR¹ described the selection of articles, presented a flow chart, and listed both included and excluded studies, but the other SR¹² did not report such details. Providing details about the literature search

increases the reproducibility of the review. None of the SRs explained their method of study selection.^{1,12} Due to these limitations, it is unclear if the selection process could capture all relevant studies.

In 1 SR,¹ 2 reviewers independently conducted the study selection, assessed the risk of bias of included primary studies, and extracted data using a piloted form. In the other SR¹² the authors did not state if study selection was performed in duplicate, which may also increase the risk of not capturing all relevant studies. Data extraction was not performed in duplicate, and it is unclear how data was extracted. Thus, the potential for data extraction errors could not be assessed.

Both SRs^{1,12} assessed the quality of included studies. One SR¹ used criteria from the Cochrane Handbook for Systematic Reviews of Interventions to assess risk of bias, while the other SR¹² used the Cochrane trial quality review criteria. One SR¹ reported level of risk for different domains; all relevant studies were scored as having high or unclear risk for at least some types of biases, though a few studies were judged as low risk of bias for some domains. They also reported a GRADE score for each outcome and concluded that all reported outcomes had very low certainty.¹ The other SR¹² summarized the method of randomization, blinding, attrition bias, and statistical analyses for each study, and concluded that most papers in the review were of low-quality.

Meta-analyses were conducted by both SRs.^{1,12} One SR¹ conducted multiple meta-analyses for different outcomes, using appropriate statistical methods.¹

Both SRs^{1,12} reported the funding received by the review authors. One SR¹ stated the funding was for their review, while the other SR¹² acknowledged the funding was received by their department. The review authors in 1 SR¹ reported no conflicts of interest, while the other SR¹² did not report conflicts of interests.

Randomized Controlled Trials

The included RCT¹³ clearly reported their objective, intervention, and findings. The authors described the randomization method and reported baseline characteristics of all randomized patients, including those who dropped. The patients were recruited at the same site over the same time, and the treatment site was likely representative of typical care. However, it is unclear if the patients were representative of the population due to the relatively small sample size.

The main outcome was assessed with appropriate statistical tests based on the intention-to-treat population and adjusted for different follow-up lengths.¹³ The outcome assessor was blinded to the patients' group assignment.¹³ Patients were not blinded; however, blinding was not feasible for them due to the nature of the intervention. Though the lack of blinding is unlikely to significantly affect objective outcomes such as stump volume; a potential exists for performance bias of subjective outcomes, such as self-reported satisfaction or complications.

Although the number of patients was smaller than what the authors predetermined in a sample size calculation, a post-study statistical analysis indicated that the study had 80% power to detect differences in treatment effect between the study groups.¹³ From the 25 randomized patients, 5 dropped out (2 from the RRD group, 3 from the control group). The reported reasons for dropping out were inconvenience, diagnosis of cancer or congestive heart failure.¹³

The authors reported their funding, stating they were supported by a university grant, though it is unclear if this grant was specifically for this study. They also did not report on conflicts of interest.¹³

Guidelines

All 3 included guidelines¹⁴⁻¹⁶ provided clear details regarding their scope and purpose, including their target users. The recommendations were also easy to identify. Only the US guideline¹⁵ clearly stated that their guideline development group included people from all relevant professional groups, although the Dutch guideline¹⁶ indicated that patient views or preferences had been considered, while the Australian guideline¹⁴ reported a consensus among expert clinicians and professional organizations regarding a preference of rigid dressings over soft dressings. All the guidelines used systematic literature searches for evidence, described their selection criteria and quality of evidence, and presented the recommendations in a way that made them easy to identify.¹⁴⁻¹⁶ Two guidelines^{15,16} ranked their recommendations as weak; while the Australian guideline¹⁴ did not report strength of recommendations, referring to them as expert consensus.

Two guidelines^{14,16} provided unambiguous recommendations regarding RRDs following transtibial amputations. The Dutch guideline¹⁶ provided a recommendation based on expert opinion against rigid dressings for people after a transfemoral amputation. Similarly, the US guideline¹⁵ recommends rigid dressings without specifying removable or non-removable, though the evidence summary supporting the recommendation specified RRDs. All guidelines reported some details regarding rigour of development, though none described how the recommendations were formulated or provided a procedure for updating the guidelines.¹⁴⁻¹⁶ Two guidelines^{15,16} were externally reviewed; the Australian guideline¹⁴ did not state if their guideline underwent external review. Overall, the guidelines did not provide advice for how to put the recommendations into practice, or monitoring and/or auditing criteria.¹⁴⁻¹⁶ The US and Dutch guidelines^{15,16} considered the availability of needed resources (potential facilitators or barriers), and resource use or costs (potential resource implications) when developing the guidelines. For both of these guidelines,^{15,16} the authors declared no conflicts of interest or reported that competing interests had been recorded and addressed. The Australian guideline¹⁴ did not state they considered facilitators, barriers, or resource use, and they did not provide conflicts of interest information. For all 3 guidelines, it is unlikely the funding body influenced the guideline's recommendations.¹⁴⁻¹⁶

Summary of Findings

[Appendix 4](#) presents the main study findings of the included SRs^{1,12} and RCT¹³ by outcome. The outcomes of interest reported were changes in swelling ([Table 8](#)), participant satisfaction ([Table 9](#)), time to events ([Table 10](#)), and complications ([Table 11](#)). [Appendix 4](#) also presents the summary of guideline recommendations¹⁴⁻¹⁶ ([Table 12](#)). There was some overlap in the included SRs: 1 RCT was included in both SRs, with the citation matrix illustrating the overlap presented in [Appendix 5](#) ([Table 13](#)). To avoid duplication of reporting, the outcome data from this RCT is reported only once as part of 1 SR.

Clinical Effectiveness of Removable Rigid Dressings

Change In Swelling

One SR¹ identified 3 studies that assessed the change in swelling as measured by the stump volume in cm³. All 3 studies assessed within 1 month (short-term) and 2 also assessed the outcome from 1 to 3 months (medium-term). The meta-analyses found that that in the

short-term, RRD was associated with a statistically significantly faster decrease in swelling compared to soft dressings. However, in the medium-term, there difference between the groups was not statistically significantly. This suggests that compared to using soft dressings, using RRDs may be associated with a faster reduction in swelling in the short-term, but not in the medium-term.

Patient Satisfaction

The RCT¹³ assessed patient satisfaction on a 5-point Likert scale, where a higher score indicated greater satisfaction, which might indicate patients' adherence to the treatment. They found that the mean scores were 4.45 and 4.11 for the RRD and elastic bandages groups, respectively, indicating a similar levels of patient satisfaction without a statistically significant difference between the devices.¹³

Time-Related Outcomes

One SR¹ reported on the length of hospital stay, time to wound healing, time to no pain, and time to walking. For each outcome, 1 relevant study of the SR reported data. Compared to soft dressing, RRD was associated with shorter time from amputation to wound healing and length of hospital stay. No significant difference between groups was found for time from amputation to no pain and time from amputation to walking.

Time to fitting or casting the prosthesis was assessed by 1 SR¹² and 1 RCT.¹³ While this SR¹² conducted a meta-analysis for this outcome, it included studies not relevant to this report (grouping RRDs with non-removable rigid dressings); thus, only data from the individual relevant studies, and not the meta-analyses, are included in this report. The SR¹² identified 4 relevant studies, 2 of which reported a statistically significantly shorter time to casting in the RRD group than the soft dressing group, while the other 2 reported no statistically significant difference between the 2 groups. The RCT¹³ reported on time to residual limb maturation, assuming that once limb maturation was achieved, it was time for prosthetic casting. The RCT¹³ found that the RRD group had a significantly shorter time to residual limb maturation than the group treated with elastic bandages, even after adjusting for the time since amputation. Thus, time to fitting or casting had mixed results across the identified studies.

Complications

A variety of complications were reported by the studies included in this report. The RCT¹³ reported that, overall, there were no complications in the RRD group; whereas 3 out of 12 patients experienced complications in the elastic bandages group. This difference was not statistically significant.

Both SRs^{1,12} and the RCT¹³ reported skin-related complications (e.g., wound infection or breakdown or trauma, skin irritation, progression to transfemoral amputation or further amputation, pressure areas). In general, skin-related complication rates were numerically similar across both the RRD and soft dressing groups, except for progression to re-amputation, reported by a retrospective cross-sectional study reported by 1 SR¹² with 5% with RRD compared to 17% with soft dressing. A RCT in the other SR¹ also assessed revisions to transfemoral amputation, and found it occurred for 4% and 8% of patients in the RRD and soft dressings groups, respectively. The included RCT¹³ identified 2 (approximately 17%) skin-related complications in the elastic bandages group compared to none in the RRD group. The level of statistical significance was not reported or observed for any of the comparisons.

One SR¹ reported non-skin-related complications including deaths, medical complications, and falls. One or 2 RCTs in the SR reported for each of the outcomes, with none showing statistically significant differences between the RRD and soft dressing groups. Pooled analysis found that approximately 18% of patients in the soft dressings group experienced falls compared to 13% in the RRD group.¹ For the other assessments, the complication rates were less than 15% in both groups. The RCT¹³ reported that 1 participant in the elastic bandages group had a knee flexion contracture, compared to none in the RRD group.

Cost-Effectiveness of Removable Rigid Dressings

No cost-effectiveness studies of RRDs versus alternative dressings for the post-operative management of people who underwent leg amputation were identified; therefore, no summary can be provided.

Guidelines

The Australian guideline¹⁴ recommends the use of RRDs for people who have undergone a transtibial amputation, based on an evidence review finding RRDs were associated with improved outcomes. The developers noted a lack of RCTs and poor quality of evidence due to risk of biases in available studies. They did not provide a strength rating for the recommendation.

The US VA and DoD clinical guideline¹⁵ recommends that a rigid or semi-rigid dressing be used as soon as possible post-amputation for transtibial amputation, with rigid post-operative dressings preferred if limb protection is a priority. The strength of the recommendation was rated as weak. While the recommendation itself does not specify RRDs, the authors refer to previous research specific to RRDs in the discussion section; implying that the recommendation may apply to RRDs.

The Dutch guideline¹⁶ states that a RRD may be considered for people with a transtibial amputation if 1 wishes to use a rigid dressing and regular wound monitoring is indicated. The literature search for post-operative management identified 2 studies comparing RRDs with soft dressings. The guideline does not recommend rigid dressings for people following transfemoral amputation. They also state that following transfemoral amputation, the current post-operative management using stump dressing (light elastic bandages or stump stockings) can be maintained. While this recommendation does not specify RRDs, it implies that specified alternative dressings are recommended over all types of rigid dressings for patients who undergo transfemoral amputation. Both recommendations were graded as based on expert opinion.

Limitations

Several limitations were identified that prevent definitive conclusions regarding the clinical effectiveness of RRDs compared to other dressings for leg amputations. Most primary clinical studies included in the SRs^{1,12} and RCT¹³ had relatively small sample sizes: all the RCTs had less than 100 patients, and only 1 non-randomized study had a sample size of more than 100. These studies varied in the outcomes they assessed, and several outcomes of interest to this review only had data from a single study. Although pooled analyses were available for a few

outcomes, they also had relatively few patients (between 45 and 76) in total. Thus, many of the presented results are based on relatively small sample sizes.

Both SRs^{1,12} included RCTs and non-randomized studies. One SR¹² did not report details regarding the individual studies' population. The included primary clinical studies also had varying levels of risk of bias.^{1,12} Some methodological limitations reported by the SRs were related to risk of selection bias in non-randomized studies,^{1,12} lack of allocation concealment,¹ incomplete outcome data,^{1,12} selective reporting,¹ inappropriate statistical tests,¹² and lack of power analysis or sample size calculation.¹² Non-blinding of patients could have led to performance bias, but due to the nature of the intervention, it is unlikely that participant blinding would have been possible. Quality issues from the primary studies can cause uncertainty in the findings presented by the SRs. The RCT was also limited by lack of blinding of the patients.¹³ Across all the included primary clinical studies, only 2 published in the past 10 years; thus, it is unclear if some findings from the older studies would still apply today, given changes in technology care delivery (e.g., if newer RRDs are better and may have improved outcomes compared to older RRDs, or if changes in post-amputation care that could affect the clinical benefits of RRDs).

Some of the guidelines were unclear as they referred to rigid dressings without specifying RRDs.^{15,16} All guidelines¹⁴⁻¹⁶ were based on low- or poor-quality evidence, and have weak^{15,16} or unranked recommendations.¹⁴

Evidence for clinical effectiveness was available for limited to transtibial amputation and comparisons of RRDs to soft dressings, with none of the included primary studies compared RRDs to other types of dressings (e.g., non-removable rigid dressings). In addition, none of the included studies were conducted in Canada, and none of the guidelines were specifically intended for use in Canada. Thus, the generalizability of the findings and recommendations to the Canadian context are unknown, due to differences between countries regarding health care systems and availability of resources.

Conclusions and Implications for Decision- or Policy-Making

This rapid review was conducted to examine the clinical effectiveness and cost-effectiveness of RRDs compared to alternative dressings, as well as summarize guidelines regarding the use of RRDs. A previous CADTH report from 2012¹⁸ addressed a similar topic, comparing RRDs to non-removable rigid dressings for people following leg amputation. That report found limited evidence (from 1 RCT published in 2008) indicating no significant differences in clinical effectiveness or adverse events between RRDs and non-removable rigid dressings, but it did not identify any evidence regarding cost-effectiveness or recommendations from evidence-based guidelines.¹⁸

The current report includes 2 SRs^{1,12} 1 RCT,¹³ and 3 evidence-based guidelines.¹⁴⁻¹⁶ The SRs and RCT provide evidence regarding the clinical effectiveness and safety of RRDs compared to soft dressings for people who had a transtibial amputation.^{1,12,13} Evidence comparing the clinical effectiveness of RRDs to alternative dressings for people following a transfemoral amputation was not identified. In addition, no evidence was identified regarding the cost-effectiveness of RRDs compared to alternative dressings for people with a leg amputation.

There was limited evidence to suggest that in the short-term (less than 1 month), using RRDs may lead to greater reduction in swelling, shorter time to wound healing, and shorter length of hospital stay compared to using soft dressings.¹ However, over the medium-term (1 to 3 months), no significant differences were found between RRDs and soft dressings regarding change in swelling, time from amputation to no pain, and time to walking.¹ The evidence was mixed regarding the time to fitting or casting the prosthesis.^{12,13} A variety of complications were reported and they occurred at generally similar rates for both the RRD and soft dressing groups.^{1,12,13} The statistical significance of the differences in the rate of complications were not reported or observed for any comparison. Thus, this review found that overall, RRDs had a beneficial or neutral effect on clinical outcomes compared to soft dressings with similar adverse events rates. However, these results should be interpreted with caution due to the small sample sizes and other methodological limitations.

Two identified guidelines^{14,16} recommended using RRDs for transtibial amputations whereas 1 guideline¹⁵ recommends rigid dressings, without specifying RRDs. One guideline recommends against the using rigid dressings for transfemoral amputations.¹⁶ All the guidelines were based on low-quality evidence and the strength of recommendations was not graded or ranked as weak.

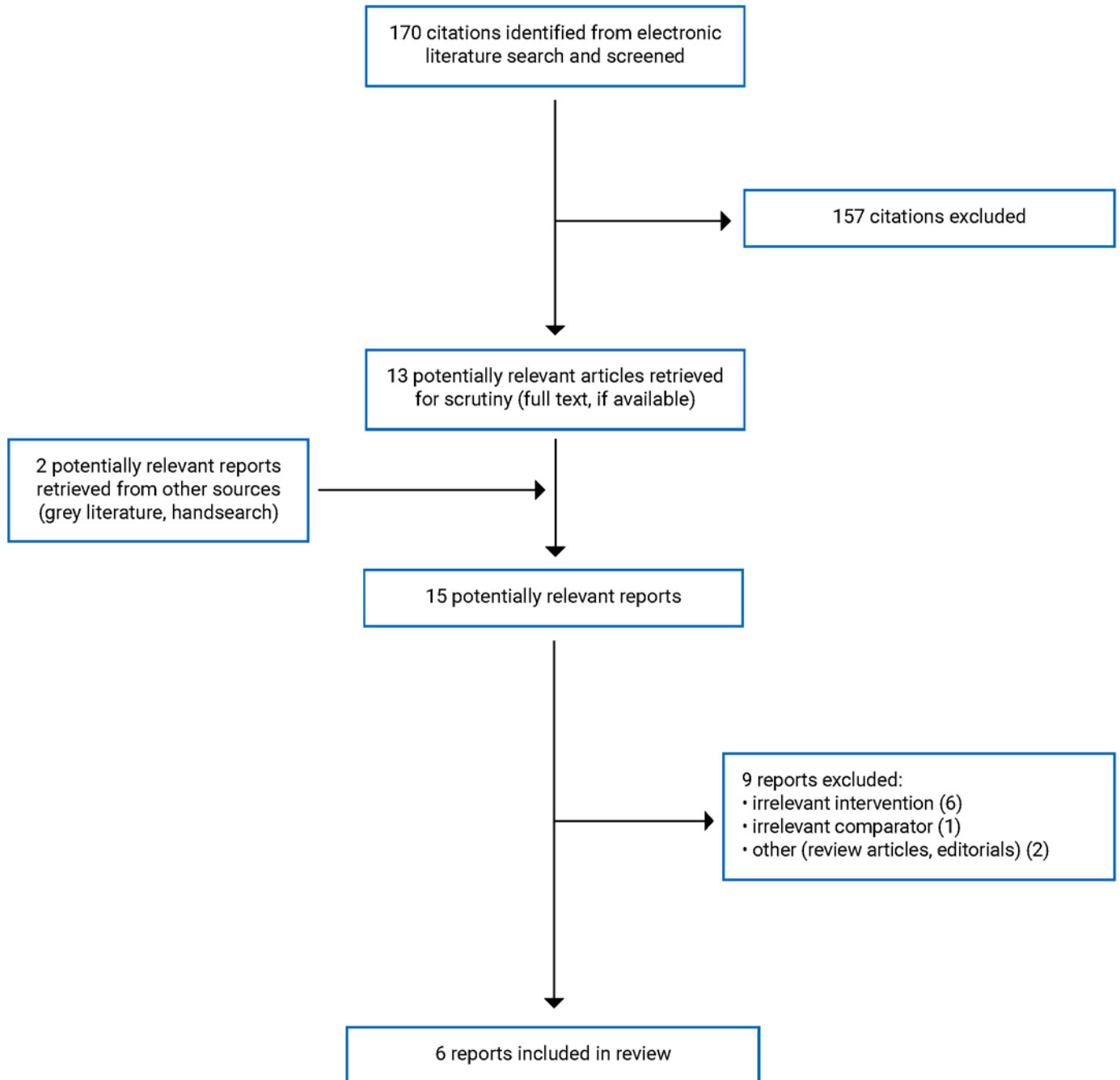
Due to the limitations of the included studies in this report, there is insufficient evidence to provide definitive conclusions about the clinical effectiveness of RRDs compared to alternative dressings following leg amputation. More robust research from well-designed studies, including research set in Canada, is required to provide evidence on the clinical effectiveness and cost-effectiveness of RRDs for people following a leg amputation.

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Appendix 1: Selection of Included Studies

Figure 1: Selection of Included Studies



Appendix 2: Characteristics of Included Publications

Note that this appendix has not been copy-edited.

Table 2: Characteristics of Included Systematic Reviews and Meta-Analyses

Study citation, country, funding source	Study designs, study objectives, search dates, number of primary studies	Population characteristics	Intervention and comparator	Clinical outcomes, length of follow-up
<p>Kwah et al. (2019)¹ Singapore Funding source: National Institute for Health Research, via the Cochrane Infrastructure funding to Cochrane Wounds</p>	<p>SR and MA of RCTs and quasi-RCTs (studies with quasi-randomized allocation procedures)</p> <p>Objective: To determine if rigid dressings are more effective than soft dressings for wound healing following transtibial amputation.</p> <p>Search dates: Up to December 2018</p> <p>Number of included studies: 9</p> <p>Number of relevant studies: 5 (4 RCT, 1 NRS)</p>	<p>People who had a transtibial amputation</p> <p>Sample sizes from relevant studies: 15 to 56</p> <p>Mean age from relevant studies: 57 to 73</p> <p>% male from relevant studies: 42 to 80%</p>	<p>Eligible intervention: Rigid dressings</p> <p>Relevant intervention: RRD</p> <p>Comparator: Soft dressing</p>	<p>Outcomes:</p> <ul style="list-style-type: none"> • Changes in swelling (cm³) • Time from amputation to wound healing • Time from amputation to no pain • Time from no amputation to walking • Proportion of wounds healed • Proportion of skin- and non-skin-related adverse events <p>Follow-up: up to 8 weeks</p>
<p>Churilov et al. (2014)¹² Australia Funding source: the Victoria Government, particularly the Operational Infrastructure Support Grant</p>	<p>SR and MA of RCTs and cross-sectional studies</p> <p>Objective: To determine if rigid dressings are more effective than soft dressings for wound healing following transtibial amputation</p> <p>Search dates: Up to December 2013</p> <p>Number of included studies: 6</p> <p>Number of relevant studies: 4 (1 RCT, 3 NRS)</p>	<p>Adults who had an amputation of the lower limb</p> <p>Sample sizes from relevant studies: 50 to 104</p> <p>Mean age from relevant studies: NR</p> <p>% male from relevant studies: NR</p>	<p>Eligible intervention: Rigid dressings</p> <p>Relevant intervention: RRD</p> <p>Comparator: Soft dressing</p>	<p>Outcomes:</p> <ul style="list-style-type: none"> • Time from surgery to prosthetic casting or fitting • Wound complications <p>Follow-up: NR; only reported mean time from amputation to casting or fitting, which varied from 19 to 76 days by study and group.</p>

MA = meta-analysis; NR = not reported; NRS = non-randomized studies; RCT = randomized controlled trial; RRD = removable rigid dressing; SR = systematic review.

Table 3: Characteristics of Included Primary Clinical Study

Study citation, country, funding source	Study design and setting	Population characteristics	Intervention and comparator(s)	Clinical outcomes, length of follow-up
Randomized controlled trial				
<p>Koonalinthip et al. (2019)¹³ Thailand Funding source: Ratchadapisek Sompoch Endowment Fund Chulalongkorn University (grant no. RA61/002).</p>	<p>Study design: Single-centre, single-blinded (assessor-blinded) RCT Setting: Department of Rehabilitation Medicine, King Chulalongkorn Memorial Hospital Sample size calculation: Yes Intention-to-treat analysis: Yes</p>	<p>Adults (18+ years) who had a transtibial amputation from July 2017 to February 2018 (n = 25, including 5 who dropped out). Mean (SD) age in years: • RRD: 65.25 (14.21) • EB: 62.15 (17.32) % male: • RRD: 69% • EB: 58% Cause of amputation (%): • RRD: infected DM foot (54), critical limb ischemia (38), trauma (8) • EB: infected DM foot (50), critical limb ischemia (50) Mean (SD) duration after trauma in days: • RRD: 24.83 (13.60) • EB: 34.62 (16.51) Mean (SD) baseline residual limb volume in cm³: • RRD: 830.92 (305.21) • EB: 894.78 (660.85)</p>	<p>Intervention: RRD Comparator: EB</p>	<p>Outcomes: • Time to residual limb maturation^a • Complications • Patient satisfaction Follow-up: Until the residual limb matured; at least 1 participant followed for over 150 days.</p>

DM = diabetes mellitus; EB = elastic bandage; RCT = randomized controlled trial; RRD = removable rigid dressing; SD = standard deviation.

^aResidual limb maturation defined as: the volume of the residual limb had stabilized (volume did not change more than 10% from previous assessment), soft tissue atrophy occurred, and residual limb had been molded into a cylindrical shape. (p.1684).¹³

Table 4: Characteristics of Included Guidelines

Intended users, target population	Intervention and practice, major outcomes considered	Evidence collection, selection, and synthesis	Evidence quality assessment	Recommendations development and evaluation	Guideline validation
New South Wales (Australia)'s Agency for Clinical Innovation (2017)¹⁴					
<p>Intended users: Clinicians managing patients who have undergone an amputation</p> <p>Target population: Individuals with lower limb amputation</p>	<p>Intervention: RRDs</p> <p>Outcomes: Swelling, wound healing, protection from potential trauma, shape for prosthetic fitting, pain control</p>	<p>Conducted a systematic review that searched PubMed, EMBASE (Ovid), EBM reviews including Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects (DARE), Cochrane Central Register of Controlled Trials (CENTRAL), ACP Journal Club, Cochrane Methodology Register, Health Technology Assessment and NHS Economic Evaluation Database (NHSEED – Ovid), and CINAHL.</p>	<p>The evidence was graded based on the study design type, level of risk of confounding and bias, and probability of causal relationship.</p>	<p>The guideline refers to the systematic review's identified evidence (findings and quality). Two reviews were rated as 'good' quality and 3 were 'poor', and the included primary studies were also rated and varied. They state that despite some limitations of the literature, emergent research suggests RRDs are associated with better clinical outcomes and thus they recommend RRDs be used. Details about process used by the development group to arrive at the recommendation were not provided.</p>	NR
US Department of Veterans Affairs and US Department of Defense (2017)¹⁵					
<p>Intended users: Veterans Affairs and Department of Defense health care providers</p> <p>Target population: Adults (18+) with lower limb amputation treated in any Veterans Affairs and Department</p>	<p>Intervention: Rigid or semi-rigid dressings</p> <p>Outcomes: Time from amputation to prosthetic fitting, wound healing rate, mobility, edema volume, residual limb healing time, hospitalization time, infection rate</p>	<p>Conducted a systematic review that searched the Cochrane Database of Systematic Reviews, CINAHL, EMBASE, Health Technology Assessment Database, MEDLINE/PreMEDLINE, PsychINFO, PubMed (in-process and Publisher records), and AHRQ. Selection</p>	<p>Used the GRADE methodology to assess the evidence and assigned the strength for each recommendation.</p>	<p>The guideline development process included formulating and prioritizing the key questions, conducting a systematic review, convening a face-to-face meeting, and drafting the guideline. After assessing the evidence quality, the working group</p>	<p>Experts from inside and outside the federal sector reviewed the draft guideline. Their comments or edits were incorporated based on panel consensus and consistency with the evidence review.</p>

Intended users, target population	Intervention and practice, major outcomes considered	Evidence collection, selection, and synthesis	Evidence quality assessment	Recommendations development and evaluation	Guideline validation
of Defense clinical setting		criteria included being a clinical study or systematic review and meeting inclusion criteria for any of the key questions.		had an in-person meeting to discuss and interpret the evidence review findings, review recommendations from the previous guideline, and develop new clinical recommendations. Each recommendation was given a strength rating by the working group based on an evidence to recommendations framework. A focus group of patients provided patient perspectives to inform the recommendation development. Following the meeting, the working group drafted the updated guideline.	
Netherlands Society of Physical and Rehabilitation Medicine, Geertzen et al. (2014)¹⁶					
Intended Users: Health care providers Target Population: Adults undergoing amputation of a lower extremity, particularly people with vascular disease	Intervention: Rigid dressings, including RRDs Outcome: Number of days to prosthesis fitting, time required for wound healing, function, adverse events (e.g., contractures)	Conducted a systematic search of the Cochrane Library, MEDLINE, Embase, PsychINFO, and CINAHL up to January 2011. Selection criteria included comparative studies with robust evidence (meta-analyses, systematic reviews, RCTs, controlled trials). If these were unavailable, further	Quality was assessed using evidence-based guideline development assessment forms; selected articles were graded by quality and low-quality articles were excluded.	Recommendations were developed based on scientific evidence, as well as other important considerations including patient preferences, availability of special techniques or expertise, organizational aspects, social consequences, and costs.	NR

Intended users, target population	Intervention and practice, major outcomes considered	Evidence collection, selection, and synthesis	Evidence quality assessment	Recommendations development and evaluation	Guideline validation
		comparative cohort studies, comparative case-control studies or non-comparative studies were searched. Case reports were also used to help with opinion-forming for certain key questions.			

AHRQ = Agency for Healthcare Research and Quality; GRADE = Grading of Recommendations Assessment, Development and Evaluation (methodology); NR = not reported; RCT = randomized controlled trial; RRD = removable rigid dressings.

Appendix 3: Critical Appraisal of Included Publications

Note that this appendix has not been copy-edited.

Table 5: Strengths and Limitations of Systematic Reviews and Meta-Analyses Using AMSTAR 2⁸

Strengths	Limitations
Kwah et al. (2019)¹	
<p>The research question and inclusion criteria were clearly stated and included the population, intervention, comparator, and outcomes.</p> <p>The methods were established before the review and published in advance (CD012427), and deviations from the protocol were reported.</p> <p>The review authors used a comprehensive search strategy including searching 7 databases, providing keywords and/or search strategy, searching reference lists of included studies, trial or study registries, and grey literature.</p> <p>The literature search was conducted within 24 months of the review’s completion, and thus should include studies that were recently published relative to the review’s completion date.</p> <p>The 2 review authors independently screened titles, abstracts, and full-text publications.</p> <p>The 2 review authors independently extracted data using a data extraction form that was piloted, with disagreements resolved by discussion or arbitration by a third review author.</p> <p>A list of excluded studies was provided, including justifications for the exclusions.</p> <p>The included studies were described in adequate detail and assessed for risk of bias in multiple domains. Risk of bias and GRADE assessments were performed independently by the 2 review authors.</p> <p>Sources of funding for the included studies were searched for by reviewers and reported where available.</p> <p>Appropriate methods were used for statistical combination of results in the meta-analysis.</p> <p>A sensitivity analysis that excluded studies with a high or unclear risk of bias for random sequence generation, concealed allocation, blinding of outcome assessor and incomplete outcome data was conducted.</p> <p>The reviewers discussed the likely impact of risk of bias on the review results.</p> <p>The review authors’ conflicts of interest and their funding source were reported.</p>	<p>The review authors did not explain their selection of study designs included in the review.</p> <p>It is unclear if content experts were consulted. Publication restrictions (study designs, languages) were not justified.</p> <p>Causes of heterogeneity were not investigated. Although the authors planned to do so, they stated that due to the small number of included studies, they could not.</p> <p>Separate estimates for RCTs and NRSs (quasi-RCTs) were not reported.</p> <p>Graphical or statistical tests were not performed for publication bias.</p>

Strengths	Limitations
Churilov et al. (2014)¹²	
<p>The research question and inclusion criteria were clearly stated and included the population, intervention, comparator, and outcomes.</p> <p>The methods provided included the objective, search strategy, inclusion and exclusion criteria, and risk of bias assessment.</p> <p>The review authors used a comprehensive search strategy including searching 3 databases and 1 trial registry, providing keywords and/or search strategy and searching reference lists of included studies.</p> <p>The literature search was conducted within 24 months of the review's completion, and thus should include studies that were recently published relative to the review's completion date. However, the systematic review was published 8 years ago (in 2014), and the advantage of its literature search's recency may not apply today.</p> <p>The number of excluded studies and their reasons for exclusion were provided.</p> <p>Data extraction was not performed in duplicate; however, 1 reviewer extracted, and another reviewer assessed the extracted data.</p> <p>The included studies were assessed for risk of bias using the Cochrane trial quality review criteria, including type of study, randomization, blinding, attrition bias, statistical analyses used, and power analysis.</p> <p>The authors investigated sources of heterogeneity in the results and discussed the likely impact on the review.</p> <p>Funding received by the review authors was reported.</p>	<p>The review authors did not state they had established the review methods before conducting the review.</p> <p>The methods did not state their plan for investigating causes of heterogeneity.</p> <p>It is unclear if there were any protocol deviations.</p> <p>The search strategy did not state if they searched grey literature or consulted content experts. Publication restrictions were not justified including the study designs included in the review.</p> <p>It is not stated if study selection was performed in duplicate.</p> <p>A list of excluded studies was not provided.</p> <p>Separate estimates for RCTs and NRSs were not reported.</p> <p>Some details about the included studies were not provided, including the mean age and proportion of male patients for each included study.</p> <p>Risk of bias in individual studies was not accounted for in the discussion of the results.</p> <p>Sources of funding for the included studies were not reported.</p> <p>Conflicts of interest were not reported.</p>

AMSTAR 2 = A MeaSurement Tool to Assess systematic Reviews 2; GRADE = Grading of Recommendations, Assessment, Development, and Evaluation; NRS = non-randomized study; RCT = randomized controlled trial.

Table 6: Strengths and Limitations of Clinical Study Using the Downs and Black checklist⁹

Strengths	Limitations
Randomized controlled trial	
Koonalinthip et al. (2020)¹³	
<p>Reporting:</p> <p>The objective, main outcomes, patient characteristics, interventions of interest, and main findings were clearly described.</p> <p>The treatment and control groups did not differ significantly at baseline based on reported characteristics.</p> <p>The number of patients who dropped out was reported, including their reasons for dropping out.</p> <p>Adverse events were reported.</p> <p>Actual P values were reported.</p> <p>External validity:</p> <p>Everyone at the site who had a transtibial amputation was screened for enrollment in this study. Therefore, patients may be representative of the population from which they were recruited.</p> <p>The proportion of people who were asked to participate and agreed was stated.</p> <p>The staff and facilities where treatment occurred was representative of the treatment typically provided.</p> <p>Internal validity – bias:</p> <p>Patients were assessed by a staff who was blinded to the intervention.</p> <p>Analyses adjusted for different follow-up lengths.</p> <p>The main outcomes used were valid and reliable, and assessed with appropriate statistical tests.</p> <p>Internal validity – confounding:</p> <p>Patients in all groups were recruited from the same population and over the same period.</p> <p>Patients were randomized to intervention groups using block-of-4 randomization.</p> <p>The randomized intervention assignment was concealed from the staff who assessed patients.</p> <p>Analyses were conducted using the intention-to-treat approach.</p> <p>Other:</p> <p>A sample size calculation was performed. While the number of patients was smaller than the calculated size, the statistical power after data analysis was 80%. It is unclear if this calculation includes the number of people who dropped out.</p>	<p>Reporting:</p> <p>20% of randomized patients dropped out, though the intervention and comparator groups had similar proportions of patients who dropped out.</p> <p>External validity:</p> <p>As the sample size was relatively small (N = 25) and patients were recruited from a single-centre, patients may not be representative of the population from which they were recruited.</p> <p>It is not clear if the distribution of confounding factors was the same in the study sample and source population.</p> <p>Internal validity – bias:</p> <p>Patients were not blinded to the intervention; however, it is unlikely this would have been possible due to the nature of the intervention.</p> <p>Compliance with the intervention was not assessed.</p>

Table 7: Strengths and Limitations of Guidelines Using AGREE II¹⁰

Item	Agency for Clinical Innovation (2017) ¹⁴	US VA and DoD (2019) ¹⁵	VRA, Geertzen et al. (2015) ¹⁶
Domain 1: Scope and purpose			
1. The overall objective(s) of the guideline is (are) specifically described.	Yes	Yes	Yes
2. The health question(s) covered by the guideline is (are) specifically described.	Yes	Yes	Yes
3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.	Yes	Yes	Yes
Domain 2: Stakeholder involvement			
4. The guideline development group includes individuals from all relevant professional groups.	Unclear	Yes	Unclear
5. The views and preferences of the target population (patients, public, etc.) have been sought.	Unclear	Yes	Yes – patient preferences noted as important when making recommendations.
6. The target users of the guideline are clearly defined.	Yes	Yes	Yes
Domain 3: Rigour of development			
7. Systematic methods were used to search for evidence.	Yes	Yes	Yes
8. The criteria for selecting the evidence are clearly described.	Yes	Yes	Yes
9. The strengths and limitations of the body of evidence are clearly described.	Yes	Yes	Yes
10. The methods for formulating the recommendations are clearly described.	No	No	No
11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	Yes	Yes	Yes
12. There is an explicit link between the recommendations and the supporting evidence.	Yes	Yes	Yes
13. The guideline has been externally reviewed by experts prior to its publication.	Unclear	Yes	Yes – published in a peer-reviewed journal.
14. A procedure for updating the guideline is provided.	No	No	No
Domain 4: Clarity of presentation			
15. The recommendations are specific and unambiguous.	Yes	Unclear – the relevant recommendation does not specify RRDs, but refers	Partially yes – 1 recommendation specifically refers to RRDs, but another recommendation

Item	Agency for Clinical Innovation (2017) ¹⁴	US VA and DoD (2019) ¹⁵	VRA, Geertzen et al. (2015) ¹⁶
		to RRDs in the supporting evidence.	refers to rigid dressings – it is unclear if this includes RRDs.
16. The different options for management of the condition or health issue are clearly presented.	Yes	Yes	Yes
17. Key recommendations are easily identifiable.	Yes	Yes	Yes
Domain 5: Applicability			
18. The guideline describes facilitators and barriers to its application.	No	Partial yes – their evidence to recommendation framework includes considering if interventions are generally available and variability in resourcing requirements.	Partial yes – they stated they considered availability of special techniques or expertise and organizational aspects when developing the recommendations.
19. The guideline provides advice and/or tools on how the recommendations can be put into practice.	No	No	No
20. The potential resource implications of applying the recommendations have been considered.	No	Yes – their evidence to recommendation framework includes considering costs of resource use.	Yes – they stated they considered social consequences and costs when developing the recommendations.
21. The guideline presents monitoring and/or auditing criteria.	No	No	No
Domain 6: Editorial independence			
22. The views of the funding body have not influenced the content of the guideline.	Likely yes – the systematic review was conducted by an independent, not-for-profit organization that receives its core funding from the local government. The guideline was developed by an agency that is part of the New South Wales government.	Likely yes – funding for this guideline was NR, but disclosure statements were used to identify any potential conflicts of interest by the project team members, and none were identified.	Likely yes – the guidelines were developed by the VRA, the authors declared no conflicts of interest, and funding came from the Quality Foundation of Dutch Medical Specialists.
23. Competing interests of guideline development group members have been recorded and addressed.	No	Yes	Yes

AGREE II = Appraisal of Guidelines for Research and Evaluation II; DoD = Department of Defense; NR = not reported; RRD = removable rigid dressing; VA = Veteran Affairs; VRA = Netherlands Society of Physical and Rehabilitation Medicine.

Appendix 4: Main Study Findings and Authors' Conclusions

Note that this appendix has not been copy-edited.

Table 8: Summary of Findings by Outcome – Change in Swelling (Stump volume in cm³)

Details	Kwah et al. (2019) ¹ – SR with MA (2 RCTs, 1 quasi-RCT)						Pooled analysis
	Hidayati et al. (2013) – RCT		Janchai et al. (2008) – RCT		Mueller (1982) – quasi-RCT		
	RRD	Soft dressing	RRD	Soft dressing	RRD	Soft dressing	
Short-term (less than 1 month)							
N	12	11	12	14	8	8	
Mean change in swelling (cm ³)	133.3	94.6	42.7	21.9	70.6	31.2	–
Standard deviation	6.2	33.6	62.7	118.5	21.3	49	–
Weight (%)	39.82		12.73		47.45		100
MD (95% CI)	38.78 (-1.64 to 79.2)		20.84 (-50.65 to 92.33)		39.5 (2.48 to 76.52)		38.84 (11.33 to 62.34)
Heterogeneity	–		–		–		Tau ² = 0; Chi ² = 0.22, df = 2 (P = 0.9); I ² = 0%
Overall effect	–		–		–		Z = 2.83 (P = 0)
Medium-term (1 to 3 months)							
N	12	11	11	11	NR	NR	
Mean change in swelling (cm ³)	87.9	106.5	79.9	83	NR	NR	–
Standard deviation	70.6	76.2	103.3	113.1	NR	NR	–
Weight (%)	69.34		30.66		–		100
MD (95% CI)	-18.53 (-78.71 to 41.65)		-3.13 (-93.64 to 87.38)		–		-13.81 (-63.92 to 36.31)
Heterogeneity	–		–		–		Tau ² = 0; Chi ² = 0.08, df = 1 (P = 0.78); I ² = 0%
Overall effect	–		–		–		Z = 0.54 (P = 0.59)

CI = confidence interval; MA = meta-analysis; MD = mean difference; NR = not reported; RCT = randomized controlled trial; RRD = removable rigid dressing; SR = systematic review.

Table 9: Summary of Findings by Outcome – Participant Satisfaction

Study citation and study design	Study details and outcomes	RRD (n = 13)	Elastic bandage (n = 12)	P value
Koonalinthip et al. (2020) ¹³ RCT	Mean participant satisfaction on a 5-point Likert Scale: <ul style="list-style-type: none"> • 1 = very dissatisfied • 2 = somewhat dissatisfied • 3 = neither satisfied nor dissatisfied • 4 = somewhat satisfied • 5 = very satisfied 	4.45	4.11	0.312

RCT = randomized controlled trial; RRD = removable rigid dressing.

Table 10: Summary of Findings by Outcome – Time to Events

Study citation and design	For SRs: individual clinical study citation, design, and details	RRD		Soft dressing		Effect estimate (95% CI)	P value
		N	Outcome	N	Outcome		
Time from amputation to wound healing in days							
Kwah et al. (2019) ¹ SR (1 RCT)	Vigier et al., 1999 (RCT)	28	Mean (SD) = 71.2 (31.7)	28	Mean (SD) = 96.8 (54.9)	MD = -25.6 (-49.08 to -2.12)	NR
Time from amputation to no pain in days							
Kwah et al. (2019) ¹ SR (1 RCT)	Hidayati et al., 2013 (RCT)	12	Mean (SD) = 4.8 (2)	11	Mean (SD) = 5.2 (2.3)	MD = -0.35 (-2.11 to 1.41)	NR
Time from amputation to walking in days							
Kwah et al. (2019) ¹ SR (1 RCT)	Vigier et al., 1999 (RCT)	28	Mean (SD) = 30.3 (16.2)	28	Mean (SD) = 33.3 (9.5)	MD = -3 (-9.96 to 3.96)	NR
Length of hospital stay in days							
Kwah et al. (2019) ¹ SR (1 RCT)	Vigier et al., 1999 (RCT)	28	Mean (SD) = 99.8 (22.4)	28	Mean (SD) = 129.9 (48.3)	MD = -30.1 (-49.82 to -10.38)	NR
Time to residual limb maturation^a or prosthetic casting/fitting in days							
Churilov et al. (2014) ¹² SR (1 RCT, 3 NRSs)	Deutsch et al., 2005 (RCT) Type of RRD: Below-knee Outcome: Time to fitting	26	NR	24	NR	SMD = 0.04 (-0.57 to 0.65)	NR
	Taylor et al., 2008 (NRS: retrospective cross-sectional study)	28	NR	37	NR	SMD = -0.47 (-0.97 to 0.03)	NR

Study citation and design	For SRs: individual clinical study citation, design, and details	RRD		Soft dressing		Effect estimate (95% CI)	P value
		N	Outcome	N	Outcome		
	Type of RRD: Below-knee Outcome: Time to casting						
	Ladenheim et al., 2007 (NRS: retrospective cross-sectional study) Type of RRD: Below-knee Outcome: Time to casting	76	NR	28	NR	SMD = -0.52 (-0.96 to -0.08)	NR
	van Velzen et al., 2005 (NRS: retrospective cross-sectional study) Type of RRD: Above-knee Outcome: Time to casting	39	NR	31	NR	SMD = -1.15 (-1.66 to -0.64)	NR
Koonalinthip et al. (2020)^{13 b} RCT Outcome: Time to limb maturation	–	13	Median (IQR) = 28 (17 to 51)	12	Median (IQR) = 54 (30 to 77)	aHR ^c = 3.3234 (1.083 to 10.203)	0.036

aHR = adjusted hazard ratio; CI = confidence interval; IQR = interquartile range; MD = mean difference; NR = not reported; NRS = non-randomized study; RCT = randomized controlled trial; RRD = removable rigid dressing; SD = standard deviation; SMD = standardized mean difference.

^aLimb maturation was defined by study authors as when the volume of the residual limb had stabilized (volume did not change more than 10% from previous assessment), soft tissue atrophy occurred, and residual limb had been molded into a cylindrical shape. (p.1684) The authors stated they assumed that once limb maturation was achieved, it was time for prosthetic casting.

^bKoonalinthip et al.'s control group was elastic bandages, a type of soft dressing.

^cAdjusted hazard ratio accounts for the time since amputation.

Note: A MD or SMD value of > 0 denotes a longer time to prosthetic casting or fitting for the intervention (RRD) compared to the control (soft dressing) group, while a value of < 0 denotes a shorter time for the RRD group compared to control.

Table 11: Summary of Findings by Outcome – Complications

Outcome	Study citation and design	For SRs: Clinical study and study details, or pooled analysis	Proportion of events in RRD group	Proportion of events in soft dressing group	Effect estimate, RR (95% CI)	P value
All types						
All types of complications	Koonalinthip et al. (2020) ¹³ RCT	–	0/13	3/12	NR	0.096
Skin-related complications						
All types of skin-related complications	Kwah et al. (2019) ¹ SR (2 RCTs, 1 quasi-RCT)	Deutsch et al., 2005 (RCT)	1/26	2/24	0.46 (0.04 to 4.77)	NR
		Janchai et al., 2008 (RCT)	1/12	1/14	1.17 (0.08 to 16.72)	NR
		Mueller, 1982 (quasi-RCT)	0/7	0/8	Not estimable	NR
	Koonalinthip et al. (2020) ¹³ RCT	–	0/13	2/12 ^a	NR	NR
Progression to TFA or re-amputation	Kwah et al. (2019) ¹ SR (1 RCT)	Deutsch et al., 2005 (RCT) Outcome: revisions to TFA	1/26	2/24	0.46 (0.04 to 4.77)	NR
	Churilov et al. (2014) ¹² SR (1 NRS)	Van Velzen et al., 2005 (NRS: retrospective cross-sectional) ^a Outcome: Progression to “re-amputation”	NR; 5%	NR; 17%	NR	NR
Wound breakdown or trauma or infection	Kwah et al. (2019) ¹ SR (2 RCTs)	Deutsch et al., 2005 (RCT)	1/26	2/24	0.46 (0.04 to 4.77)	NR
		Janchai et al., 2008 (RCT)	1/12	1/14	1.17 (0.08 to 16.72)	NR
	Churilov et al. 2014) ¹² SR (1 NRS)	Van Velzen et al., 2005 (NRS: retrospective cross-sectional)	NR	NR	NR	No significant difference in “wound problems.”

Outcome	Study citation and design	For SRs: Clinical study and study details, or pooled analysis	Proportion of events in RRD group	Proportion of events in soft dressing group	Effect estimate, RR (95% CI)	P value
	Koonalinthip et al. (2020) ¹³ RCT	–	0/13	2/12 ^b	NR	NR
Pressure areas	Kwah et al. (2019) ¹ SR (1 NRS)	Mueller, 1982 (NRS: quasi-RCT)	0/7	0/8	Not estimable	NR
Non-skin related						
All non-skin-related complications	Kwah et al. (2019) ¹ SR (2 RCTs)	Deutsch et al., 2005 (RCT)	3/26	3/24	0.92 (0.21 to 4.14)	NR
		Janchai et al., 2008 (RCT)	1/12	1/14	1.17 (0.08 to 16.72)	NR
Deaths	Kwah et al. (2019) ¹ SR (1 RCT)	Deutsch et al., 2005 (RCT)	3/26	3/24	0.92 (0.21 to 4.14)	NR
Medical complications^c	Kwah et al. (2019) ¹ SR (1 RCT)	Deutsch et al., 2005 (RCT)	2/26	0/24	4.63 (0.23 to 91.81)	NR
Falls	Kwah et al. (2019) ¹ SR (2 RCTs)	Deutsch et al., 2005 (RCT)	4/26	6/24	0.62 (0.2 to 1.92)	NR
		Janchai et al., 2008 (RCT)	1/12	1/14	1.17 (0.08 to 16.72)	NR
		Pooled analysis (Deutsch and Janchai)	5/38	7/38	0.68 (0.24 to 1.93) Heterogeneity: Tau ² = 0; Chi ² = 0.19, df = 1 (P = 0.66); I ² = 0% Z = 0.73 (P = 0.47)	NR
Knee flexion contracture	Koonalinthip et al. (2020) ¹³ RCT	–	0/13	1/12	NR	NR

CI = confidence interval; NR = not reported; NRS = non-randomized study; RCT = randomized controlled trial; RR = risk ratio; RRD = removable rigid dressing; SD = soft dressing; TFA = transfemoral amputation.

^aThe reporting is unclear for this outcome because there are differences in how the related data were reported in different tables of the SR and in this specific study. Thus, the accuracy of the reported percentage of complications is unclear.

^bIncludes skin irritation (n = 1) and wound dehiscence (n = 1).

^cMedical complications include outcomes like organ failure or illness not directly related to residual wound healing. (p.31).¹

Table 12: Summary of Recommendations in Included Guidelines

Recommendations and supporting evidence	Strength of recommendations and quality of evidence
New South Wales (Australia)'s Agency for Clinical Innovation (2017)¹⁴	
<p>Recommendations: Recommends the use of a RRD for patients who have undergone a transtibial amputation.</p> <p>Supporting evidence: A commissioned systematic review identified 5 systematic reviews and an additional 6 primary studies, and found RRDs were consistently associated with faster wound healing compared to soft dressings. RRDs were also associated with lower rates of surgical revision, and reduced time from amputation to several outcomes (wound healing, initial prosthetic casting, and independent walking) for people with transtibial amputation. However, there was a notable lack of randomized trials, inconsistent outcome measures, failure to blind outcome assessors, and risk of biases.</p>	<p>Strength of recommendation: NR</p> <p>Quality of evidence: Poor</p>
US Veteran Affairs and Department of Defense (2017)¹⁵	
<p>Recommendations: Recommends the use of rigid (or semi-rigid dressings) after transtibial amputations, with a preference for rigid dressings if limb protection is a priority.</p> <p>Supporting evidence: Refers to evidence that supports RRDs or semi-rigid removable dressings over soft dressings, including reduced acute post-amputation edema volume, faster healing time, and reduced hospitalization time. (p.33).</p>	<p>Strength of recommendation: Weak for</p> <p>Quality of evidence: Low</p>
Netherlands Society of Physical and Rehabilitation Medicine (VRA), Geertzen et al. (2015)¹⁶	
<p>Recommendations:</p> <ul style="list-style-type: none"> • Recommends a rigid dressing for people with transtibial amputation; states that a RRD can be considered if using a rigid dressing and regular wound monitoring is indicated (p.357). • Recommends against rigid dressings for TFAs. <p>Supporting evidence: In a systematic literature search for post-operative management, 2 studies were identified that assessed RRDs. One RCT compared a vacuum-formed RRD to a conventional rigid dressing after TTA and had similar results for time to prosthetic fitting and patients' function with their prosthesis. The other RCT compared RRDs to soft dressings and found residual limb volume was smaller in the RRD group at 2 weeks, but no difference was found at 4 weeks. Supporting evidence against rigid dressings for TFA was not provided; the guideline states this is based on the working group's opinion.</p>	<p>Strength of recommendations: Level 4 – Expert opinion.</p> <p>Quality of evidence:</p> <ul style="list-style-type: none"> • Comparison to conventional (non-removable) rigid dressing: Level 3 – one study (a comparative study that is not a double-blind RCT of good quality and sufficient scope, or a non-comparative study) • Comparison to soft dressing: Level 4 – expert opinion • For TFAs: Expert opinion

GRADE = Grading of Recommendations Assessment, Development and Evaluation; KD = knee-disarticulation; NR = not reported; RRD = removable rigid dressing; TFA = transfemoral amputation; TTA = transtibial amputation.

Appendix 5: Overlap Between Included Systematic Reviews

Note that this appendix has not been copy-edited.

Table 13: Overlap in Relevant Primary Studies Between Included Systematic Reviews

Primary study citation	Kwah et al. (2019) ¹	Churilov et al. (2014) ¹²
Deutsch et al. Prosthet Orthot Int. 2005;29(2):193 to 200.	Yes	Yes
Hidayati et al. Med J Indones. 2013;22:16 to 21.	Yes	No
Janchai et al. J Med Assoc Thai. 2008;91(9):1441 to 6.	Yes	No
Mueller. Phys Ther. 1982;62(10):1438 to 41	Yes	No
Vigier et al. Arch Phys Med Rehabil. 1999;80(10):1327 to 30.	Yes	No
Taylor et al. Prosthet Orthot Int. 2008;32:223 to 30	No	Yes
Ladenheim et al. J Prosthet Orthot. 2007;19: 2 to 5.	No	Yes
van Velzen et al. Prosthet Orthot Int. 2005;29:3 to 12	No	Yes

Appendix 6: References of Potential Interest

Previous CADTH Reports

Rigid dressings for edema management for leg amputation: a review of clinical and cost-effectiveness. (*CADTH Rapid response report: summary with critical appraisal*). Ottawa (ON): CADTH; 2017; <https://www.cadth.ca/sites/default/files/pdf/htis/2017/RC0933-RigidDressing-Final.pdf> Accessed 2022 May 12.

Removable Rigid Dressings for Leg Amputation: A Review of the Clinical Effectiveness, Cost Effectiveness and Guidelines. (*CADTH Rapid response report: summary with critical appraisal*). Ottawa (ON): CADTH; 2012; <https://www.cadth.ca/sites/default/files/pdf/htis/feb-2012/RC0325%20Amputation%20Dressings%20Final.pdf> Accessed 2022 May 12.

Review Articles

Reichmann JP, Stevens PM, Rheinstein J, Kreulen CD. Removable rigid dressings for postoperative management of transtibial amputations: a review of published evidence. *Pm R*. 2018;10(5):516-523. [PubMed](#)