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CADTH RAPID RESPONSE REPORT:
SUMMARY WITH CRITICAL APPRAISAL

Rigid Dressings for Edema Management for Leg Amputation: A Review of Clinical and Cost-Effectiveness

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Context and Policy Issues

Patients may need to undergo lower extremity amputation because of dysvascular disease, malignancy or injuries.[1] Patients with diabetes are reported to have a greater risk for lower extremity amputation than those who do not have diabetes.[2-4] With the aging population, the incidence of diabetes and the associated comorbidities are increasing, and is likely to substantially impact the health care resource use and associated costs.[2] In 2008/09 about 2.4 million (6.8%) Canadians were living with diabetes and if the incidence and mortality rates continue at levels seen in 2008/09, it is estimated that this number will reach 3.7 million by 2018/19.[5] The reported worldwide incidence of amputations was variable and ranged from 0.4 to 116 amputations per 10,000 individuals.[3] The incidence of lower limb amputations was reported at 37.4 amputations per 100,000 individuals in Australia,[6] 24 per 100,000 in the USA[1] and 26 per 100,000 in the UK.[1] A Canadian retrospective study reported that 5342 adult patients underwent lower extremity amputations in 207 hospitals, during 2006 to 2009.[3] Lower extremity amputations are associated with considerable health care challenges such as mobility issues, psychological impact, and health care resource use.

Post-amputation management plays an important role in the recovery process. Quicker return to ambulation and independence can have an important positive psychological impact. Return to ambulation may be facilitated by faster wound healing and decrease in time duration between amputation and prosthetic fitting.[7] Edema often occurs post-amputation. Edema is swelling caused by accumulation and retention of fluid in response to trauma.[8] It delays wound healing because the swelling limits blood circulation.[8] Edema control is an important aspect of post-amputation management. Following amputation, dressings are used for wound healing, prevention of edema, pain control, and shaping of the residual limb.[7,9] These dressings are of various types and include rigid cast dressing, removable rigid dressings, prefabricated pneumatic dressings, and soft (or non-rigid) dressings such as elastic bandages.[1,2,10] Each type has its advantages and disadvantages. Soft dressings are easy to apply and relatively inexpensive; however, improper tight application can result in pressure damage.[7] Supporters of rigid dressings believe that rigid dressings result in faster recovery however they are more labor intensive to apply and inconvenient to remove for wound inspection.[7,9] There appears to be variability in use of these dressings in clinical practice and no consensus regarding the optimal treatment modality.

A previous CADTH Rapid Response report of 2012 assessed removable rigid dressing in comparison to rigid dressing for management of leg amputations.[11] It included one randomized controlled trial (RCT) with 27 patients and reported no statistically significant difference between the two modalities with respect to wound healing or time duration from amputation to prosthetic fitting. The purpose of this review is to evaluate the more recent evidence regarding the clinical effectiveness and cost-effectiveness of rigid dressings compared with standard dressings for management of patients with lower extremity amputation.

Research Questions

1. What is the clinical effectiveness of rigid dressings for edema management for leg amputation?

2. What is the cost-effectiveness of rigid dressings for edema management for leg amputation?

Key Findings

There is a suggestion of faster recovery (reduction in time duration between amputation and prosthetic fitting or reduction in edema volume) with the use of rigid dressings compared to non-rigid dressings in patients who underwent transtibial amputation. However, the evidence is from low quality studies and needs to be interpreted with caution.

No relevant studies on the cost-effectiveness of rigid dressings for the management of edema in patients after leg amputations were identified.

Methods

Literature Search Methods

A limited literature search was conducted on key resources including PubMed, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No methodological filters were applied to limit retrieval by publication type. The search was limited to English language documents published between January 1, 2012 and September 13, 2017

Rapid Response reports are organized so that the evidence for each research question is presented separately.

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

Population	Patients with leg amputations based on diagnoses of diabetes, perivascular diseases, trauma, cancer, multiple conditions, or other conditions
Intervention	Rigid dressings
Comparator	Standard dressings
Outcomes	Clinical benefits and harms (pain, length of hospital stay, injury, safety, time from amputation to prosthetic fitting)
Study Designs	Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, and economic evaluations

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications, or were published prior to 2012. Studies included in a selected systematic review were excluded.

Critical Appraisal of Individual Studies

The included systematic review was critically appraised using AMSTAR,[12] and the randomized controlled trial was critically appraised using Downs and Black checklist.[13] Summary scores were not calculated for the included studies; rather, a review of the strengths and limitations of each included study were described narratively.

Summary of Evidence

Quantity of Research Available

A total of 82 citations were identified in the literature search. Following screening of titles and abstracts, 72 citations were excluded and 10 potentially relevant reports from the electronic search were retrieved for full-text review. One potentially relevant publication was retrieved from the grey literature search. Of these 11 potentially relevant articles, nine publications were excluded for various reasons, while two publications met the inclusion criteria and were included in this report. These comprised one systematic review[6] and one randomized controlled trial.[14] Appendix 1 describes the PRISMA flowchart of the study selection.

Additional references of potential interest are provided in Appendix 5.

Summary of Study Characteristics

One relevant systematic review[6] and one relevant RCT[14] were identified. The study characteristics are summarized below and details are available in Appendix 2, Tables 2 and 3.

Study Design

One relevant systematic review[6] was identified. It included six studies published between 2004 and 2013. These studies comprised two RCTs and four retrospective cross-sectional studies; two studies were from Australia, two studies from the USA, and one study each from England and the Netherlands.

One relevant RCT[14] was identified.

Country of Origin

The included systematic review[6] was published in 2014 from Australia. The included RCT[14] was published in 2013 from Indonesia.

Patient Population

The included systematic review[6] included a total of 527 patients; the mean age ranged between 58.2 years and 74.5 years in the individual studies and the proportion of males was 67.5% in the studies that reported on gender. The majority of the patients had undergone transtibial amputation due to peripheral vascular disease.

The included RCT[14] was on adult patients with diabetes mellitus, who had undergone transtibial amputation. The total number of patients was 23, the mean age was 54.3 years in the group with removal rigid dressing (RRD) and 59.9 years in the group with elastic bandage (EB), the proportions of females were 58% in the RRD group and 27% in the EB group, and the duration of diabetes mellitus was 8.4 years in the RRD group and 12.6 years in the EB group. Three of nine patients in the RRD group and two of 11 patients in the EB group had uncontrolled blood glucose results at baseline.

Interventions and Comparators

The included systematic review[6] compared rigid dressing with non-rigid dressing (also sometimes referred to as soft dressing by the authors). The rigid dressings were of various types: removable or non-removable, custom made or pre-fabricated, and applied above or below the knee. Details of the non-rigid dressings were not presented. The included RCT[14] compared RRD with EB.

Outcomes

The included systematic review[6] reported on time from amputation to prosthetic casting or fitting. It also reported on adverse effects, when data were available. The included RCT[14] reported on stump edema, stump pain, and adverse effects.

Summary of Critical Appraisal

The critical appraisals of the studies are summarized below and details are presented in Appendix 3, Tables 4 and 5.

In the systematic review[6] the objective and inclusion criteria were stated; multiple databases were searched up to December 2013; data extraction was done by one reviewer and checked by a second reviewer; and meta-analysis was conducted. Quality assessment was conducted and the included studies were considered by the authors to be generally of low quality. Though publication bias was explored and there appeared to be no issues, the tests may be underpowered as there were few (six studies) included studies. In the systematic review[6] it was unclear if article selection was done in duplicate; a list of excluded studies was not presented, and conflicts of interest were not mentioned.

In the RCT,[14] the objective, inclusion and exclusion criteria, and descriptions of patient characteristics, interventions and outcomes were presented. However, reporting and interpretations of some outcomes were not always clear. Therefore, study conclusions are presented as verbatim quotations in Appendix 4, Table 6. Details of randomization were not presented. It was unclear if sample size had been determined and hence if the study had sufficient power to detect a difference between the groups. It was unclear if there were any patients lost to follow-up, or if the analysis was intention-to-treat. There was no mention of conflicts of interest of the authors.

Summary of Findings

The findings are summarized below and details are presented in Appendix 4, Table 6.

What is the clinical effectiveness of rigid dressings for edema management for leg amputation?

The included systematic review[6] showed that the time duration from amputation to prosthetic fitting was statistically significantly less for patients who had used rigid dressing

compared to patients who had used non-rigid dressings. Adverse effects were reported in three of the six included primary studies and generally appeared to be similar in both groups. Adverse effects included progression to transfemoral amputation, and wound infection or wound problems.

The included RCT[14] showed that the stump edema volume decreased statistically significantly faster in the RRD group compared to the EB group. Decrease in stump pain was not statistically significantly different in the two groups. The authors reported that the patients in the RRD group felt comfortable and safe, whereas those in the EB group experienced adverse effects (damage to the skin flap); however, specific data for the two groups were not presented.

What is the cost-effectiveness of rigid dressings for edema management for leg amputation?

No relevant studies on the cost-effectiveness of rigid dressings for the management of edema in patients after leg amputations were identified.

Limitations

There was considerable variability among the studies included in the systematic review[6] with respect to design, types of rigid dressings used, and outcome measures. In addition, specifics of the rigid dressings and the comparator soft dressings (non-rigid dressings) were not reported. Adverse effects were not always reported. Hence comparability across studies was difficult.

The included studies were generally of low quality hence findings need to be interpreted with in the light of this.

No relevant studies on the cost-effectiveness of rigid dressings for the management of edema in patients after leg amputations were identified.

None of the studies were conducted in Canada hence generalizability to the Canadian setting is unclear.

Conclusions and Implications for Decision or Policy Making

One relevant systematic review[6] including six studies; and one relevant RCT[14] that compared the use of rigid dressing with non-rigid dressing for patients who underwent transtibial amputation, were identified.

The included systematic review[6] showed that that the time duration from amputation to prosthetic casting or fitting was less for patients who were provided rigid dressing compared to patients who were provided non-rigid dressings. The RCT[14] showed that there was faster decrease in edema volume when rigid dressing was used compared to non-rigid dressing. It appears there is faster recovery with the use of rigid dressings compared to non-rigid dressings in patients who underwent transtibial amputation. However the evidence is from low quality studies, and needs to be interpreted with caution. Adverse effects appeared to be similar or less with rigid dressing compared with non-rigid dressing, however not all studies reported on adverse effects.

No relevant studies on the cost-effectiveness of rigid dressings for the management of edema in patients after leg amputations were identified.

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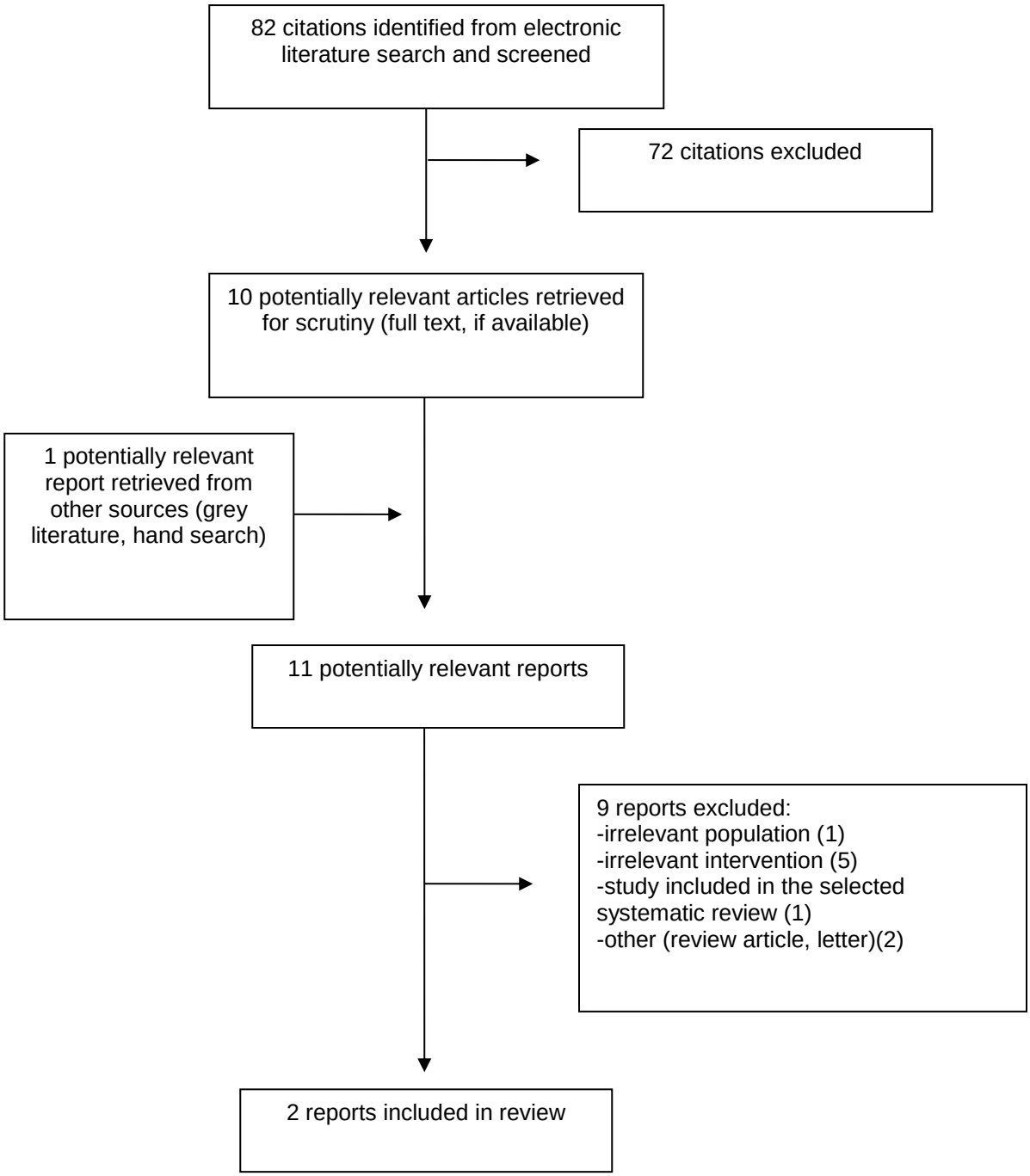
Abbreviations

CI	confidence interval
EB	elastic bandage
ITT	intention-to-treat
RCT	randomized controlled trial
RD	rigid dressing
RR	relative risk
RRD	removable rigid dressing
SD	soft dressing
SMD	standardized mean difference
TFA	transfemoral amputation
VAS	visual analog scale

Appendix 1: Selection of Included Studies



Appendix 2: Characteristics of Included Publications

Table 2: Characteristics of Included Systematic Review

Author, Year, Country	Study Design	Population Characteristics	Comparison	Outcomes
Churilov,[6] 2014, Australia	Systematic review including 6 studies (2 RCTs and 4 retrospective cross-sectional studies). The studies were published between 2004 and 2013. Two studies were conducted in Australia, 2 studies in the USA, and one study each in England and the Netherlands. Aim: To assess the comparative effectiveness of rigid dressing and soft dressing with respect to time required from transtibial amputation to prosthetic casting or fitting.	Adults patients who have undergone transtibial amputation. Majority had amputation because of peripheral vascular disease. N = 527 (number of patients in the individual studies ranged between 50 and 154) Mean age ranged between 58.2 years and 74.5 years. For studies where gender was reported, 67.5% were males.	Rigid dressing versus non-rigid dressing The types of rigid dressing were above or below the knee and could be removable or non-removable, and custom made or prefabricated. Time from surgery to application of rigid dressing was immediate (in 2 studies), immediately after wound closure (in 1 study), within 20 minutes of wound closure (in 1 study), within 24 hour (in 1 study), and not reported in one study.	Time required from transtibial amputation to prosthetic casting or fitting; adverse effects. Four studies measured time to casting and 2 studies measured time to fitting of the first prosthesis.

RCT = randomized controlled trial.

Table 3: Characteristics of Included Randomized Controlled Trial

Author, Year, Country	Study Design	Population Characteristics	Comparison	Outcome, Follow-up
Hidayati,[14] 2013, Indonesia	RCT Setting: Three hospitals in Indonesia.	Adult patients with diabetes mellitus, who had undergone transtibial amputation N = 23 (12 in RRD and 11 in EB) Age (years) ± SD: 54.33 ± 8.06 in RRD, 59.91 ± 8.95 in EB % Female: 58% in RRD, 27% in EB. Number of years with diabetes mellitus: 8.42 ± 6.90 in RRD, 12.55 ± 9.55 in EB.	Removable rigid dressing (RRD) versus elastic bandage (EB). RRD used Plaster of Paris mold and there would be refitting every 7 days during the 8 weeks treatment period. Patients were required to wear extra layer socks under the RRD to provide continuous contact between the stump and RRD. EB was reapplied every 4 hours each day	Stump edema, stump pain, and adverse effects. *"Stump edema volume was measured by the amount of water spilled out from volume glass."* Page 17 Stump pain was assessed using VAS (scale range: 0 to 10 with 0 indicating no pain and 10 indicating unbearable pain.

Author, Year, Country	Study Design	Population Characteristics	Comparison	Outcome, Follow-up
				Stump edema volume and stump pain were assessed every 7 days during the 8 weeks treatment period

EB = elastic bandage; RCT = randomized controlled trial; RRD = removable rigid dressing; VAS = visual analog scale.

Appendix 3: Critical Appraisal of Included Publications

Table 4: Strengths and Limitations of Systematic Reviews and Meta-Analyses using AMSTAR

Strengths	Limitations
Churilov,[6] 2014, Australia	
• The objective was clearly stated. • The inclusion criteria were stated. • Medline, Embase, CINAHL, and Cochrane Central Register of Controlled trials) were searched. Literature was searched up to December 2012, and then updated in December 2013. Also, reference lists of relevant retrieved articles were searched. • Study selection was described • Flow chart of study selection was provided • List of included studies was provided • Data extraction was done by one reviewer and checked by a second reviewer. • Characteristics of the individual studies were provided • Quality of the included studies was assessed using the Cochrane trial quality review criteria and the authors reported that quality was variable and most studies were of low quality • Meta-analysis was conducted • Publication bias was explored using Begg's test or Egger's test, and did not appear to be an issue, however as there were only few studies, the tests could be underpowered to detect bias.	• The exclusion criteria were not explicitly stated • List of excluded studies was not provided • Unclear if article selection was done in duplicate • There was no mention of conflicts of interest

ITT = intention-to-treat.

Table 5: Strengths and Limitations of Randomized Controlled Trials using Downs and Black checklist

Strengths	Limitations
Hidayati,[14] 2013, Indonesia	
• The objective was clearly stated • The inclusion and exclusion criteria were stated • Patient characteristics, intervention and outcomes were described. Description of outcomes and their interpretation were not always clear • Randomization was performed in blocks of two. • *P*-values were reported	• Details of randomization were lacking. • Unclear if sample size determinations had been undertaken • Unclear if any patients were lost to follow, nothing was mentioned specifically • Unclear if ITT analysis was undertaken • There was no mention of conflicts of interest

Appendix 4: Main Study Findings and Author's Conclusions

Table 6: Summary of Findings of Included Studies

<table>
<tr><th>Main Study Findings</th><th>Author's Conclusion</th></tr>
<tr><td colspan="2">Systematic Review</td></tr>
<tr><td colspan="2">Churilov,[6] 2014, Australia</td></tr>
<tr><td>Adult patients who had undergone transtibial amputation; majority because of peripheral vascular disease

Comparison of RD with SD with respect to time from surgery to prosthetic casting of fitting
<table>
<tr><th>Outcome</th><th>No. of studies</th><th>No. of patients</th><th>SMD (95% CI)</th><th>Heterogeneity, I^2</th></tr>
<tr><td>Time from surgery to prosthetic casting of fitting</td><td>6</td><td>527</td><td>0.46 (0.19 to 0.73; favors RD</td><td>0.54</td></tr>
</table>
Comparison of RD with SD with respect to wound complication[a]
<table>
<tr><th rowspan="2">Outcome</th><th rowspan="2">Study (first author)</th><th rowspan="2">No. of patients</th><th colspan="2">Proportion (%) of patients with outcome</th></tr>
<tr><th>RD</th><th>SD</th></tr>
<tr><td rowspan="2">Progression to TFA</td><td>Deutsch</td><td>50</td><td>4</td><td>4</td></tr>
<tr><td>Woodburn</td><td>154</td><td>3</td><td>4</td></tr>
<tr><td>Progression to “re-amputation”</td><td>van Velzen</td><td>70</td><td>5</td><td>17</td></tr>
<tr><td rowspan="2">Wound infection</td><td>Woodburn</td><td>154</td><td>21</td><td>18</td></tr>
<tr><td>van Velzen</td><td>70</td><td colspan="2">Reported as - no statistically significant difference</td></tr>
<tr><td colspan="5">[a]Only studies (3 of 6 studies) with available data are presented in the table. The authors (Churilov et al.) of the systematic review reported that for the study by Sumpio et al. there were two progressions to TFA in each of the two groups; however, they mentioned that percentage values could not be determined.</td></tr>
</table>
</td><td>“Patients who are fitted with RD post transtibial amputation commence prosthetic management sooner than those managed with SD.” Page 1801</td></tr>
<tr><td colspan="2">Randomized Controlled Trial</td></tr>
<tr><td colspan="2">Hidayati,[14] 2013, Indonesia</td></tr>
<tr><td>Adult patients with diabetes mellitus and who had undergone transtibial amputation

Comparison of RRD with EB with respect to decrease in stump edema volume.
<table>
<tr><th rowspan="2">Time period-week</th><th colspan="2">Decrease in in stump edema volume (cm^3)</th><th>P value</th></tr>
<tr><th>RRD</th><th>EB</th><th></th></tr>
<tr><td>Week 0 to 1</td><td>84.33 ± 54.02</td><td>44.54 ± 25.93</td><td>0.03</td></tr>
<tr><td>Week 0 to 2</td><td>123.33 ± 76.02</td><td>66.36 ± 28.46</td><td>0.01</td></tr>
<tr><td>Week 0 to 3</td><td>133.33 ± 62.24</td><td>94.55 ± 33.57</td><td>0.08</td></tr>
<tr><td>Week 0 to 4</td><td>155.06 ± 60.83</td><td>110.91 ± 36.46</td><td>0.05</td></tr>
<tr><td>Week 0 to 5</td><td>171.08 ± 58.97</td><td>130.91 ± 45.06</td><td>0.08</td></tr>
<tr><td>Week 0 to 6</td><td>182.75 ± 56.96</td><td>141.37 ± 55.41</td><td>0.09</td></tr>
<tr><td>Week 0 to 7</td><td>87.92 ± 70.6</td><td>100.45 ± 76.17</td><td>0.07</td></tr>
<tr><td>Week 0 to 8</td><td>87.92 ± 70.6</td><td>106.45 ± 76.17</td><td>0.6</td></tr>
<tr><td colspan="4">P value using unpaired T-test</td></tr>
</table>
</td><td>“This study found that there was stump edema volume acceleration in RRD group, it was three times faster for stump to become not edematous compared to elastic bandage group. There was a tendency of faster decreasing stump pain in RRD group than elastic bandage group, even though this result was not statistically significant.” Page 16</td></tr>
</table>

Main Study Findings	Author's Conclusion

"[…] the differences between two groups in speed of stump edema volume which happened in the first 2 weeks in RRD group with average 63.85% compared to elastic bandage group of only 34.35%. There is no significant in decrease stump edema volume in week III – VIII. The stump will be free of edema at week 5.08 ± 1.17 in the RRD group and 6.82 ± 1.31 weeks in the elastic bandage group which was statistically significant (p = 0.03)." Page 19

Comparison of RRD with EB with respect to decrease in stump pain (using VAS).

Time period-week	Decrease in in stump pain		*P* value
	RRD	EB	
Week 0 to 1	0	0	1.00
Week 0 to 2	1.42 ± 1.08	1.09 ± 1.22	0.90
Week 0 to 3	2.5 ± 1.24	1.73 ± 1.00	0.32
Week 0 to 4	3.0 ± 1.35	2.00 ± 1.00	0.40
Week 0 to 5	3.25 ± 1.42	2.00 ± 1.56	0.62
Week 0 to 6	3.25 ± 1.42	2.64 ± 1.03	0.38
Week 0 to 7	3.5 ± 1.44	3.01 ± 1.22	0.63
Week 0 to 8	3.66 ± 1.56	3.36 ± 1.28	0.75
P value using unpaired T-test			

"RRD group will reach a condition of stump with no pain in 4.83 ± 1.946 weeks and in the elastic bandage group in 5.18 ± 2.31 weeks, although the result was not statistically significant (p = 0.699)." Page 19

The authors conducted a Cox regression analysis and reported a RR of 3.09 and 95% CI, 1.38 to 4.92, indicating that decrease in stump volume with RRD was three times faster than with EB.

There were no significant differences with respect to disappearance of phantom pain in both treatment groups.

Patients with RRD felt safe and comfortable whereas patients with EB experienced a side effect: damage of the skin flap.

CI = confidence interval; EB = elastic dressing; RD = rigid dressing; RR = relative risk; RRD = removable rigid dressing; SD = soft dressing; SMD = standardized mean difference; TFA = transfemoral amputation; VAS = visual analog scale.

Appendix 5: Additional References of Potential Interest

Clinical studies of potential interest (alternative intervention)

Chin T, Toda M. Results of prosthetic rehabilitation on managing transtibial vascular amputation with silicone liner after wound closure. J Int Med Res. 2016 Aug;44(4):957-67.

Hordacre B, Birks V, Quinn S, Barr C, Patritti BL, Crotty M. Physiotherapy rehabilitation for individuals with lower limb amputation: a 15-year clinical series. Physiother Res Int. 2013 Jun;18(2):70-80.