



**TITLE: Removable Rigid Dressings for Leg Amputation: A Review of the Clinical Effectiveness, Cost Effectiveness and Guidelines**

**DATE:** 13 February 2012

**CONTEXT AND POLICY ISSUES**

Dressings used after amputation of a limb help promote wound healing, prevent edema formation, and facilitate stump shrinkage. Different types of dressings available to use on amputated legs include soft gauze dressing applied with elastic bandage, rigid dressing (cast), removable rigid dressing, and pre-fabricated pneumatic dressing.<sup>1</sup> Elastic bandage may cause skin breakdown, whereas a cast needs to be removed and reapplied to inspect the wound. A cast also needs to be changed frequently to ensure that progressive shrinkage of the stump occurs. The removable rigid dressing (RRD) for below the knee amputation was first described by Wu et al. in 1979.<sup>2</sup> It has the same advantages as a rigid dressing, but its ease of removal allows for more frequent wound inspection. It also facilitates rapid stump shrinkage because it permits tube sock changes.<sup>2</sup>

The purpose of this report is to review the clinical evidence, cost effectiveness and guidelines for the use of removable rigid dressings compared with rigid dressings for patients undergoing leg amputation.

**RESEARCH QUESTIONS**

1. What is the clinical effectiveness of removable rigid dressings for postoperative management of patients undergoing leg amputation?
2. What is the cost effectiveness of removable rigid dressings for postoperative management of patients undergoing leg amputation?
3. What are the evidence-based guidelines for the use of removable rigid dressings for postoperative management of patients undergoing leg amputation?

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**KEY MESSAGE**

One study suggested that removable rigid dressings are similar to rigid dressings when comparing time from amputation to prosthesis and wound healing rate. No evidence was identified on the cost-effectiveness or guidelines for use of removable rigid dressings.

**METHODS**

**Literature Search Strategy**

A limited literature search was conducted on key resources including PubMed, EBSCOhost CINAHL, The Cochrane Library (2012, Issue 1), 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 study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2007 and January 13, 2012.

**Selection Criteria and Methods**

One reviewer screened the titles and abstracts of the retrieved publications, and evaluated the full-text publications for the final article selection, according to the selection criteria present in Table 1.

**Table 1: Selection Criteria**

|                      |  |
|----------------------|--|
| <b>Population</b>    | Patients undergoing below the knee (trans-tibial) or trans-femoral leg amputation  |
| <b>Intervention</b>  | Removable rigid dressing   |
| <b>Comparator</b>    | Rigid dressing   |
| <b>Outcomes</b>      | Clinical Effectiveness (limb damage, speed of recovery, swelling, need for further medical intervention)<br><br>Cost Effectiveness   |
| <b>Study Designs</b> | Health technology assessments, systematic reviews and meta-analyses, randomized controlled trials, non-randomized controlled trials, economic evaluations, evidence-based clinical practice guidelines |

**Exclusion Criteria**

Studies were excluded if they did not meet the selection criteria, were duplicate publications, were abstracts or conference proceedings, were included in a selected systematic review, or were published prior to 2007.

## **Critical Appraisal of Individual Studies**

The strengths and limitations of one RCT were summarized and described using the Sign-50 checklist. No health technology assessments, systematic reviews and meta-analyses, non-randomized studies, economic evaluations or evidence-based guidelines were identified for critical appraisal.

## **SUMMARY OF EVIDENCE**

### **Quantity of Research Available**

The electronic database, grey literature and hand search identified 42 reports of which three were reviewed in full text. One randomized controlled trial (RCT) met the inclusion criteria.<sup>3</sup> Two non-randomized trials were excluded based on the comparator (soft dressing).<sup>4,5</sup> Appendix 1 describes the PRISMA flowchart of the included studies in this report.

No health technology assessments, systematic reviews, meta-analyses, economic evaluations, or clinical practice guidelines were found that met the inclusion criteria.

### **Summary of Study Characteristics**

Details on the study characteristics are found in Appendix 2.

The RCT compared a vacuum-formed RRD (ORD by Össur Inc.) to a rigid circulated plaster of Paris dressing.<sup>3</sup> In both groups, the dressing was left in place for five to seven days and then removed for wound inspection, followed by standardized compression therapy using a silicone liner which was continued until prosthetic fitting.

The RCT included 15 patients allocated to RRD and 12 patients allocated to rigid dressing. A total of four patients (two in each group) discontinued the trial after randomization and were excluded from the analysis. The patients had a mean age of 76 years (range 43 years to 91 years) and all had undergone trans-tibial amputation due to peripheral vascular disease. The number of days from amputation to prosthetic fitting was reported as the primary outcome. Wound healing status was also reported.

### **Summary of Critical Appraisal**

Details on the critical appraisal of the included study are presented in Appendix 3.

Briefly, the methods of randomization and allocation concealment were considered adequate. The withdrawals were well-described and the disposition of patients was described using a flow chart. The two groups had similar baseline characteristics, although they were not compared for prognostic factors. The study used an as-treated analysis and may have been underpowered to show a statistical difference.

### **Summary of Findings**

The data were extracted and presented in Appendix 4.

*Limb damage*

Not evaluated in the identified literature.

*Swelling*

Not evaluated in the identified literature.

*Speed of recovery*

The speed of recovery was evaluated as the time from amputation to prosthesis. The mean time from amputation to prosthetic fitting (time when the patient receives a custom-made prosthesis) was 37 days (range 26 to 54 days) in the RRD group compared with 34 days (range 21 to 47 days) in the control group ( $P = 0.4$  after adjusting for age and sex). Complete wound healing was not required for prosthetic fitting. The status of the wound (complete closure or incomplete closure) was reported when the patient received the definitive prosthesis. The wound was deemed completely closed (defined as the absence of leakage from the wound) in 6 of 13 patients in the RRD group compared to 4 of 10 patients in the control group ( $P = 0.6$ ).

*Need for further medical intervention*

Not evaluated in the identified literature.

**Limitations**

The RCT is limited by several factors. The study randomized 27 patients and analyzed the results of 23 patients (not intention to treat). Further, the study may have been underpowered to show a statistical difference. Wound healing was monitored by the members of the rehabilitation team which included an orthopedic surgeon, a nurse, a physiotherapist and a prosthetist. Only the physiotherapist and the prosthetist were blinded as to the type of dressing the patients received which may have affected how the outcomes were assessed. The patients were not compared for prognostic factors and were of various ages (range 43 years old to 91 years old). The trial was conducted in Sweden which may limit the generalizability of findings to a Canadian healthcare context.

**CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:**

One RCT compared RRD to rigid dressings. The RCT is limited by its sample size and the fact that not all investigators were blinded as to the type of dressing received. The RCT found no statistically significant difference between RRD and rigid dressings in the number of days from amputation to prosthetic fitting. Similarly, there was no statistically significant difference in wound healing between the two groups. Other outcomes of interest such as limb damage, swelling, or the need for further medical intervention were not reported in the RCT. No clinical practice guidelines were found; no evaluation was found on the cost effectiveness of RRD.

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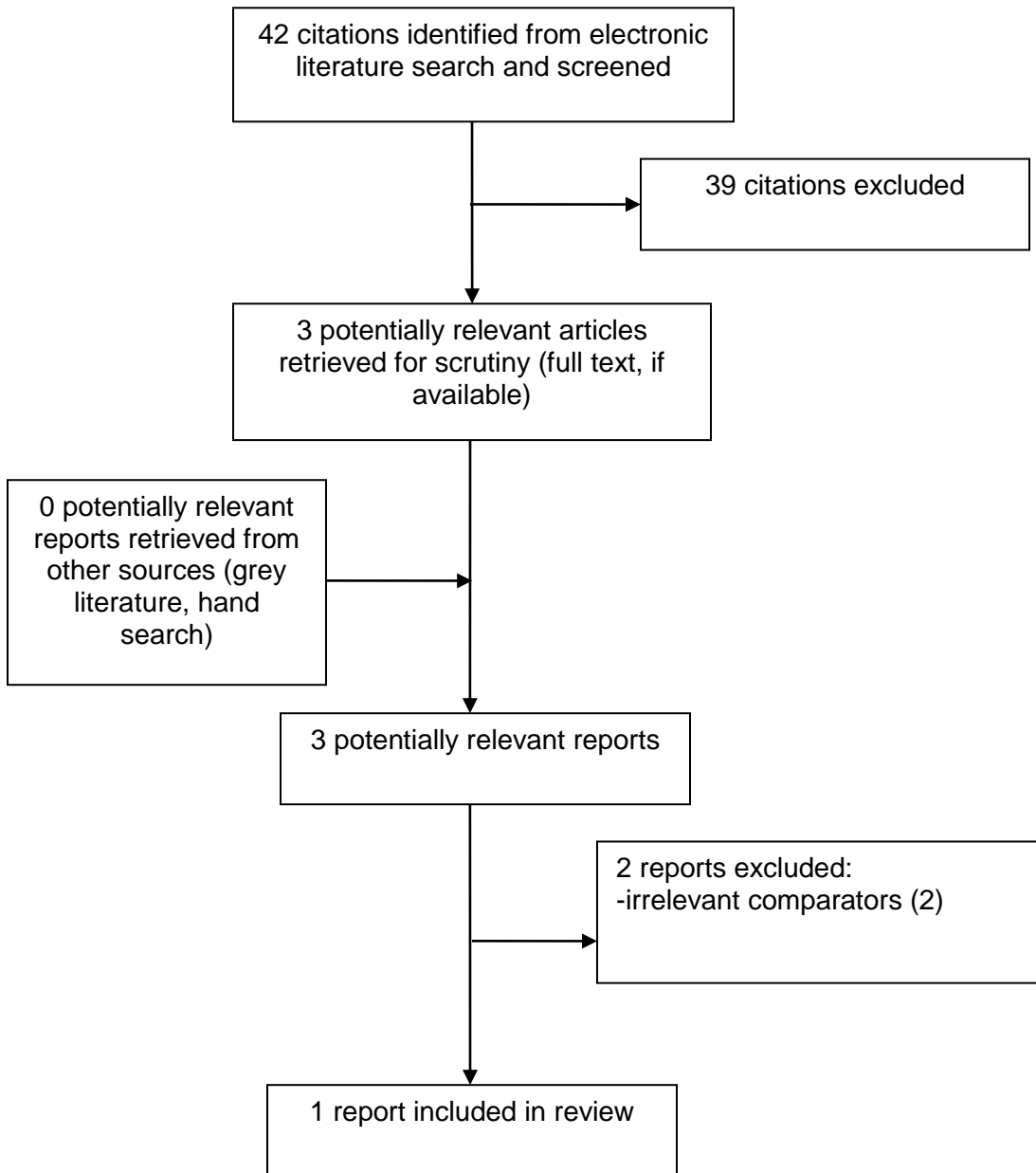
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Appendix 1: Selection of Included Studies



Appendix 2: Characteristics of the Randomized Controlled Trial

| First Author, Year, Country, Funding  | Patient Characteristics, Sample Size  | Intervention   | Comparator   | Clinical Outcomes Reported in the Trial  |
|---|---|--|--|--|
| <p>Johannesson, 2008<sup>3</sup></p> <p>Sweden</p> <p>Study funded by a research grant from Hässleholm Hospital</p>         | <p>Patients with trans-tibial amputation due to PVD</p> <p>n=27 randomized<br/>n=23 included in analysis<br/>n=22 remaining at 3 months</p> <p>mean age=76 years (range 43 to 91)</p> | <p>Vacuum-formed removable rigid dressing (ORD by Össur Inc.)</p> <p>n=15</p> <p>n=2 discontinued trial at intervention stage due to severe ischemia in other leg</p> <p>n=1 discontinued trial at prosthetic stage due to death</p> <p>Both groups had the dressing on for 5 to 7 days then removed for wound inspection, followed by standardized compression therapy using a postoperative silicone liner which was continued until prosthetic fitting.</p> | <p>Conventional rigid circulated plaster of Paris dressing</p> <p>n=12</p> <p>n=2 discontinued trial at intervention stage due to death (1) and knee contracture (1)</p> | <p><u>Primary outcome</u></p> <ul style="list-style-type: none"> <li>• Number of days from amputation to prosthetic fitting</li> </ul> <p><u>Secondary outcomes</u></p> <ul style="list-style-type: none"> <li>• Wound healing</li> <li>• Shape of residual limb</li> <li>• Functional outcome using LCI and TUG test (at 3 months)</li> <li>• Need for socket change</li> <li>• Proportion who returned to their previous living condition (at one year)</li> </ul> |
| <p>LCI=Locomotor Capability Index; PVD=peripheral vascular disease; RRD=removable rigid dressing; TUG=Timed "Up and Go"</p> |   |  |  |  |

**Appendix 3: Critical Appraisal of the Randomized Controlled Trial**

| Study, Year                    | Strengths  | Limitations   |
|--------------------------------|--|---|
| Johannesson, 2008 <sup>3</sup> | <ul style="list-style-type: none"> <li>• Methods of randomization (computer generated list) and allocation concealment (serially numbered sealed opaque envelope) adequate</li> <li>• Withdrawals well-described (includes flow chart of patient disposition)</li> <li>• Similar surgical technique, postoperative care, and prosthetic socks used in both groups</li> </ul> | <ul style="list-style-type: none"> <li>• Not intention to treat</li> <li>• Study may be underpowered (sample size is 27 patients)</li> <li>• Wound healing was monitored by the members of the rehabilitation team (orthopedic surgeon, nurse, physiotherapist and prosthetist) but not all were blinded (physiotherapist and prosthetist blinded as to type of dressing patients received) which may have affected the assessment of outcomes</li> <li>• Groups not compared for prognostic factors</li> <li>• Wide range of age (43 years old to 91 years old)</li> </ul> |

Appendix 4: Results of the Randomized Controlled Trial

| Study, Year                    | Outcomes   | Results  |                               |
|--------------------------------|--|--|-------------------------------|
|                                |  | Treated Group                                  | Control Group                 |
| Johannesson, 2008 <sup>3</sup> | Number of days from amputation to prosthetic fitting (days, mean ± sd) | 37±7<br>(range 26 to 54 days)                  | 34±8<br>(range 21 to 47 days) |
|                                |  | Mean difference*=4 (95%CI: -2 to -11)<br>P=0.4 |                               |
|                                | Wound healing (complete closure when received prosthesis, n/N)         | 6/13   | 4/10                          |
|                                |  | P=0.6  |                               |

CI=confidence interval; LOS=length of stay; sd=standard deviation

\*adjusted for age and sex