General Review

Do Rigid Dressings Reduce the Time from Amputation to Prosthetic Fitting? A Systematic Review and Meta-analysis

Irina Churilov,1 Leonid Churilov,2 and David Murphy,1 Fitzroy and Melbourne, Australia

Objective: To investigate whether application of a rigid dressing (RD) to the residual limb soon after transtibial amputation reduces the time from amputation to the first prosthetic casting/fitting compared with the residual limb managed with a soft dressing (SD).

Data Sources: Studies in humans were identified by a systematic search of MEDLINE, EMBASE, CINAHL, and Cochrane Central Register of Controlled Trials to December 2013. Search terms were based on appropriate medical subject headings and other free-text headings combining the following key words: “amputation,” “amputation stumps,” “transtibial,” “lower limb,” “post operative dressing,” “removable rigid dressing,” “rigid dressing,” “wound healing,” “rehabilitation,” and “prosthetic.” Reference lists of the relevant retrieved studies were checked for further studies. Papers could be published in English or other languages.

Study Selection: Randomized controlled trials (RCT) and cross-sectional studies that included adults who had an amputation of the lower limb were included. Initial literature search identified 356 potentially relevant articles. Review of abstracts and subsequently full text identified 6 studies included in the meta-analysis. Of these studies, 2 were RCT and 4 were retrospective cross-sectional studies.

Data Extraction: Data were extracted by one reviewer and then checked by another reviewer.

Data Synthesis: The use of RD resulted in significantly shorter time from amputation to casting or fitting of the prosthesis. Pooled standardized mean difference (SMD) from meta-analysis using DerSimonian and Laird random effect model was 0.46 (95% confidence interval: 0.19–0.73; \( P = 0.001 \)), with 54% variation in SMD attributable to heterogeneity (\( I^2 = 0.539, P = 0.06 \)). No evidence of small study effect has been found. The quality of reporting of the results varied, with some important elements omitted in the publications.

Conclusions: Patients who are fitted with RD post transtibial amputation commence prosthetic management sooner than those managed with SD.

INTRODUCTION

Management of lower limb amputation remains a significant issue worldwide, with annual incidence rates estimated to be between 5.8 and 31 per 100,000.1 About 1.6 million Americans were estimated to live with a loss of a limb in 2005,2 and approximately 159,000 lower limb amputations are performed each year in the United States.3 In Australia, the incidence of lower limb amputations is 37.4 procedures per 100,000.4 A significant proportion of above-ankle lower limb amputations are transtibial amputations, quoted as over 50% in the United States.5 The majority of patients who undergo a transtibial

---

1St Vincent’s Health, Department of Rehabilitation - Melbourne, Fitzroy, Australia.
2The Florey Institute of Neuroscience and Mental Health, Melbourne, Australia.

Correspondence to: Irina Churilov, MBBS, FAFRM (RACP), St Vincent’s Health - Melbourne, Fitzroy Campus, 41 Victoria Parade, Fitzroy, VIC 3065, Australia; E-mail: irina.churilov@gmail.com

http://dx.doi.org/10.1016/j.avsg.2014.05.002
© 2014 Elsevier Inc. All rights reserved.
Manuscript received: February 20, 2014; manuscript accepted: May 6, 2014; published online: June 6, 2014.
amputation are discharged either directly to home or to an inpatient rehabilitation facility,\(^6,7\) and most of these patients (67% of those discharged to home and 81% of those discharged to rehabilitation) are fitted with a prosthesis.\(^7\) For most transtibial amputees who are deemed to be potentially suitable for prosthetic management, the aim of the rehabilitation team is to fit a prosthesis and commence prosthetic mobilization before discharge to the community. The time when the patient is ready for the first prosthetic fitting is an important milestone in amputees’ management and discharge planning. Understanding when prosthetic casting or fitting is likely to occur assists in planning prosthetic and other resource utilization, therapy time, and likely discharge timing and destination. Optimizing these factors can have a significant impact on patient’s quality of life,\(^8\) while a delay in prosthetic management may lead to hospital-acquired morbidity and prolong the patient’s length of stay, potentially leading to excessive use of hospital resources.

There is ongoing debate regarding whether application of a rigid dressing (RD) to the residual limb soon after transtibial amputation improves patient outcomes. Two most recent nonsystematic literature reviews dedicated to this topic\(^5,10\) argue that, while the choice of postoperative dressing in transtibial amputees has the potential to improve the patient outcomes, there is little consensus on which type of dressing is superior. Supporters of RD application argue that its main benefits are edema reduction and protection of the residual limb from external trauma, which in turn may lead to faster wound healing, reduced pain, reduced risk of infection, and, ultimately, faster progress to prosthetic fitting for appropriate patients. While many hospital units that look after amputee patients advocate the use of RDs, there is a gap in the knowledge manifested by the absence of universally accepted evidence-based guidelines regarding the use of RD in the immediate postoperative setting.

The objective of the present systematic review of the studies that compare time from amputation to prosthetic casting or fitting in transtibial amputees is to contribute to rehabilitation knowledge by addressing the identified gap.

**METHODS**

**Eligible Studies**

We sought all studies that compare RD with soft dressing (SD) early post amputation. Studies that included adults who had an amputation of the lower limb for any indication were eligible. Included studies could be published in any language provided the abstract was in English.

**Types of Intervention**

We considered studies that compared the time from amputation to prosthetic casting or fitting in transtibial amputees whose wounds were managed by the application of RD versus SD in the immediate postoperative period following amputation. Randomized controlled trials (RCTs) and cross-sectional studies were included in the analysis.

**Outcome Measure**

The outcome of interest was the time to first prosthetic casting or fitting. We considered that both casting and fitting could be used as end points as they generally occur within a few days of each other (up to a week in some centers), and are both indicators of the time when the rehabilitation team consider the residual limb to be ready for the first prosthetic fitting. We expected that, while the time from casting to fitting may vary between facilities, it will be similar in the RD and SD groups within each facility; hence the difference in time between amputation and outcome of interest should not be affected by the use of the 2 end points.

**Study Selection**

Studies were identified by a systematic search of MEDLINE, EMBASE, CINAHL, and Cochrane Central Register of Controlled Trials. Studies were searched to December 2012; the search was updated in December 2013. Search terms were based on appropriate medical subject headings and other free-text headings and were combinations of the following key words: “amputation,” “amputation stumps,” “transtibial,” “lower limb,” “post operative dressing,” “removable rigid dressing,” “non removable rigid dressing,” “wound healing,” “rehabilitation,” and “prosthetic.” The search was restricted to studies in humans. Reference lists of the relevant retrieved studies were also checked for further studies.

Based on the information given in the abstracts, studies were selected if they addressed postoperative management of amputees. No language restrictions were applied. Full texts of studies that addressed postoperative management of amputees were retrieved and reviewed. RCTs and cross-sectional studies that included a control group using an SD were selected.
Data Extraction

Data were extracted by one reviewer (I.C.). These data were then assessed by another reviewer (L.C.). Authors of individual included studies were contacted if further information or data clarification was required.

Assessment of Methodological Quality and Bias Risk

Using the commonly accepted trial quality review criteria as reported by Higgins et al. and Egger et al., we investigated the reporting of method of randomization (for RCTs), blinding, attrition rates, conduct of power analysis, adherence to intention-to-treat principles, and statistical analysis and results.

Data Analysis

We compared the time from amputation to prosthetic fitting or casting because they occur as early as possible after removal of staples or sutures provided there is sufficient healing of the residual limb in patients who are deemed to be potential prosthetic candidates.

Average treatment effects in the form of pooled standardized mean differences (SMDs) in the time from amputation to either casting or fitting the first prosthesis between intervention and control arms, and corresponding 95% CIs, were estimated using DerSimonian and Laird random effects meta-analysis model. SMD expresses the size of the intervention effect in each study relative to the variability observed in that study. Therefore, studies where the ratio of mean difference to standard deviation is the same will have the same SMD, regardless of the actual scale of measurement.

For studies included in this meta-analysis that did not report means and standard deviations but reported P values resulting from either nonparametric analysis using Wilcoxon–Mann–Whitney test or a comparison of geometric means, the effect sizes were estimated by obtaining standard normal deviates associated with these P values and translating them into appropriate SMDs as described in.

A random effect meta-analysis model assumes that the observed estimates of treatment effect can vary across studies because of real differences in treatment effect in each study as well as sampling variability (chance). Statistical heterogeneity was assessed using the I² index. The presence of small-study effects (publication bias) was tested using both Begg’s and Egger’s tests. The analysis was undertaken using a meta-analysis suite implemented in Stata IC v 13 software (STATA Corp LP, College Station, TX).

RESULTS

Figure 1 shows the exclusion flow chart. Of the 356 papers identified through the search, 341 were excluded after examining the titles and abstracts. The main reasons for exclusion were that the paper was a case report or did not address postoperative management. Fifteen papers were identified as suitable for further review. All were published since 1979. Further 9 papers were excluded because the study did not include SD control group, did not report the outcome of interest, or had missing or incomplete data. Six papers were included in the quantitative synthesis, of which 2 were RCTs and 4 were cross-sectional studies. For the study by Taylor et al., the mean and standard deviation were provided via personal communication with the researchers.

Interventions and Treatment Providers

Nature of intervention in individual studies is summarized in Table 1. The 6 studies included a total of 527 patients, with mean age reported as from 58.2 to 74.5 years. For studies where gender was reported, 67.5% were men. The majority of patients had the amputation because of peripheral vascular disease.

Two studies were conducted in Australia, 2 in the United States, and 1 each in England and the Netherlands. Not all studies specified whether the patients were managed in acute or subacute (rehabilitation) wards. All patients in the 2 Australian studies were transferred to an inpatient rehabilitation facility; the other 4 studies did not report whether the patients participated in inpatient or outpatient postoperative rehabilitation. Four studies measured the time to casting, and 2 measured the time to fitting of the first prosthesis. The decision on when to proceed with casting and fitting was made by a multidisciplinary team, which included various combinations of vascular surgeon, rehabilitation physician, nurse, prosthetist, and physiotherapist.

Methodological Quality and Bias

Using the Cochrane trial quality review criteria, we found that the quality of reporting of the results varied and most papers in this review fell short (Table II). Although the authors of 2 studies indicated that participants were randomized, only 1 described the randomization method. Of the 4 retrospective cross-sectional studies, only 2 had parallel controls, with the other 2 using historic ones. Blinding was attempted in one RCT, where one of the several decision makers on the timing of casting,
the prosthetist, was blinded to the intervention. Attrition was adequately described in both randomized trials for the intervention and control groups, and in 2 retrospective studies for the intervention group only. Intention-to-treat principle was mentioned in a single RCT only. Power analysis was conducted and the desired power was achieved in one RCT, was not achieved in the other RCT, and was not reported in the retrospective studies. Statistical reporting included the mix of descriptive and estimation measures, with appropriate measure of precision in the form of the confidence interval (CI) reported in one publication. All studies reported \( P \) values resulting from chosen statistical tests.

**Time from Surgery to Prosthetic Casting or Fitting**

In 6 studies (\( n = 527 \)), the time from surgery to first prosthetic casting or fitting was reported and these data were included in the meta-analysis. As shown in forest plot (Fig. 2), DerSimonian and Laird random effect estimation of the pooled SMD was 0.46 (95% CI: 0.19–0.73; \( P = 0.001 \)). Also, a strong trend toward a significant effect heterogeneity was observed with nearly 54% variation in pooled SMD attributed to heterogeneity (\( I^2 = 0.539 \), \( P = 0.06 \)). These results indicate that the average time from amputation to casting or fitting was
<table>
<thead>
<tr>
<th>Study</th>
<th>Type of RD</th>
<th>Time from surgery to RD</th>
<th>End point: time to</th>
<th>Wound complications reported</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deutsch et al. (2005) (Australia)</td>
<td>Custom made below-knee removable RD applied by the prosthetist</td>
<td>Within 20 min of wound closure</td>
<td>Fitting</td>
<td>Progression to TFA: RD group 1 (4%), non-RD group 1 (4%). Wound infection: not known</td>
<td>Center has early fitting policy</td>
</tr>
<tr>
<td>Woodburn et al. (2004) (England)</td>
<td>Nonremovable above-knee RD applied by vascular surgeons, who were trained in the technique</td>
<td>Immediately after wound closure</td>
<td>Casting</td>
<td>Progression to TFA: RD group 2 (3%), non-RD group 3 (4%). Wound infection: RD group 12 (21%), non-RD group 10 (18%)</td>
<td>RD applied for 14 days</td>
</tr>
<tr>
<td>Taylor et al. (2008) (Australia)</td>
<td>Custom made below-knee removable RD applied by the prosthetist</td>
<td>Within 24 hr</td>
<td>Casting</td>
<td>Data not available</td>
<td>The authors state that the protocol was largely the same as for Deutsch et al. (2005)</td>
</tr>
<tr>
<td>Ladenheim et al. (2007) (USA)</td>
<td>Prefabricated below-knee removable RD, unclear who applied by</td>
<td>“Postoperative,” time not specified</td>
<td>Casting</td>
<td>Data not available</td>
<td>In some patients immediate weight bearing allowed postoperatively</td>
</tr>
<tr>
<td>van Velzen et al. (2005) (The Netherlands)</td>
<td>Removable above-knee RD, unclear who applied by</td>
<td>Immediate</td>
<td>Fitting</td>
<td>Progression to “re-amputation”: RD group 3 (5%), non-RD group 9 (17%). Wound infection not specifically reported, but no statistically significant difference in “wound problems”</td>
<td>In control patients, soft dressing changed to elastic bandaging in few days</td>
</tr>
<tr>
<td>Sumpio et al. (2013) (USA)</td>
<td>Prefabricated or custom made above-knee or below-knee RD, unclear who applied by</td>
<td>Immediate</td>
<td>Casting</td>
<td>Progression to TFA: RD group 2, non-RD group 2 (percentage values unable to be determined)</td>
<td>Patient deemed fit for casting when wound completely healed</td>
</tr>
</tbody>
</table>

TFA, transfemoral amputation.
<table>
<thead>
<tr>
<th>Study</th>
<th>Type of study</th>
<th>Randomization</th>
<th>Blinding</th>
<th>Attrition bias</th>
<th>Statistical analysis</th>
<th>Power analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deutsch et al. (2005)</td>
<td>RCT</td>
<td>Method described</td>
<td>No</td>
<td>Randomized: RD $(n=26)$ versus non-RD controls $(n=24)$; Prosthesis fitted: RD $(n=22)$ versus non-RD controls $(n=19)$; Attrition explained</td>
<td>ITT analysis not mentioned; Tests/models used: $t$-test; Reported: means, SDs, $t$-test $P$ value</td>
<td>Sample size calculated and achieved</td>
</tr>
<tr>
<td>Woodburn et al. (2004)</td>
<td>RCT</td>
<td>Method not described</td>
<td>Prosthetist only</td>
<td>Randomized: RD $(n=78)$ versus non-RD controls $(n=76)$; Prosthesis cast: RD $(n=46)$ versus non-RD controls $(n=50)$; Attrition explained</td>
<td>ITT analysis mentioned; Tests/models used: WMW; Reported: medians, confidence intervals, WMW $P$ value</td>
<td>Sample size calculated but not achieved</td>
</tr>
<tr>
<td>Taylor et al. (2008)</td>
<td>Retrospective cross-sectional study</td>
<td>N/A</td>
<td>N/A</td>
<td>Prosthesis cast: RD $(n=28)$ versus non-RD controls $(n=37)$; Exclusions explained</td>
<td>Tests/models used: $t$-test on log-transformed data; Reported: geometric means, IQRs, $t$-test $P$ value</td>
<td>Sample size not calculated</td>
</tr>
<tr>
<td>Ladenheim et al. (2007)</td>
<td>Retrospective cross-sectional study</td>
<td>N/A</td>
<td>N/A</td>
<td>Prosthesis cast: RD $(n=76)$ versus non-RD controls $(n=28)$; Controls matched for age, gender, and principal disease; Exclusions explained</td>
<td>Tests/models used: $t$-test; Reported: means, SEs, $t$-test $P$ value</td>
<td>Sample size not calculated</td>
</tr>
<tr>
<td>van Velzen et al. (2005)</td>
<td>Retrospective cross-sectional study</td>
<td>N/A</td>
<td>N/A</td>
<td>Prosthesis fitted: RD $(n=39)$ versus non-RD controls $(n=31)$; Exclusions explained</td>
<td>Tests/models used: $t$-test; Reported: means, SDs, $t$-test $P$-value</td>
<td>Sample size not calculated</td>
</tr>
<tr>
<td>Sumpio et al. (2013)</td>
<td>Retrospective cross-sectional study</td>
<td>N/A</td>
<td>N/A</td>
<td>Prosthesis cast: RD $(n=91)$ versus non-RD controls $(n=60)$; Exclusions explained</td>
<td>Tests/models used: Kaplan–Meier time-to-event analysis with a log-rank test; Reported: mean, median, 25th and 75th percentiles, log-rank test $P$ value</td>
<td>Sample size not calculated</td>
</tr>
</tbody>
</table>

IQR, interquartile range; ITT, intention-to-treat; N/A, not applicable; SD, standard deviation; SE, standard error; WMW, Wilcoxon–Mann–Whitney.
nearly 0.5 standard deviations shorter in the RD group than in the control group and that this difference was statistically significant.

Meaningful translation of the effect estimated as SMD to the natural scale (i.e., expressed as the difference in days) cannot be achieved because of marked heterogeneity observed in the individual studies: the SMD \(= 0.46\) expressed in days could range from 8 to 36 days depending on the individual study. No evidence of small-study effect (publication bias) has been observed in a funnel plot and detected by either Begg’s \((P > 0.99)\) or Egger’s \((P = 0.7)\) tests, although both these tests could be underpowered because of the small number of studies.

**DISCUSSION**

Prosthetic management is an established part of early management of transtibial amputees who are able to participate in therapy, and it depends on wound healing and edema control.

This is the first meta-analysis that examines whether RD reduces time to prosthetic casting or fitting compared with SD in transtibial amputees. This meta-analysis complements the 2 most recent nonsystematic literature reviews on this subject.\(^9,10\) It indicates that, in patients who are managed with an RD, the average time from amputation to casting or fitting was nearly 0.5 standard deviations shorter in the RD group than in the control group and that this difference was statistically significant. This difference is in the range between 8 and 36 days because of marked heterogeneity of the included studies.

This heterogeneity is manifested by the fact that the mean time from amputation to casting or fitting varied from 22 to 76 days in the RD group and from 19 to 75 days in the control group. The reason for this marked variation is not clear from 4 of the papers. Deutch et al. stressed that their center has an “early fitting policy,” and their times to fitting were indeed lower than those of the other studies. Interestingly, the original paper by Wu et al.\(^20\) that introduced the concept of RD but could not be included in the analysis because of incomplete data reported mean time to casting as 46.2 days for RD and 109.5 days for SD.

The studies included in this meta-analysis varied in their design and outcome measures. The types of RD were above or below knee and could be removable or nonremovable and custom made or prefabricated. In 4 studies the RD was applied in the operating theatre or recovery room, in 1 study it was done within 24 hr of surgery, and in 1 study it did not specify how soon after surgery the RD was applied. However, this study by Ladenheim et al. refers to occasionally allowing patients to weightbear in an “immediate postoperative prosthesis”—another point of difference between this study and the others, which allows us to presume that the RD is also applied very soon after surgery. Four studies measured time to casting and 2 measured time to fitting. This variability in management of patients with RDs further emphasizes a lack of consensus worldwide regarding optimal patient management, even within the patient cohort who receive an RD.

It is important to note that in 2 prospective randomized studies that reported the numbers of patients fitted with prosthesis, there were no significant differences reported between the SD and RD groups, that is, the application of RD did not affect the proportion of patients who were able to progress to fitting. In the studies that provided enough information regarding the rates of wound infection\(^15\) or “wound problems,”\(^18\) all the studies reported no significant difference in those rates between the SD and RD groups.\(^9,18\)

**Study Strengths and Limitations**

This study is the first systematic review and meta-analysis of studies that compare time from amputation to prosthetic casting or fitting in transtibial amputees whose immediate postoperative wound management involved application of either an SD or an RD. It was conducted in accordance with the published guidelines.\(^11,12\)

Varied methodological quality of the included studies is the main limitation of this meta-analysis. Only 2 studies were RCTs, and of the 4 retrospective cross-sectional ones, 2 included historic rather than
parallel controls. The decision of the timing of the casting or fitting was made by several clinicians, of whom one (the prosthetist) was blinded in one RCT. We do acknowledge that blinding the treating clinicians to the intervention of the RD is a challenge because of the RD’s appearance and texture being quite different to that of the SD, but involving a blinded assessor not familiar with patients’ treatment could be feasible.

CONCLUSIONS

This study demonstrates that the use of RD in transtibial amputees reduces time from amputation to prosthetic casting or fitting when compared with SD. In the absence of universally accepted evidence-based guidelines regarding the use of RD in the immediate postoperative setting, the results of this meta-analysis will assist in guiding postoperative management of transtibial amputees. Further well designed, executed, and reported randomized clinical studies are required on this subject.

REFERENCES