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A Multicentre Retrospective Evaluation of Rigid Removable Dressing Post-Operative Outcomes in Individuals Undergoing Transtibial Amputation

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1. Abstract

1.1. Background

The British Association of Chartered Physiotherapists in Amputee Rehabilitation (BACPAR) guidelines recommend the use of Rigid Removable Dressings (RRDs) following a transtibial amputation to prevent the formation of post-operative oedema. The use of RRDs can reduce hospital length of stay (LOS), time to prosthetic casting (TPC) and improve wound healing. This multicentred retrospective audit compared outcomes of individuals who received an RRD to those managed using conventional soft dressings following transtibial amputation.

1.2. Methods

Retrospective data was collected for individuals who underwent a transtibial amputation at 2 arterial centres between September 2022 and December 2023. Site 1 routinely applied RRDs, whilst site 2 used conventional soft dressings consisting of wool and crepe post-operatively. Data collected included demographics, LOS, TPC, incidence of falls and revision surgery rates.

1.3. Results

A total of 206 individuals were included: 96 at site 1 (78 had an RRD and 18 did not) and 110 at site 2 (no RRDs). Among individuals who received an RRD, 8% required revision surgery, with mean time from amputation to revision surgery longer in the RRD group (62 days) compared with site 2 (31 days), although this difference was not statistically significant. Site 1 demonstrated a significantly longer LOS (17 days verses 10 days; $p=0.003$) but statistically shorter TPC (122 days verses 183 days $p<0.05$).

1.4. Conclusion

Use of RRDs was associated with a lower proportion of revision surgeries and a longer time to revision when required. Although statistically significant differences were observed in LOS and TPC between centres, it is unclear whether these differences reflect the impact of RRD use or institutional differences. A prospective randomised controlled trial is required to determine the clinical and cost-effectiveness of RRDs following transtibial amputation.

2. Introduction

The United Kingdom (UK) National Vascular Registry (NVR) reported, 3,688 major lower limb amputations were performed in 2023 due to peripheral arterial disease or diabetes [1]. However, this figure excludes bilateral amputations and those performed within 30 days of revascularisation, and has a case ascertainment of approximately 88%, meaning the actual number is likely to be higher. In a recent National Confidential Enquiry into Patient Outcome and Death (NCEPOD) report, residual limb breakdown occurred twice as often in transtibial compared to transfemoral amputations (26.5% verses 13.4%) with non-healing potentially indicating the need for further surgery [2]. Bergman et al [3], reported a 3.1% revision rate following transtibial amputation

at 30 days which increased to 12.2% after a year [3]. However, due to better rehabilitation and functional outcomes, a transtibial amputation is preferrable to a transfemoral amputation [4].

Importantly, it is well recognised that following amputation, oedema can form in the residual limb due to the trauma of surgery leading to post-operative inactivity, which can hinder rehabilitation [5]. Thus, controlling post-operative oedema is important and has been shown to quicken wound healing, control pain and facilitate early mobilisation and prosthetic fitting [6-8]. Equally, the formation of excessive residual limb oedema can delay casting of a prosthetic limb and increase hospital length of stay (LOS) thus increasing the total cost of treatment [9-10].

Traditional care of the residual limb involves the use of conventional soft dressings consisting of wool and crepe bandaging but these do not prevent what can be considerable post-operative oedema [11]. An alternative to the conventional soft dressings is the use of a rigid removable dressing (RRD) which encompasses the residual limb at a fixed circumference and potentially limits the formation of excessive post-operative oedema [12].

The benefits of RRDs have been well documented in the literature and include; facilitate wound healing, oedema reduction, residual limb protection, reduced time to prosthetic casting, improved pain control and reduced hospital LOS [6,10,11,13-16]. BACPAR guidelines on the management of post-operative oedema concluded that rigid dressings should ideally be used when time and expertise allow [12]. With a recent systematic review concluding that RRDs should be considered as the first choice in post-operative care [17]. Both the guidelines and systematic review were based on RCTs comparing the use of RRDs to standard care.

The NCEPOD also reported that post-amputation individuals are at a higher risk of falling with 12.8% of cases having an inpatient fall [2,17]. Of these 27% were identified as having adverse consequences following the fall, including further surgery to the residual limb. Consequently, protection of the residual limb is imperative, with a recent meta-analysis concluding that the use of RRDs led to a significant decrease in the proportion of surgical revisions required [16]. However, trauma to the residual limb is not the only post-operative complication that can lead to the need for revision surgery, others include wound dehiscence, infection and poor vascularity [2]. The presence of oedema can add pressure across the suture line potentially causing wound dehiscence therefore optimising management of this through RRDs can be of benefit.

This retrospective multicentre audit compared practice between 2 large acute arterial centres both of which carry out over 150 major amputations a year. Whilst RRDs are widely advocated by current evidence, only a few centres in the UK currently offer RRDs routinely as they are more costly, time consuming and require appropriate training to apply.18 Therefore, the aim of this audit was to evaluate the benefit of using an RRD in a clinical setting to provide valuable information to clinicians wishing to introduce RRDs into practice.

3. Method

Retrospective data was collated from electronic patient records for individuals who had a transtibial amputation between 01/09/2022 and 31/12/2023 across both sites. Individuals who had an amputation performed solely due to infection were excluded. This was registered as an audit at each site with approval numbers allocated (11391 and CARMS 21177 IG1045). Further approval was not required as using the Health Research Authority decision tool this study was not deemed to be research.

3.1. Standard Of RRD Care (Site 1):

RRDs were applied during the first 4-days following surgery and monitored by the physiotherapy team. The RRDs were fabricated by the Physiotherapists using a combination of non-fibreglass and fibreglass tapes. A lateral cut with Velcro fastening was incorporated to enable removal as required. Due to clinician rationale, not all individuals at site 1 had an RRD fabricated. Compression socks were used from day 4 and an early walking aid used from day 7 post-operatively as appropriate. All individuals are referred to the limb fitting service following surgery and an initial telephone appointment made within 4-6 weeks. A decision was then made regarding the timeline to review suitability for prosthetic casting.

3.2. Standard of Conventional Care (Group 2):

Soft dressings comprising of wool and crepe bandages were utilised post operatively with compression socks used from day 5 post-operatively. All individuals were referred to the limb fitting service following surgery and received a telephone and/or face to face appointment within 6 weeks. Inpatient rehabilitation with early walking aids was not available.

3.3. Data Collection

Age, gender, reason for amputation, date of surgery, days until RRD fitted (if applicable), LOS, inpatient falls, date of revision surgery if applicable and time to prosthetic casting (TPC) were recorded (Microsoft Excel, Microsoft inc. Version 2406).

3.4. Statistical Analysis

A statistical package (R version 4.2.1, 2022, The R Foundation for Statistical Computing) was used for the statistical analysis. Normalities were assessed using the Shapiro–Wilk test. The age data was normally distributed. For the LOS and TPC, the data was non normal with skewed results. Group comparisons were conducted using Welch's two sample t test due to its robustness to heteroscedasticity and deviations from normality, but a non parametric Mann–Whitney U test produced consistent results (data not shown). Statistical significance was deemed at $p<0.05$.

4. Results

4.1. Demographics

Data was available for 206 individuals from 2 hospitals, site 1 (n =96) and site 2 (n = 110). No statistical significance was seen between the groups in terms of age, gender or cause of amputation (Table 1).

Table 1: Demographics.

	Site 1 (n = 96)	Site 2 (n=110)
Age	63 years ±13	63 years ±11
Gender	70 male, 26 female	92 male, 19 female
Cause of amputation	6 Diabetes, 47 Diabetes and Vascular, 43 Vascular	15 Diabetes, 72 Diabetes and Vascular, 23 Vascular

4.2. Fabrication of RRD

Seventy-eight individuals at site 1 were fitted with an RRD with a median time to fabrication of 3-days (IQR 4-days). The remaining 18 individuals at site 1 were not fitted with an RRD, reasons RRDs were not fabricated were: issues with residuum (7), unwell medically (7), early discharge from hospital (3) or the individual declined (1). None of the individuals at site 2 were fitted with an RRD.

4.3. Falls

During their inpatient stay, 20 (21%) individuals had falls at site 1 and 20 (18%) at site 2. At site 1, 6 of the individuals who fell hadn't had an RRD fabricated, the remaining 14 had received an RRD however, due to documentation, we were unable to ascertain whether the RRD was in situ at the time of the fall.

4.4. Revision Rate

The same percentage (14%) of individuals required revision surgery from site 1 and site 2 with a smaller percentage of these falling at site 1. Only a small percentage of individuals at site 1 who had an RRD underwent revision surgery, none of which had fallen, with a longer time from initial surgery to revision compared to those without at site 1 and site 2. However, statistically there was no effect on time to revision surgery between the sites (p=0.682). Those without an RRD at site 2 had the highest rate of revision surgery with the shortest time to surgery (Table 2).

The fact that no individuals had revision surgery after a fall at site 1 who received an RRD, may be clinically significant, but due to the low sample size no statistically significant difference was found between those at site 1 with an RRD and those at site 2 (p=0.126).

4.5. Length of Stay and Time to Prosthetic casting

Individuals at site 1 had a statistically significant longer overall LOS (p=0.033) and time from surgery to discharge (p=0.003) compared to site 2. However, site 1 statistically had a shorter TPC compared to site 2 (p<0.05) as shown in Table 3 and Figure 1.

Table 2: Comparison of Revision surgery.

	Revision surgery		Time from Surgery to revision	
	Number individuals	Number who fell	Median (days)	IQR
Site 1 (n=96)	13 (14%)	2	40	46
Site 1 with an RRD (n=78)	6 (8%)	0	62	55
Site 1 without an RRD (n=18)	7 (39%)	2	21	25
Site 2 (n=110)	15 (14%)	4	31	42

The fact that no individuals had revision surgery after a fall at site 1 who received an RRD, may be clinically significant, but due to the low sample size no statistically significant difference was found between those at site 1 with an RRD and those at site 2 (p=0.126).

Table 3: Comparison of overall LOS, LOS from surgery and TPC.

	Overall LOS		LOS from Surgery		TPC	
	Median (days)	IQR	Median (days)	IQR	Median (days)	IQR
Site 1 (n=96)	26	27	17	22	122	46
Site 1 with an RRD (n=78)	24	25	15	20	119	41
Site 1 without an RRD (n=18)	32	36	27	23	139	23
Group 2 (n=110)	18	18	10	11	183	140

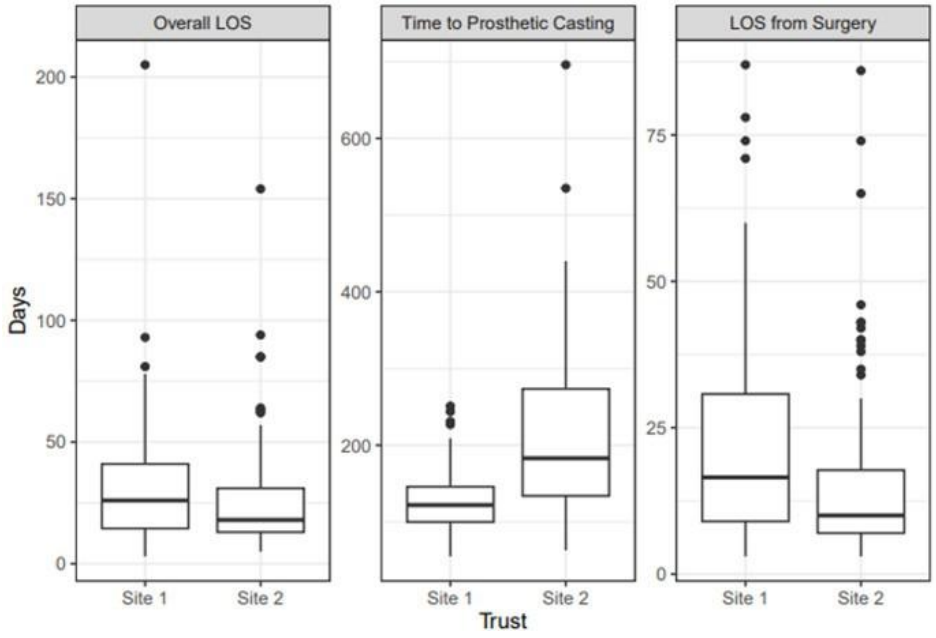

Figure 1: Comparison of LOS and TPC.

5. Discussion

This study examined the impact of rigid removable dressings (RRDs) compared with soft dressings following transtibial amputation, with particular focus LOS, TPC, and rates of revision surgery. The findings demonstrate differences in LOS and TPC between dressing types and across study sites, highlighting potential influences of postoperative management practices and institutional protocols. Notably, individuals fitted with an RRD at Site 1 were less likely to require revision surgery.

Current literature suggests the application of an RRD immediately post-operatively can reduce the amount of oedema that can form [12]. Whilst this is recognised as clinically important, operationalising this level of care faces practical challenges, including access to trained therapists for out of hours fabrication and delays related to medical instability. Consequently, site 1 aimed to apply and RRD within 4-days post-operatively. A median time to application of 3-days was reported among the 78 individuals who received an RRD at site 1, which falls within the service target and therefore reduces the likelihood that timing of application contributed to variability within the findings. However, it should be acknowledged that even within this timeframe, earlier versus later application may still influence outcomes.

Interestingly [18], individuals at site 1 did not receive an RRD. This aligns with recommendations from Kwah et al. [18]. Systematic review, which advises caution when considering RRD application in individuals with compromised skin integrity, as conventional dressings may pose a lower risk of breakdown.18 Although contraindications to RRD use are not widely documented, previous studies have excluded individuals with uncontrolled infection or severe ischemia.16 In this study the primary reason RRDs were not applied at site 1 was due to residuum complications, such as ischaemia or bleeding, which fits with the above suggestions from the literature. Other reasons included medical instability, early discharge from hospital or individual preference. Importantly, the findings of this study must be interpreted with caution due to the potential influence of selection bias and confounding by indication. The decision to fit an RRD was not randomised and was likely influenced by clinical judgement and reflect greater baseline clinical complexity and higher risk of delayed healing and wound complications independent of dressing type.

Furthermore, the appropriateness of an RRD was determined through clinically reasoning by the therapy team and discussed with the vascular medical team were uncertainty existed. Whilst this pragmatic decision making introduces potential selection bias, the retrospective design reflects real world clinical practice. Therefore, analysing outcomes both between the 2 sites and within site 1 by separating individuals into RRD and non-RRD groups was considered appropriate and clinically informative. Future prospective or controlled studies would be required to minimise bias and better isolate the impact of RRD use.

It is recognised that the need for revision surgery or hospital readmission can have a negative impact on patient outcomes, placing additional financial burden on the healthcare system [19]. When revision rates were compared between sites, no overall difference was identified (14% at each site). However, at site 1, individuals fitted with an RRD demonstrated a lower revision rate (8%). The 8% revision rate observed in our cohort is consistent with the finding of [4]. Who reported a large reduction in revision surgery from 43% to 8% after the introduction of RRDs [4[. The mean time to revision surgery in our study was 62 days which is higher than the 28 day follow up time used by [4].

It is worth noting that 39% of individuals at site 1 without an RRD required revision, it is important to acknowledge that individuals deemed unsuitable for RRD fitting may have had greater medical complexity, which likely contributed to the higher revision rate observed in this subgroup. Time to revision for those at site 1 without an RRD was the shortest at 21-days whilst site

2 saw an average of 31-days. As this was a retrospective audit, without a predefined follow up timeframe the extended time to revision among those fitted with an RRD may indicate delayed or reduced wound complications for this sub-group. Therefore, the differences seen appears to support initial use of an RRDs to support surgical site healing. While the findings support the potential benefit of RRDs in promoting surgical site healing, appropriate patient selection appears critical. A standardised investigation is required to determine the full clinical and cost-effectiveness of RRDs and to minimise confounding factors and bias that may be associated with retrospective analysis.

Critically, both sites reported a similar proportion of inpatient falls (21% at site 1 and 18% at site 2) which exceeds the 12.8% recorded by the NCEPOD report [2]. As none of the individuals fitted with an RRD who experienced a fall subsequently required revision surgery, it suggests that RRDs may provide protection due to their solid nature. The retrospective nature of this audit limited the ability to confirm whether the RRD was in situ at the time of a fall, as documentation was inconsistent. Prospective studies with predefined reporting of falls and documentation of RRD status at the time of injury would be required to fully evaluate this potential benefit.

The majority of existing studies use LOS and TPC as primary outcome measures, frequently demonstrating reductions in both following the use of RRDs [9,10,20-22]. In contrast, our study reported a statistically significant shorter LOS at site 2 (overall and from surgery to discharge) while site 1 demonstrated a statistically significant shorter TPC. Given the multicentre design and absence of standardised pathways and protocols, it is difficult to attribute these differences directly to the use of RRDs. LOS, in particular, is multifactorial with medical issues, rehabilitation needs and social circumstances contributing to delays. Individuals are often deemed medically fit yet remain in hospital whilst waiting for rehabilitation, social care availability and housing. Whilst LOS has previously been used as an outcome measure it is difficult to attribute a targeted treatment such as the use of RRDs on differences in LOS.

Similarly, TPC is influenced by several variables including institutional differences and protocols. Following surgery, individuals were referred to their local limb centre, in total 3 centres were referred to, 1 from site 1 and 2 from site [2]. Whilst casting of a prosthetic limb is typically deferred until satisfactory wound healing is seen and residual limb volume has stabilised; timing will also depend on availability of appointments and protocols at each centre. Therefore, differences seen in TPC may be due to differing systems and caseloads rather than clinical readiness. A definitive RCT with a standardised protocol for timing of application and clearly defined outcome measures would be required to validate the differences seen between LOS and TPC, evaluate cost-effectiveness and guide clinical practice and help to prioritise caseloads. While an RCT would address the bias and confounding issues evident with a retrospective audit, real-world observational data remain valuable in reflecting routine clinical practice and identifying clinically meaningful signals that warrant further investigation.

6. Conclusion

In summary, this multicentre retrospective audit suggested potential benefits of rigid removable dressings (RRDs), particularly in relation to reduced revision rates and a possible protective effect following inpatient falls. Individuals fitted with an RRD post-operatively were less likely to require revision surgery and, where necessary, this occurred later in their recovery. This is an under reported outcome within the existing literature therefore further research is required. These findings contribute to the growing body of evidence supporting the clinical use of RRDs. However, definitive conclusions cannot be drawn regarding their impact on LOS or TPC, despite these outcomes being reported in previous small randomised controlled trials. Further adequately powered prospective research is required to determine overall clinical and cost-effectiveness, establish optimal timing of RRD application, and evaluate whether timing itself influences post-operative outcomes.

Statements and Declarations

7. Ethical Considerations

This was registered as an audit at each site with approval numbers allocated (11391 and CARMS 21177 IG1045). Further approval was not required as using the Health Research Authority decision tool this study was not deemed to be research., therefore ethical approval was not required.

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