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INTERVENTIONS TO MANAGE RESIDUAL LIMB ULCERATION DUE TO PROSTHETIC USE IN INDIVIDUALS WITH LOWER EXTREMITY AMPUTATION: A SYSTEMATIC REVIEW OF THE LITERATURE

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Abstract

Patients with lower extremity amputation (LEA) experience 65% more dermatologic issues than non-amputees, and skin problems are experienced by $\approx 75\%$ of LEA patients who use prostheses. Continuously referring LEA patients to a dermatologist for every stump related skin condition may be impractical. Thus, physical rehabilitation professionals should be prepared to recognize and manage common non-emergent skin conditions in this population. The purpose of this study was to determine the quantity, quality, and strength of available evidence supporting treatment methods for prosthesis-related residual limb (RL) ulcers. Systematic literature review with evidence grading and synthesis of empirical evidence statements (EES) was employed. Three EESs were formulated describing ulcer etiology, conditions in which prosthetic continuance is practical, circumstances likely requiring prosthetic discontinuance, and the consideration of additional medical or surgical

interventions. Continued prosthetic use is a viable option to manage minor or early-stage ulcerated residual limbs in compliant patients lacking multiple comorbidities. Prosthetic discontinuance is also a viable method of residual limb ulcer healing and may be favored in the presence of severe acute ulcerations, chronic heavy smoking, intractable pain, rapid volume and weight change, history of chronic ulceration, systemic infections, or advanced dysvascular etiology. Surgery or other interventions may also be necessary in such cases to achieve restored prosthetic ambulation. A short bout of prosthetic discontinuance with a staged re-introduction plan is another viable option that may be warranted in patients with ulceration due to poor RL volume management. High-quality prospective research with larger samples is needed to determine the most appropriate course of treatment when a person with LEA develops an RL ulcer that is associated with prosthetic use.

Keywords

Decubitus ulcer; Dermatopathology; Hot spot; Prosthesis; Rehabilitation; Skin

INTRODUCTION

Rehabilitation for persons with lower extremity amputation (LEA) is complex and requires an interprofessional healthcare team. Members of the multidisciplinary healthcare team for individuals with LEA may include orthopedic and vascular surgeons, physiatrists, prosthetists, physical therapists, dermatologists, mental health professionals, and others. Patients with amputation spend considerable time with physical rehabilitation professionals to learn selfcare with their new prostheses. During this period, rehabilitation professionals frequently encounter skin ulceration of the patient's residual limb (RL) related to prosthetic use. Continuously referring patients to a dermatologist for every skin condition may not be practical. Therefore, it is important that physical rehabilitation professionals are prepared to recognize and manage common non-emergent skin conditions in this population. Proper management should be recommended and may include teaching self-care strategies to the patient as well as recognition of conditions requiring referral.

Currently, more than 80% of amputations in the U.S. are the result of complications from vascular disease and diabetes (1,2). Less than 10% of LEA results from trauma (3,4). People with amputation experience nearly 65% more dermatologic issues than the general population. Skin problems are experienced by approximately 75% of patients with LEA who use lower limb prostheses (5). With LEA, the normal pressure-distributing anatomy is missing or altered. Therefore, the RL is exposed to several atypical conditions with prosthetic use. These include elevated shear forces, stress risers, increased humidity, and prolonged moist contact within the prosthesis, which can macerate tissue and contribute to ulceration. Ulcers or pressure sores, among the more common skin conditions in prosthetic users, may be mitigated with minor prosthetic adjustments to redistribute pressure (6). However, the size of areas over which pressures are applied and their magnitude can be considerable and may require recovery time out of the prosthesis or even a new socket to be fit (5). Prosthetic disuse can have many adverse consequences for the patient. These may include weakness, decreased flexibility, reduction of ambulatory ability, functional decline,

decreased physical activity, difficulty performing activities of daily living and occupational tasks, increased fall risk, decreased exercise tolerance, weight gain, financial hardship, and psychological implications.

Alteration to RL shape and volume are common, with fluctuation, daily and over the lifespan, contributing to mismatch between prosthetic socket and RL. Socket to RL volume mismatch is a common problem often contributing to skin ulceration. Patients can have a high level of influence on this situation, for example, by adding socks. Therefore, monitoring fit and comfort along with other self-management techniques are vital to minimize a breakdown of skin integrity and function. This project's aim was to review the intervention and management of RL ulcers in persons with LEA who use prostheses. The purpose of this literature review was specifically to determine the quantity, quality, and strength of available evidence to formulate evidence statements supporting treatment methods for prosthesis-related RL ulcers.

Methods

An interprofessional team was recruited to design the search term set that would best capture manuscripts to address the project's aim and purpose. The team included the following disciplines: prosthetics, physical therapy, physiatry, dermatology, and information science. The PICO (Participants, Interventions, Comparison, Outcome) framework was used to identify key terms relevant to the project's aim and purpose (7). On the assumption that available evidence regarding the treatment of pressure ulcers in lower extremity prosthetic users would be limited, PICO related search terms were selected, tested, and kept non-specific to identify as many potential manuscripts as possible. On November 1, 2014, the following search terms, Medical Subject Headings (MESH) terms, and Boolean Operators were agreed upon and utilized to search the MEDLINE (Pubmed), The Cumulative Index to Nursing and Allied Health Literature (CINAHL)(Ovid) and Embase databases:

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((((((((((((((lower extremity OR lower extremit*)) OR (lower limb OR lower limb*) OR leg) OR hip) OR foot) OR knee) OR ankle) OR (above knee OR AK)) OR (below knee OR BK)) OR (transfemoral OR "trans-femoral")) OR (transtibial OR "trans-tibial")) OR (transpelvic OR "trans-pelvic")) OR (syme's OR symes))) AND (((("Amputation"[Mesh]) OR amput*) OR disarticulation) OR (hemipelvectomy OR "hemi-pelvectomy")) OR stump) NOT (((((((pirogoff ) OR chopart) OR lisfranc) OR (transmetatarsal OR "trans-metatarsal")) OR "ray resection") OR "ray resections") OR "ray amputation") OR "ray amputations")) AND (ulcer OR ulcerat* OR pressure sore OR pressure ulcer OR decubit* OR breakdown)) AND (intervention OR treatment OR management OR non-use OR dressing OR negative pressure OR wound vacuum).
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Inclusion criteria were based on the definition of prosthesis-related ulcer and LEA as defined by the authors. Prosthesis-related ulceration, as defined by the authors, referred to an uninfected wound on the RL of a patient with an LEA that occurred from excessive pressure associated with prosthetic use. In this review, LEA referred to any Syme's, transtibial, knee disarticulation, transfemoral, hip disarticulation, or hemipelvectomy amputation of any

etiology. Foot and toe amputations were excluded. To be included, manuscripts were required to:

1. Include subjects with a lower extremity amputation and a prosthesis-related ulcer on their residual limb(s)
2. Be published after 1990
3. Study interventions, treatments, or management of wounds or ulcers in the amputated residual limb(s) of a person with lower extremity amputation who has used or uses a prosthesis

Manuscripts were excluded if they were:

1. Studies involving animals, cadavers, or computational modeling (i.e., non-human)
2. Published before January 1, 1990
3. Not written in English

Search results were exported into Endnote reference management software (V7, Thompson, CA, USA). Once imported, reference titles and then abstracts were screened for inclusion. Full text articles were then obtained for review of remaining articles that were not included initially through title and abstract screening. Articles not meeting inclusion criteria were eliminated. Included articles were then evaluated using the American Academy of Orthotists and Prosthetists' (AAOP) evidence rating tool because of its content and population specificity (8). This rating tool was also selected because it permits evaluation of the full range of manuscripts and study designs (i.e., editorials to meta-analyses). The AAOP rating tool identifies 18 potential threats to internal validity and eight potential threats to external validity of the included experimental, quasi-experimental, and observational research articles reviewed (Table 1). Following review and rating, internal and external validity were then classified as "high," "moderate," or "low." Articles were classified as having high internal or external validity if they met >80% of the tool's criteria, moderate internal or external validity if they met 60% to 80% of criteria, and low internal or external validity if they met <60% of the criteria (Table 2).

RESULTS

The search identified 3,024 peer-reviewed articles (Figure 1). Studies involving animal, cadaver, or modeling; written before January 1, 1990; and/or not written in English were excluded. Additionally, articles were eliminated based on title when the title failed to reasonably support manuscript inclusion. These two steps resulted in the elimination of 2,956 articles. A further 46 articles were excluded following abstract review. Full text articles were obtained and reviewed for the remaining 22 references. Of these, 17 were excluded based on eligibility criteria. The remaining five articles (Table 3) were included in the evaluation and synthesis. All studies were clinically oriented, including one randomized-control trial (9), one observational cohort study (10), one case series (5), and two case studies (11,12). None of the included studies incorporated blinding nor reported effect size. All studies addressed accommodation and washout and were free of conflicts of interest.

Also, attrition was addressed in all studies and was <20%; however, attrition rates were not equal among groups due to the inclusion of case studies. Only valid and reliable outcome measures were used in the included studies. One study addressed the AAOP instrument's fatigue and learning criteria. Statistical analysis was appropriate, adequately powered, and reported in two of the five studies. Additionally, exclusion criteria were not discussed in three of the five included studies. Finally, since all articles had high external validity, total confidence in the synthesized evidence statements were predominantly in accordance with the internal validity ratings.

In total, conclusions from this report were made from 117 subjects with a mean (interquartile) age of 61.8 years (range: 44 to 80 years) who completed their respective studies. Eight subjects did not complete their studies, so attrition was 6% when all five studies were considered. The majority of subjects were male (74%) and unilaterally involved at the transtibial level. Only four subjects were bilaterally involved. Most subjects sustained their amputation as a result of peripheral vascular disease. At least three comorbid diagnoses, but as many as eight comorbidities, were reported in some cases. Most ulcers were classified as stage II level (13), and the leading diagnostic methodology was history and physical examination. In some cases, the physical examination was augmented with either wound measurement or Duplex imaging. Two dependent variables—time to wound healing and wound size (or area)—have the promise of aggregation and synthesis. Unfortunately, due to reporting at an apparently preset follow-up date, rather than at the date of complete healing, wounds were in various stages of healing upon follow-up. Therefore, time to healing data could not be aggregated. Time to healing or time to follow-up were widely varied, with a range from two to 20 weeks. Regarding wound size, the wounds in the Trallesi et al. study (9) were nearly two times the size of those reported in the Salawu et al. study (10). Trallesi et al. reported mean initial wound areas of 7 cm² (Vacuum Assisted Suction Suspension (VASS) group) and 6.3 cm² (control/suction socket group) compared with mean initial wound areas of 3.6 cm² in established prosthesis users and 3.1 cm² in new prosthesis users reported by Salawu et al. (9,10). Further, these wound area measures were made using vastly different methodologies. For instance, there were manual measurements (10) and scaled on-screen measurements taken in software (9). These differences in wound area measurement methodologies further complicate the ability to aggregate data for meta-analyses.

Ultimately, prosthetic continuance or prosthetic discontinuance were the predominant intervention options available to manage RL ulcers related to prosthetic use. Multiple adjuvant interventions were included within the themes of prosthetic continuance (i.e., use) or discontinuance (i.e., disuse). These adjunct interventions included:

1. Prosthetic modification or adjustment
2. Planned progressive prosthetic re-introduction
3. Patient education
4. Continued prosthetic use (VASS, suction, or usual suspension) with wound care (during disuse periods or scheduled)

Finally, three evidence statements were synthesized from the results. The topics addressed were 1) ulcer etiology, 2) continued prosthetic use, and 3) cessation of prosthetic use (Table 4).

DISCUSSION

The purpose of this review was to determine the quantity, quality, and consistency of available evidence to formulate evidence statements supporting treatment methods for prosthesis-related RL ulcers. The review identified five articles (Table 3) that described the treatment of RL ulceration in 117 amputee subjects. With the exception of four bilaterally involved individuals, subjects had a history of unilateral transtibial amputation of vascular or unknown etiologies. The subjects were mostly elderly and had multiple comorbidities, including Type 2 Diabetes Mellitus, coronary artery disease, hypertension, hyperlipidemia, chronic venous insufficiency, neuropathy, anemia, post-herpetic neuralgia, pruritus, and chronic smoking. All subjects received modification of prosthetic use, including restriction and disuse, as an intervention.

The first empirical evidence statement (EES) addressed development of an ulcer relative to improper volume management and utilization of interface components (Table 4). Scenarios that can contribute to ulceration include weight gain or loss, changes in activity, medication and physiologic changes, componentry damage, patient compliance issues, and improper patient education. Confidence in this statement was moderate. It is standard practice for prosthetists to educate patients regarding the risk of developing an ulcer as well as numerous methods of preventing and managing them should they arise, including proper device utilization and volume management. Specifically, skin ulcers reportedly develop in nearly 27% of diagnosed skin problems in prosthetic users (14). The responsibility for preventing and managing ulcers in the residual limbs of prosthetic users is shared between the prosthetist, who provides a properly fit device and educates the patient, and the patient, who should practice diligent self-care and compliance.

Controversy exists as to whether continued prosthetic use is indicated for amputees with RL ulcerations because ambulation has many physiological benefits that improve wound healing (15), such as increased circulation (16), tissue oxygenation (16,17), and fluid filtration (17). Prolonged inactivity, which is often associated with prosthetic disuse, is associated with several deleterious effects on health, including reduced functional capacity, respiratory function, skin integrity, and oxygen transportation (17) as well as muscle atrophy (18). This list is not inclusive of negative psychological effects of inactivity, such as depression, anxiety, and psychosomatic fatigue (19).

In the event that an ulcer develops, there are numerous management options, including prosthetic use or disuse. EES 2 (Table 4) indicates that, in the absence of comorbidities that may delay healing and impair cognition, patient education and modified prosthetic use with or without elevated vacuum suspension is safe, can reduce ulcer size, and result in limited but continued function during healing. Conversely, EES 3 (Table 4) indicates that prosthetic disuse with or without alternative interventions such as surgery or systemic antibiotics may be indicated in the case of residual limbs that ulcerate in the presence of chronic heavy

smoking, intractable pain, rapid volume and weight change, history of chronic ulceration, systemic infections, or advanced dysvascular etiology. The confidence in both statements is moderate based on available evidence.

An additional case series, published after conducting this review, reported on continued prosthetic use in ulcerative care. Hoskins et al. described six ($n = 6$) unilateral transtibial patients (five male, one female, mean age = 66.5 years, mean weight = 94.6 kg) of vascular ($n = 5$) and traumatic ($n = 1$) etiology prescribed VASS prostheses upon presentation with an open RL wound (20). Subjects had several comorbidities, including Diabetes Mellitus Type 1 and 2, peripheral vascular disease, Charcot joint disease, retinopathy, hearing impairment, dermatillomania, and history of chronic alcohol and tobacco use. All subjects received physiatrist-prescribed wound care and were instructed to continue prosthetic use “as much as possible given any pain they may experience and not to limit their activities” (20). Vacuum pump and prosthetic foot type were not controlled. Wound size (determined by software analysis of ulcer photographs) and time to complete wound closure were primary outcome measures. Wound surface area was $2.17 \pm 0.65 \text{ cm}^2$ (initially) and mean time to wound closure was $117 \pm 113 \text{ d}$ (range: 40 to 380 d). During that period, one subject was non-compliant with proper use protocols for a short time ($\approx 20 \text{ d}$), another had a hole in the sealing sleeve that required repair (at $\approx 100 \text{ d}$), and a third subject suffered a fall requiring surgery and rehabilitation (at $\approx 30 \text{ d}$). Authors concluded VASS prostheses may be used while managing RL wounds in transtibial amputation patients. Results further suggest a well-fitting VASS socket does not preclude RL wound healing and closure in compliant users even without activity limitation (20). This recently published data supports EES 2 and suggests that continued prosthetic use without activity restrictions may be possible in the presence of common diabetic-related complications when VASS is utilized. It further suggests that, on a per-case basis, comorbidities do not preclude continued prosthetic use in the presence of a residual limb ulcer.

Limitations

Though most included articles demonstrated moderate to high internal validity and high external validity, only one randomized control trial was included. This indicates substantial need for more high-quality research including more randomized control trials to determine the optimal treatment methods to reduce wound healing time and increase overall function for patients with a prosthesis-related RL ulcer. Meta-analyses were not possible due to a lack of standardized wound assessment scales and measures. Additionally, subjects in the included studies ranged in age from 44 to 80 years and had predominantly stage II ulcers, so it is unclear if results will generalize to younger subjects with ulcers in different stages.

CONCLUSION

This systematic review indicates that continued prosthetic use is a viable option to manage a residual limb with minor early stage ulceration in the compliant patient lacking comorbidities that would likely delay healing. Conversely, prosthetic discontinuance is also a viable method of residual limb ulcer healing in the presence of multiple comorbidities that delay healing, such as chronic heavy smoking, intractable pain, rapid volume and weight

change, history of chronic and complex ulceration, systemic infections, or advanced dysvascular etiology. Surgery, physical rehabilitation, or other interventions may also be necessary in such cases to achieve restored prosthetic ambulation. Evidence suggests that continued use of specific sockets (i.e., VASS) in select compliant patients, even with comorbidities that could delay wound healing (i.e., diabetes), may not be detrimental to wound healing under some circumstances. The results of this review show that a short bout of prosthetic discontinuance with a staged re-introduction plan is also viable and may be warranted in patients with ulceration due to poor residual limb volume management. Ultimately, the majority of amputees studied returned to prosthetic use and ambulation upon conclusion. Finally, high-quality prospective research with larger samples is needed to determine the most appropriate course of treatment when the residual limb of a person with amputation develops an ulcer associated with prosthetic use.

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Figure 1.
Study flow diagram and elimination process.

Table 1

Distribution of Included Studies by Study Design

Study Design	Number of Publications
Meta-Analysis (S1)	0
Systematic Review	0
Randomized Control Trial (E1)	1
Controlled Trial (E2)	0
Interrupted Time Series Trial (E3)	0
Single-Subject Trial (E4)	0
Controlled Before and After Trial (E5)	0
Cohort Study (O1)	1
Case-Control Study (O2)	0
Cross-Sectional Study (O3)	0
Qualitative Study (O4)	0
Case Series (O5)	1
Case Study (O6)	2
Group Consensus (X1)	0
Expert Opinion (X2)	0
Total	5

Table 2

Internal and External Validity of Included Studies

Study	Study Design	Internal Validity														External Validity		
		1-4	5	6	7	8	9	10-11	12	13	14	15	16	17	18	TOTAL	1-8	TOTAL
Bruno & Kirby (2009)	O6	NA	NA					•		•						Mod	•	High
Karakos (2006)	O6	NA	NA					•		•					•	Low	•	High
Highsmith & Highsmith (2007)	O5	NA	NA		•			•		•					•	Mod	•	High
Salawu et al. (2006)	O1	NA	NA		•	•		•		•	•		•	•	•	High	•	High
Trabellesi et al. (2012)	E1	•	NA		•	•	•	•	•	•	•		•	•	•	High	•	High

NA is not an available criteria for the indicated study type. Blank spaces indicate the criteria was not identified whereas “•” indicates the criteria was observed. Mod is moderate.

Table 3

Study Design, Intervention (Use versus Disuse), Demographics, Outcome Measures, Evidence Quality

Study	Study Design*	Intervention Use/Disuse	Sample Size	Mean Age (y)	Outcome Measures	Overall Quality of Evidence
<i>Bruno & Kirby (2009)</i>	O6	Use, 6 hours per day proper use of silicone liners otherwise they will lead to pressure sores. Ulcer healed 4 months d/c	1	84	FIM, Ulcer measurements, Silicone use/disuse for ulcer prevention	Moderate
<i>Karakos (2006)</i>	O6	Disuse, additional interventions: surgery (Angioplasty) 6 months due to pain and ulceration	1	64	Duplex scan	Moderate
<i>Highsmith & Highsmith (2007)</i>	O5	Case 1: Use, 4 hours per day Case 2: Disuse, 1 month + Case 3: Use, with frequent adjustments Case 4: Disuse 1 week Case 5: Use with wound protection	5	45	Returned to independent ambulation and function	Moderate
<i>Salawu et al. (2006)</i>	O1	Use of prosthetic device with healing ulceration	102	60	Changes in surface area of ulcers and photographs, wound cultures	High
<i>Trabellesi et al. (2012)</i>	E1	Use of prosthetic device, VAS vs Suction socket system following ulcers/ wounds healing. 12 weeks	20	61	demographics, locomotor capability index, visual analogue scale	High

Table 4

Empirical Evidence Statements

Empirical Evidence Statement	Supporting Studies	Level of Confidence	Category
Improper volume management and utilization of interface components can result in ulceration to the skin of the residual limb.	Bruno & Kirby (2009) [Moderate] Highsmith & Highsmith (2007) [Moderate]	Moderate	Ulcer etiology
Following development of an ulcer, in the absence of comorbidities that delay healing and impair cognition, patient education and modified prosthetic use with or without elevated vacuum suspension is safe, can reduce ulcer size, and result in limited but continued function during healing.	Bruno & Kirby (2009) [Moderate] Highsmith & Highsmith (2007) [Moderate] Salawuetal. (2006) [High] Trabellesietal. (2012) [High]	Moderate	Continued prosthetic use
Prosthetic disuse and/or alternative interventions such as surgery or systemic antibiotics, may be indicated in the case of residual limbs that ulcerate in the presence of chronic heavy smoking, intractable pain, rapid volume and weight change, history of chronic ulceration, systemic infections, or dysvascular etiology.	Karakos (2006) [Moderate] Highsmith & Highsmith (2007) [Moderate]	Moderate	Cessation of prosthetic use