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Review

The evidence-base for elevated vacuum in lower limb prosthetics: Literature review and professional feedback

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ABSTRACT

Background: An optimal suspension system can improve comfort and quality of life in people with limb loss. To guide practice on prosthetic vacuum suspension systems, assessment of the current evidence and professional opinion are required.
Methods: PubMed, Web of Science, and Google Scholar databases were explored to find related articles. Search terms were amputees, artificial limb, prosthetic suspension, prosthetic liner, vacuum, and prosthesis. The results were refined by vacuum socket or vacuum assisted suspension or sub-atmospheric suspension. Study design, research instrument, sample size, and outcome measures were reviewed. An online questionnaire was also designed and distributed worldwide among professionals and prosthetists (www.ispoint.org, OANDP-L, LinkedIn, personal email).
Findings: 26 articles were published from 2001 to March 2016. The number of participants averaged 7 (SD = 4) for transtibial and 6 (SD = 6) for transfemoral amputees. Most studies evaluated the short-term effects of vacuum systems by measuring stump volume changes, gait parameters, pistoning, interface pressures, satisfaction, balance, and wound healing. 155 professionals replied to the questionnaire and supported results from the literature. Elevated vacuum systems may have some advantages over the other suspension systems, but may not be appropriate for all people with limb loss.
Interpretation: Elevated vacuum suspension could improve comfort and quality of life for people with limb loss. However, future investigations with larger sample sizes are needed to provide strong statistical conclusions and to evaluate long-term effects of these systems.

1. Introduction

Amputation causes a permanent disability and people with limb loss rely on prostheses for the rest of their lives. Thus, prosthetic technology innovation is vital to improve a person's quality of life. Socket suspension is an essential technological requirement since prosthetic care has failed if the prosthesis is not attached securely and efficiently to the stump (Baars and Geertzen, 2005; Board et al., 2001; Gholizadeh et al., 2014a, 2014b). However, despite the importance for a person's limb health and mobility, conclusive evidence of the current state of prosthetic suspension systems is lacking.

Choosing an appropriate suspension system is an important step in the prosthetic rehabilitation process. A better understanding of suspension systems may facilitate selection based on the needs of a person with limb loss, leading to better stump fit inside the prosthetic socket that leads to better balance, gait, and satisfaction (Board et al., 2001; Czerniecki and Gitter, 1996).

After World War II, new materials and designs revolutionized transtibial prosthetic design (Gholizadeh et al., 2014b; Lemaire and Johnson, 1996; Sewell et al., 2000). A thigh corset was traditionally used for suspension (Radcliffe and Foort, 1961) but introduction of the patellar-tendon bearing (PTB) prosthesis leads to other suspension methods; such as, cuff, supracondylar–suprapatellar (SCSP), and figure-of-eight suprapatellar strap. Afterward, silicone suction suspension (3S) and Icelandic roll-on silicone socket (ICEROSS) systems were introduced to the rehabilitation market (Baars and Geertzen, 2005; Fillauer et al., 1989; Kristinsson, 1993) and improved total surface bearing and suspension (Sewell et al., 2000; Staats and Lundt, 1987).

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However, PTB and supra-condylar sockets are still used by many people with limb loss.

Currently, popular suspension systems fix the stump inside the socket with either a single distal pin/lock, suction (i.e. Seal-In liners, sleeve), or vacuum (i.e. Otto Bock Harmony System, Ohio Willow Wood LimbLogic VS, Ossur Unity) (Baars and Geertzen, 2005; Board et al., 2001; Gholizadeh et al., 2014a). In the Harmony (OttoBock) and LimbLogic VS (Ohio WillowWood) systems, a knee sleeve creates a seal around the top edge of the prosthetic socket and then all air between the liner and socket is evacuated using a pump and exhaust valve. The Unity (Ossur) system combines a hypobaric sealing membrane around a silicon liner, so that an external sleeve is not required. The main difference between suction and vacuum systems is that suction systems do not require a pump to remove air between the socket and liner.

Based on a recent systematic review (Gholizadeh et al., 2014a), a total surface bearing socket (TSB) with a pin/lock system was indicated as more popular among people with limb loss. Pin/lock systems secure a soft liner to the socket via a distal stainless steel pin attached to the liner. However, pistoning and distal tissue stretching (milking) can occur with pin/lock suspension systems (Gholizadeh et al., 2014a, Sanders et al., 2006).

Seal-In liner (Ossur) suction suspension systems have less stump displacement inside the socket than pin/lock or sleeve systems (Brunelli et al., 2013; Gholizadeh et al., 2012b, 2014a). Consequently, gait asymmetry, skin sores, and stump pain at the distal end are reduced. However, donning and doffing Seal-In liner systems are challenging for elderly people with limb loss (Gholizadeh et al., 2012a).

Daily stump volume fluctuation is an important issue for many people with limb amputation since prosthetic socket fit can be adversely affected and cause pistoning, gait deviations, pain, wounds, and dissatisfaction (Samitier et al., 2014; Sanders and Fatone, 2011; Sanders et al., 2011; Sanders et al., 2012). Stump volume loss can range from 4 to 10% when using a total surface bearing suction socket (Board et al., 2001).

Vacuum assisted suspension systems (VASS) were first introduced in 1995 by Caspers (1996) to reduce residual limb volume loss over time. This system consisted of a Total Environmental Control (TEC) urethane liner, suspension sleeve, and air evacuation pump. VASS decreased limb volume changes during the day and improved prosthesis control and proprioception (Board et al., 2001; Samitier et al., 2014; Sanders et al., 2011) Furthermore, pistoning decreased compared to normal suction systems.

A number of lower limb prosthetic suspension systems are available in the market (Baars and Geertzen, 2005; Board et al., 2001; Gholizadeh et al., 2014a, 2014b; Kristinsson, 1993) and clinicians typically base selection criteria on subjective experiences. Assessment of the evidence on prosthetic vacuum suspension systems is required to guide prosthetic prescription and characterize this technology within the current scope of prosthetic suspension systems. However, there is no comprehensive review of elevated vacuum suspension in the literature. This lack of evidence affects clinical practice, as demonstrated by removal of elevated vacuum suspension system coverage by a healthcare provider in the United States, possibly due to weak clinical evidence (Spencer, 2015). While a literature review to assess the available evidence for VASS systems was needed, the quality of research evidence in the VASS area is insufficient. Evidence based practice is important in provision of the best possible care and enhancement of amputee quality of life. Therefore, opinions from the prosthetic community could be combined with the literature to better characterize the contribution of VASS to prosthesis suspension. This research can help enhance quality of life in people with limb loss by enhancing prescriber understanding of VASS and helping designers and manufacturers enhance their products.

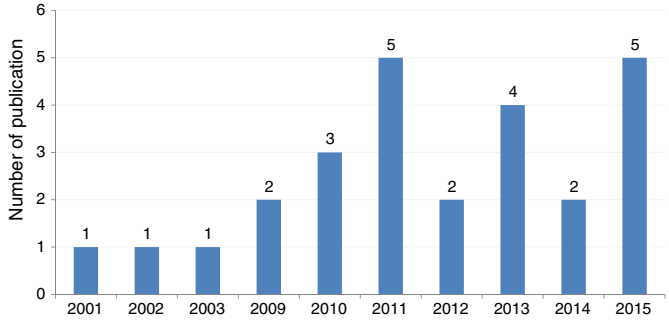

Fig. 1. Number of published articles per year.

2. Methodology

A search was conducted to find related research documents (i.e., articles) using PubMed, Web of Science, and Google Scholar databases from 1995 to March 2016. VASS was first introduced in 1995 Caspers (1996), therefore this year was selected as the lower search limit. Amputees, artificial limb, prosthetic suspension, prosthetic liner, vacuum, and prosthesis were used as keywords, refined by vacuum socket or vacuum assisted suspension or sub-atmospheric suspension. Studies were included if they evaluated a VASS (retrospectively or prospectively) and were written in English. Study design and protocol, research instrument, sample size, and outcome measures were reviewed.

Since the quality of evidence from the literature review was moderate, an online questionnaire was developed to collect feedback from prosthetic professionals on the advantages and disadvantages of VASS systems. The questionnaire results were compared with the literature review outcomes. The questionnaire was formulated by creating a preliminary list of advantages and disadvantages of VASS systems from the literature. Seven experts in VASS were recruited globally and interviewed for content validity, confirming and expanding the list of advantages and disadvantages and recommending additional information relevant to VASS implementation.

The final questionnaire consisted of 28 questions and a comments section (http://goo.gl/forms/6HV7VsAoRj) and asked about the effects of VASS on pistoning and rotation inside the socket, proprioception, stump volume, skin problems, circulation, healing and overall tissue health, comfort, forces (pressure), sweating, prosthetic use (time), quality of life, stump heat, knee range of motion, traction at the distal limb, gait symmetry, energy expenditure, load distribution within the socket, pain, evaluation/maintenance, time for donning, blisters, and socket size (undersized (3–5%), neutral, oversized (3–5%)). Professionals were also asked about the number of elevated vacuum prostheses they have fit (TT, TF), participation in formal training on elevated vacuum techniques, and their typical limb casting method.

The survey was distributed worldwide through the ISPO website (www.ispoint.org) and Facebook page, OANDP-L, and LinkedIn. Furthermore, the questionnaire link was emailed to 702 rehabilitation professionals worldwide. While no formal validity and reliability research was performed on the questionnaire, the questionnaire was designed to collect direct answers (Yes, No, N/A) as to whether the respondents agreed with the literature claims for vacuum assist sockets and content validity was confirmed from expert opinion. Ethical approval was obtained from the University of Malaya Medical Centre (UMMC) Ethics Committee.

3. Results

3.1. Literature review

The review identified 26 articles published from 2001 to March 2016. The earliest study was published by Board et al., 2001 and the