ELEVATED VACUUM SOCKET SUSPENSION IMPROVES REHABILITATION IN DYSVASCULAR TRANSTIBIAL AMPUTEES WITH OPEN RESIDUAL LIMB WOUNDS – A RANDOMIZED CONTROLLED CLINICAL TRIAL

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INTRODUCTION

Vacuum suspension in total surface bearing (TSB) sockets can be created by an active pump or passively by a one way check-valve at the distal part of the socket. Anecdotal reports suggest that vacuum suspension might promote healing of residual limb wounds. The aim of this study was to evaluate the benefits of two different vacuum suspension systems in transtibial (TT) amputees with unhealed stump wounds.

METHOD

20 dysvascular TT amputees with open residual limb wounds gave informed consent and were enrolled. Subjects were randomized to either the VACUUM GROUP using the VASS Harmony® system (Otto Bock HealthCare, Duderstadt, Germany) or the CONTROL GROUP using a regular suction TSB with a standard one-way expulsion valve.

Each subject underwent a 12 week rehabilitation program with 60 minutes of physical therapy twice a day, 5 days a week, and was followed-up over the program as well as 2, 4, and 6 months after the completion of the rehabilitation program.

Outcome measures were the time until prosthesis fitting was possible, walking capabilities (Locomotor Capability Index - LCI), weekly prosthesis use after the 12-week rehab progam, wound healing trend and pain (VAS). Statistical analysis was done using the t-test, the chi-square-test, and the Mann-Whitney U-test with $p<.05$ and a power of 80%.

RESULTS

17 male and 3 female patients with a mean age of 61.3±13.2 years were enrolled. 10 subjects each were randomized to the two study groups, with no statistical difference between group demographics, cause of the wound, and wound size (average long axis 2.5±2.4 cm, short axis 1.6±1.7 cm). Three patients dropped out of the CONTROL GROUP (reasons: no caregiver, loss of motivation, second dysvascular amputation) and one patient out of the VACUUM GROUP treatment groups (reason: pain in the residual limb).

In the VACUUM GROUP, prosthesis fitting was possible on average 19.4±13.3 days after enrollment. In the CONTROL GROUP, patients had to wait for substantial reduction of the wound area and received their prosthesis after a significantly longer mean period of 58.6±24.7 days ($p=.012$). After the 12-week rehabilitation program all ten patients in the VACUUM GROUP were able to independently walk with their prosthesis as compared to only five patients in the CONTROL GROUP ($p=.001$). Walking capabilities were significantly better in the VACUUM GROUP with a median LCI score of 42 (1^{st}-3^{rd} quartile 40-42) as compared to only 21 (1^{st}-3^{rd} quartile 20-31) in the CONTROL GROUP ($p=.002$). Two months after the completion of the rehab program the duration of weekly prosthesis use was 62±29 hours in the VACUUM GROUP and thus significantly longer than in the CONTROL GROUP with 12±21 hours ($p=.003$). Until the 6 months post-rehab follow-up, prosthesis use increased more in the CONTROL GROUP (45± 38 days) than in the VACUUM GROUP (70±35 days), still leaving a clinically yet not statistically significant difference between groups. Wound healing and pain did not differ between groups despite the earlier and more intense prosthesis use in the VACUUM GROUP.

DISCUSSION

Van Velzen et al. (1) reported that many studies on prosthesis fitting in the presence of unhealed residual limb wounds have shown both positive and negative results. Salawu et al. (2) observed that continued use of the prosthesis was associated with a significant reduction in ulcer size. However, the mean size of the ulcers in their patient group was considerably smaller than that of the patients in this study. Reasons for the favorable effects of elevated vacuum in amputees with residual limb wounds may be improved residual limb fluid balance and linkage between the residual limb and the prosthetic socket that minimizes pistoning and resulting shear forces (3, 4), thus reducing the mechanical stress to the skin.

CONCLUSION

This study has shown that the use of the VASS Harmony does not interfere with wound healing in transtibial amputees with residual limb wounds. It allows earlier prosthesis fitting or continued prosthesis use and helps patients reach walking autonomy faster and at a higher level than a regular suction socket.

REFERENCES

1. van Velzen AD, et al. *Prosthet Orthot Int*. 2005;29(1):3-12.
2. Salawu A, et al. *Prosthet Orthot Int*. 2006;30(3):279-85.
3. Goswami J, et al. Prosthet Orthot Int 2003, 23: 107-113
4. Beil TL, et al. J Rehab Res Dev 2002, 39 (6): 693-700

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