

2015 LCD PROPOSED CHANGES REGARDING VACUUM ASSISTED SUSPENSION-

Mechanical Suspension- Page 9

“Active suction is created by using a suction pump as part of the socket design (L5781, L5782). Active suction systems claim to improve residual limb volume management and moisture evacuation. In addition, active systems claim to increase suspension, proprioception and improve gait. There is insufficient published clinical evidence to support these claims. Claims for L5781 and L5782 will be denied as not reasonable and necessary.”

Published Evidence – Jason T. Kahle, MSMS, CPO, FAAOP

Kahle JT, Orriola JJ, Johnston W, Highsmith MJ. The effects of vacuum-assisted suspension on residual limb physiology, wound healing, and function: a systematic review. *Technol Innov* 2014, 15: 333-341.

Summary: This is a systematic review (SR) of only Level III (strong methodological quality) or higher evidence. Evidence statements from reports included in this SR are:

- Beil, et al. 2002, VAS created an environment of less positive pressure in stance, or greater negative pressure in swing, creating less of a variance between pressure during the 2 phases of gait. This resulted in a more stable residual limb volume.
- Klute, et al. 2011, The use of VAS significantly reduced pistoning.
- Traballesi, 2012, VAS allows socket fitting and prosthetic use in the presence of a recent amputation and wound healing. There was no delay in healing during VAS prosthetic use.
- Kahle and Highsmith, 2013, VAS allows a reduction in socket surface area (sub-ischial design) without compromising skeletal biomechanics while reducing socket pressure. All subjects preferred the VAS TFA design.
- Board, et al. 2001, VAS reduced pistoning and stabilized RL volume.
- Goswami, et al. 2003, VAS minimizes RL volume fluctuation. A RL will accommodate to socket size while using VAS, better accommodating fluctuations.
- Farraro, 2011, Subjects using VAS had a lower predicted incidence of falls.

2 Known Level III articles have been published since this SR:

Kahle JT, Highsmith MJ, Gait and Posture, 2014

Summary: It is important to understand when testing an intervention (in this case the VAS socket) against a known standard of care (IRC socket with ~30% more surface

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area) equivalence is a “win” for the intervention. Simply stated, in a socket design that is less obtrusive and subjectively superior, there was no significant compromise in measures of gait and balance. The variable that allowed this alternative interface design (TFA) was **vacuum assisted suspension**.

Regarding gait, step length was statistically significantly more symmetrical towards the IRC ($p = 0.04$), when calculating degree of asymmetry. The ambulatory base of support was narrower ($p = 0.03$) when using the brimless socket. All other gait and balance measures failed to reach statistical significance on comparing the IRC to the brimless.

All subjective measures reached statistical significance in favor of improvement with the brimless design, compared to the IRC. Further, as a result of utilizing the brimless interface, eight of the nine PEQ categories achieved the minimal detectable change (MDC). MDC values of all groups except one were different significantly.

Samitier CB, et al, Prosthetics Orthotics International, 2014

Summary: Subjects using **vacuum assisted suspension** sockets (TTA) significantly improved.

Using the vacuum-assisted socket system, the patients significantly improved in balance, gait, and transfers: scores of the Berg Balance Scale increased from 45.75 (standard deviation = 6.91) to 49.06 (standard deviation = 5.62) ($p < 0.01$), Four Square Step Test decreased from 18.18 (standard deviation = 3.84) s to 14.97 (3.9) s ($p < 0.01$), Timed Up and Go Test decreased from 14.3 (standard deviation = 3.29) s to 11.56 (2.46) s ($p < 0.01$). The distance walked in the 6-Min Walk Test increased from 288.53 (standard deviation = 59.57) m to 321.38 (standard deviation = 72.81) m ($p < 0.01$).

Evidence Harmony – Andreas Kannenberg, MD

As confirmed by a recent systematic review of the research (1), vacuum-assisted socket systems are known to provide excellent suspension and prosthesis control by eliminating relative movements and reducing pressure and shear forces between the residual limb and the socket (1-5), and to prevent volume fluctuations of the residual limb that may result in loose socket fit (5) that needs to be compensated for by putting on several pairs of socks in the course of the day.

Dysvascular transtibial amputees, especially those with MFCL-3 mobility grade, benefit from the improved suspension of vacuum-assisted socket systems by reducing their risk of falling, improving their balance and overall walking capabilities. A recently published clinical study (6) has demonstrated that, after 4 weeks of use of a vacuum-assisted socket (Harmony® VASS, Ottobock), dysvascular below-knee

amputees with MFCL-3 mobility presented statistically significant improvements in the four square step test (FSST, $p=.01$) and timed up and go test (TUG, $p=.01$) as validated indicators of the risk of falling, the Berg Balance scale (BBS, $p=.03$) as a validated outcome measure of balance, and the 6-minute walk test (6MWT, $p=.01$) and the Locomotor Capabilities Index (LCI-5, $p=.04$) as validated outcome measures of the overall walking capabilities. The improvements in these outcome measures showed similar trends in the MFCL-2 subgroup of this study, but, due to the relatively small patient subgroup, attained statistical significance only for the fall risk indicator FSST ($p=.046$) and overall prosthesis use as measured with the Houghton scale ($p=.046$). The authors conclude that the improvements in safety and function can be explained by the dramatically better suspension in the vacuum socket that seems to be achieved by residual limb volume control (5), resulting in improved proprioception and motor control of the prosthesis (6). Thus, vacuum socket technology can help amputees maintain or even further improve an active lifestyle.

Furthermore, there is evidence that vacuum socket technology can improve residual limb health. Wounds and distal limb pain are usually caused by relative movements and the resulting shear forces between the residual limb and regular (including suction) below-knee sockets. This problem can be further deteriorated by residual limb volume fluctuations: The volume of the residual limb usually shrinks over the day due to the high pressure acting on it in each and every step, resulting in an increasingly loose fit of the socket that, in turn, aggravates the relative movements and resulting shear forces. The standard treatment of residual limb wounds includes that the patient discontinues the use of the prosthesis to unload the wound from pressure and shear forces to allow for healing. As a result, the patient then has to use a wheelchair or two crutches to walk until substantial wound healing is achieved, which can take weeks or sometimes even months. One randomized prospective clinical trial (7) and two case studies (8, 9) have meanwhile shown that a vacuum-assisted sockets allow for using the prosthesis in spite of residual limb wounds without interfering with wound healing or causing pain or discomfort. In the randomized prospective clinical trial (7), residual limb wounds healed equally fast while continuously using the prosthesis with a vacuum-assisted socket as in the control group that had discontinued prosthesis use. As a result, the intervention group using the vacuum-assisted socket was able to stay active and walking and demonstrate better mobility and increased prosthesis use over several months after the start of the study/wound treatment. The authors of the clinical trial (7) and the case studies (8, 9) assume that the residual limb volume control (5) and the consequent reduction/elimination of relative movements and the resulting shear forces between the residual limb and the socket (1-5) is the reason why vacuum-assisted socket systems neither interfere with wound healing nor cause considerable pain or discomfort while wearing these sockets in the presence of residual limb wounds. Although not yet studied, but supported by field experience and anecdotal reports from prosthetists, it can therefore also be assumed that the

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reduction/elimination of these relative movements and shear forces may also contribute to the prevention of residual limb wounds and pain. For the reasons and scientific evidence stated above, we are convinced that the technology of vacuum-assisted sockets is medically necessary to support mobility and an active lifestyle and preserve residual limb health in below-knee amputees with MFCL mobility grades K2-K4.

References

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9. Traballesi M, Averna T, Delussu AS, Brunelli S: Trans-tibial prothesization in large area of residual limb wound: Is it possible? A case report. *Disabil Rehabil* 2009, 4 (5): 373-375.

Evidence –Presented and In Review for Publication Matt Wernke, PhD

Article published in *Academy Today*. Abstract for the 2015 AAOP conference and Thranhardt winner.

<http://www.oandp.org/AcademyTODAY/2015Apr/3.asp>

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Summary: This evidence is currently in review with JRRD for the RCT comparing elevated vacuum to non-elevated vacuum suspension. The manuscript provides much more detail on the methods and results than the abstract from AAOP last year. A few key outcomes and summary points from the paper are:

1) Skin Health Measurement: Transepidermal water loss is a measure of epidermal barrier function and is linked to early indication of ulcer development. Increased measurement of transepidermal water loss (measured by a probe placed on the skin surface) indicates a disruption in epidermal barrier function and lower values indicate a preservation of epidermal barrier function. The results found a significant decrease in TEWL values after 16 weeks of elevated vacuum suspension use compared to the non-vacuum condition. Water loss increased during the 16 weeks of non-EVS use and decreased during the 16 weeks of EVS use.

2) In-socket probe based measurement: Transcutaneous oxygen measurement was deployed within a socket and capture tissue oxygenation levels during rest and activity. Tissue oxygenation while out of a socket was compared to oxygenation levels during activity. The results found that after 16 weeks of use, there was no longer a significant decrease in tissue oxygenation during activity that had been observed during the other time point measurements and non-vacuum suspension.

3) Out of socket circulation imaging: Out of socket circulation imaging was collected before and after activity since the measurements had to be performed out of the socket. The percent change between pre- and post-activity measurements were used for comparison. The results found a significant reduction in reactive hyperemia (transient increase in blood flow following a period of occlusion) with 16 weeks of EVS use. Reactive hyperemia is considered a negative response in these terms since it occurs after occlusion. That fact that elevated vacuum suspension significantly reduced reactive hyperemia suggests improved blood flow during activity and use of the prosthesis. This is supported by the in socket probe based measurements which found improved tissue oxygenation (likely from improved blood flow) during activity thereby reducing/eliminating the occlusive period.

Taken together, the results suggest that EVS-dependent differences in the prosthetic socket residual limb interface account for residual limb health improvement in part by beneficial changes in residual limb perfusion and stress applied to the soft tissues of the residual limb.

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Current Department of Defense Funded projects:

Principle Investigators: Highsmith MJ, Kahle JT

MR140125 - "The Effect of Prosthetic Socket Interface Design on Socket Comfort, Residual Limb Health, and Function for the Transfemoral Amputee"

Award Amount: \$936,000.00

Summary: This study of 15 subjects uses VAS in TFA interface design to primarily determine if sub-ischial socket design will reduce local and total skin temperature and perspiration.

Principle Investigator: Fatone S.

OR090122- Development of Subischial Prosthetic Sockets with Vacuum-Assisted Suspension for Highly Active Persons with Transfemoral Amputations

Award Amount: \$2,099,865.00

Summary: The prosthetic socket technology in this proposal will enable clinicians to provide better prosthetic care and rehabilitation of highly active military service persons with transfemoral amputation. Increased comfort, hip range of motion, and connectivity between the residual limb and prosthesis will result in better functional performance for individuals with combat-related transfemoral amputations.