THESIS ABSTRACT (POST-DOCTORAL RESEARCH ABSTRACT)

ENHANCING PROSTHETIC SOCKET PERFORMANCE (UNITY ELEVATED VACUUM SUSPENSION SYSTEM)

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ABSTRACT

BACKGROUND
The prosthetic suspension system is a critical component that connects the residual limb to the socket. Choosing an appropriate suspension system is an important step in the prosthetic rehabilitation process, leading to better stump fit inside the socket that improves gait, balance, and satisfaction. While elevated vacuum systems may have some benefits over the other suspension systems, VASS may not be appropriate for all amputees since more maintenance is required for sleeve, liners, and valves that wear out and need to be replaced. VASS systems with a knee sleeve may also limit knee range of motion. To overcome some of these issues, the Unity elevated vacuum suspension system (Össur) was developed. Unity consists of a mechanical vacuum pump and a hypobaric sealing membrane around an Iceross Seal-In V silicon liner, so that an external sleeve is not required. Research is lacking on the Unity system's effect on gait performance and comfort. Therefore, a prospective study with trans-tibial amputees was required to enhance understanding about Unity suspension system.

OBJECTIVES
• To evaluate kinetic and kinematic gait parameters with the Unity (vacuum) and compare with suction sus-pension (inactive vacuum).
• To evaluate satisfaction rates with the Unity (vacuum) and compare with the person's previous prostheses.

METHODOLOGY
Twelve active individuals with unilateral transtibial amputation were recruited from The Ottawa Hospital Rehabilitation Centre (TOHRC) Prosthetics and Orthotics Service. Participants were included if they walked without walking aids, reported steady limb volume changes over the previous year, and wore their prosthesis daily.

CITATION

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KEYWORDS
Prosthetics, Rehabilitation, Amputee, Lower limb amputee, Gait analysis, Motion analysis, VASS, Elevated vacuum suspension, Silicon liner, Prosthetic socket, Satisfaction.
Exclusion criteria were medical conditions or medications that adversely affect locomotion or balance and stump length less than 10 cm.

This research was approved by The Ottawa Hospital Research Ethics Board and all participants provided written informed consent. Nine participants wore pin/lock suspension systems and three participants wore suction sockets at the start of the study. Prosthetic components were selected for each participant, according to manufacturer guidelines, including an Iceross Seal-In V liner (high or standard profile) and Pro-Flex XC foot with Unity pump. One prosthetist completed casting, modification, socket fabrication, alignment, and training tasks to ensure consistent prosthetic procedures throughout the study. A total surface bearing check socket was fabricated using polyethylene terephthalate glycol-modified (PETG) to verify socket fit. Prosthetic training sessions were provided for all participants until they were comfortable with new system. Following prosthetic training sessions, the test sockets were laminated and the participant wore the prosthesis for a one month acclimation period.

The CAREN-Extended virtual reality system (Motek Force Link, Amsterdam, NL) was used in this study, combining a six degree-of-freedom motion platform with embedded dual-belt instrumented treadmill, 12 camera Vicon motion capture system, 180 degree screen to display a 3D virtual Park scenario, and safety harness frame. Platform motion was tracked by three markers and a set of 57 markers was used to track full body kinematics. Kinematic data were collected at 100 Hz and ground reaction force (GRF) data were collected at 1000 Hz.

Participants completed a 10-min warm-up trial to become familiar with the Park virtual scenario and treadmill self-paced mode (i.e., treadmill speed adapts to the person's walking speed). Following the warm-up trial, participants completed two walking trials while the vacuum was active (ON) and two walking trials while the vacuum was inactive (OFF). The presentation order for ON and OFF vacuum conditions was randomized and blinded. Walking trials consisted of level, 7° uphill, -7° downhill, side slopes, rolling hills, simulated uneven ground and medial-lateral translations.

Marker data were processed using Vicon Nexus software before exporting to Visual3D (version 6.00.31) for 3D kinematic and kinetic calculations. Ten gait cycles were selected for each vacuum condition. SPSS 23.0 was used for statistical analysis and p<0.05 was considered statistically significant. Limb symmetry was calculated using a symmetry index (SI).

**FINDINGS**

Effects of the Unity elevated vacuum system on gait parameters were evaluated while the vacuum was active or inactive. Small statistically significant differences between vacuum conditions were found for most temporal spatial, kinematic, and kinetic gait parameters. After completed the study protocol, nine participants preferred to continue with the Ossur Unity suspension system since they felt more comfortable walking. Two people preferred their original pin/lock suspension system because they felt more comfort and freedom during kneeling and their job required kneeling most of the time. One participant preferred to continue with his original suction system (Seal-In X5, one way valve) because he felt more pressure around the seal area with Seal-In V and elevated vacuum.

**CONCLUSIONS**

Gait performance in a moderately high functioning amputee population would not be immediately affected following a mechanical vacuum pump failure. However, if the vacuum were off for an extended period the residual limb volume would be expected to fluctuate, resulting in inferior socket fit. Unity suspension system can improve amputee satisfaction and comfort compared to pin/lock and suction sockets. However, Unity may not be appropriate for some amputees since there is less freedom and comfort during kneeling compared to pin/lock systems. The Unity system’s effect on comfort for people with lower activity levels is still unclear.
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LAY ABSTRACT
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. The prosthetic suspension system is a critical component that connects the residual limb to the socket. Choosing an appropriate suspension system is an important step in the prosthetic rehabilitation process, leading to better stump fit inside the socket that improves gait, balance, and satisfaction. Based on the literature, elevated vacuum systems may have some benefits over the other suspension systems, but may not be appropriate for all amputees since more maintenance is required. Elevated vacuum systems with a knee sleeve may also limit knee range of motion. To overcome some of these issues, the Unity sleeve-less elevated vacuum suspension system (Össur) was developed. This study determined how the Unity system could affect satisfaction and gait in people with transtibial amputation. After completed the study, 75% of participants preferred to continue with the Unity system since they felt more comfortable walking and less movement inside their prosthesis. Their gait was also more symmetrical between prosthetic and intact side.

SHORT SCIENTIFIC BIOGRAPHY
Hossein Gholizadeh is a Postdoctoral fellow at the Ottawa Hospital Research Institute (OHRI), University of Ottawa, with a focus on lower limb prosthetic suspension systems. He has sound clinical and academic background in Prosthetics and Orthotics, especially in amputee rehabilitation and lower limb prosthetic care for more than 18 years. He received his PhD in Biomedical Engineering from the University of Malaya, Malaysia, with a focus on designing and developing suspension systems for lower limb prostheses. He also served as a prosthetics lab instructor in the University of Malaya (2009-2014). Hossein graduated from Iran University of Medical Sciences with a BSc in Prosthetics and Orthotics followed by MEngSc in Biomedical Engineering from the University of Malaya. He has over 50 scientific publications and serves as a reviewer for several scientific journals.