An Initial Comparison of the High-Fidelity Interface Design to Traditional Socket Designs: The Effects on Gait of Transfemoral Amputees

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Objectives

Transfemoral socket designs have, for many years, utilized ischial containment and proximal pressure to lock amputees in during gait and secure an adequate fit. The High-Fidelity Interface, designed by Randy Alley, CP, LP of Biodesigns, Inc., utilizes the concept of oppositional compression of tissue in pressure-tolerant channels in conjuction refief of volume to lock the femur into the prosthesis. This interface is reported to give amputees increased control and prosthetic pseudoproprioception. In addition, traditional sockets have been known to cause skin breakdown due to poor fit, pistoning of the residual limb within the socket, and inconsistent limb volume control due to insufficient pressure. The HiFi interface was designed to adjust all these issues along with the increased control it presents to the amputee. The functionality of this interface has not yet been evaluated as it relates to its effects on gait. The objective of this study was to compare the effects on gait of transfemoral amputees of the High-Fidelity Interface to that of traditional socket designs.

Methods

Three transfemoral amputees had their gait evaluated in the gait analysis lab at Eastern Michigan University. The subjects had to possess adequate length in their residual limb, had to currently be using a prosthesis with an ischial containment socket, and had to complete the Oswestry Low Back Pain Disability Questionnaire and the Western Ontarior and McMaster University Osteoarthritis Index to be included in the study. The subjects were marked with a full body marker set according to the plug-in gait model and walked on a 8mx1.5m elevated platform while being recorded with a Vicon 3D Motion Analysis system with integrated ATMI forceplates while wearing their prescribed socket, a traditional ischial contrainment design. The subjects also completed the Amputee Mobility Predictor and two sets of 10-meter walk tests, the first at a self-selected gait velocity and second at their fastest possible walking velocity. Rates of perceived exertion (RPE) were recorded of each subject after each component of the data capture session. One subject was also fitted with an iPecs to measure forces within that subject's prosthesis. The subjects were then fitted with the HiFi interface and given a one-month acclimation period before repeating the protocol. Temporal-spatial parameters were calculated using Matlab R2013a. Gait symmetry was evaluated using a gait symmetry index metric on the 3D trajectory data. Variables were tested for significance in difference with a 2-tailed repeated measures t-test using IBM SPSS 22 statistical software. The level of significance was set at $p=0.05$.

Results

The second data capture session yielded improvements in many temporal-spatial parameters including gait velocity and prosthetic step length. The subjects' times on the functional assessments were also found to improve during the second session. The force plates and integrated iPecs unit measured decreased peak ground reaction forces as well as within the prosthesis at terminal swing. The recorded RPEs between sessions decreased on each task for which an RPE was recorded. Gait symmetry was also found to improve between sessions spatially, as a comparison of phases, and according to the index.

Conclusion

The High-Fidelity Interface was shown to improve several aspects of gait and function in transfemoral amputees after one month of wear. According to the results of the RPEs recorded between sessions, amputees percieved that they did not have to work as hard to achieve better results in the same assessments they had performed in their traditional socket design. This socket design could prove to be a beneficial tool for prosthetists and patients in the future.

Biographical Sketch

Tyler Klenow, BS, CPT-ACSM is a senior graduate student in and Student Research Coordinator for the Master of Science in Orthotics and Prosthetics Program at Eastern Michigan University. He is also the President and Director of Biomathematics at K & K Innovations. K & K Innovations is a prosthetic and orthotic production company that also consults on and conducts research in the field. Jeff Ropp, BS, CP is the President and staff prosthetist at Ropp Orthopedic in Commerce, MI and is an adjunct faculty member for the Master of Orthotics and Prosthetics Program at Eastern Michigan University. He also is a licensee of Biodesigns, Inc. for the High-Fidelity Socket. David Trevisan, BS is a first-year graduate student in the Master of Science in Orthotics and Prosthetics program at Eastern Michigan University. Both Tyler and Jeff have worked on several research projects together with the University in the past including projects with the iPecs and Feldenkrais rehabilitation method.