INTRODUCTION
Transfemoral amputees present many challenges for today’s prosthetists, from achieving a comfortable fitting socket and interface to achieving adequate suspension during daily ambulation. Clinicians remain very interested in seeking new technologies or techniques to better treat their patients. Recent advances in socket design and technologies have led to the advent of many new socket systems to the prosthetic market. The purpose of this study is to focus on research outcomes surrounding one of these novel systems. The development of this novel socket system (NSS) was realized during a VA funded project focused on improving the fit, function, and comfort of transfemoral prosthetic sockets. The resulting system consists of three main components; 1. An internal sealing system, 2. An intelligent, streamlined and hose-less side mounted elevated vacuum pump, and 3. A liner incorporating phase change material to regulate residual limb temperature and perspiration.

METHOD
Subjects: Forty-Five transfemoral amputees fit with the NSS were included in various parts of the testing procedures.

Apparatus: The Prosthetics Evaluation Questionnaire (PEQ) (Legro 1998) was administered to identify changes in the validated scales compared to the subjects’ previous suspension system. Additional surveys were used to further probe into the differences between socket systems. A gait mat was used to collect kinetic data during level ground walking. A video camera was used to record and quantify additional functional performance outcomes.

Procedures: A variety of prosthetic socket styles and suspension methods were used by the total subject population at the time of enrollment in the study. Following enrollment and initial assessment of outcomes, subjects were fit was the NSS. The shape of the limb was captured by scanning over the liner worn by the subjects using the Omega scanner. A 5-7% reduction of volume total surface bearing socket was made for all subjects.

Non-PEQ survey responses were collected after 30 days post-delivery of the NSS (n=45). PEQ responses from a subset (n=9) of the entire study population were collected immediately before being fit with the NSS and one year following the fitting.

Temporal and spatial gait data was collected from two transfemoral amputee subjects with their previous socket system prior to being fit with the NSS as well as during a 30-day follow up appointment after delivery of the NSS.

Data Analysis: PEQ responses for individual questions were calculated and grouped into the 9 validated scales according to the questionnaire directions. Additional survey responses were grouped with similar responses and averages were calculated for the group. Temporal and spatial gait outcomes were processed in the instrumented flooring software.

RESULTS
The PEQ showed moderate to significant improvements for many of the validated scales when comparing the NSS to their previous socket system. No change was found for 2 of the scales.

Additional survey responses from all subjects (n=45) found that over 70% of subjects rated the ease of donning the NSS as excellent/good and 77% reported the donning process as better or the same compared to their previous socket system. Additionally, 70% reported better comfort while the remaining 30% reported comparable comfort of the NSS compared to their previous socket system. 96% reported better security with the OSS.

Temporal and spatial gait outcomes for one of the two subjects involved in this portion of the study found increased velocity, increased cadence, more symmetric step length, decreased base of support, and decreased double support time. The second subjects result found moderate improvements or no changes for the same outcomes.

DISCUSSION
Qualitative outcome measures from amputee subjects identified improvements in quality of life and overall satisfaction with the prosthetic socket. Subjective feedback from the non-PEQ surveys suggest a larger change would exist in the PEQ scores between the previous socket system and the NSS if subjects were asked to return to their previous socket system and repeat the PEQ after some time.

CONCLUSION
The OSS made significant improvements to quality of life for the subjects. Further research exploring these and additional benefits of the system are warranted.

CLINICAL APPLICATIONS
The OSS provides clinicians and amputees a highly effective and comfortable socket system for transfemoral amputees.

REFERENCES

American Academy of Orthotists & Prosthetists
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