INTRODUCTION
Currently there is a lack of clinically relevant methods to quantify socket fit, nor is there any method to quantify changes to socket fit or the level of suspension a prosthetic user is experiencing. Monitoring the sub-atmospheric pressure profile during gait may enable a clinically relevant method of assessing socket fit. Understanding Boyle’s Law, which states that pressure is inversely related to volume in a closed system where temperature remains constant. Therefore any change in the sub-atmospheric vacuum pressure must be a result of movement of the residual limb within the socket.

A previous clinical investigation of transfemoral amputees found a strong linear correlation between distal displacement of the socket relative to the residual limb and changes in the elevated vacuum pressure profile (Gershutz 2010). Related work (see complimentary abstract) conducted in a controlled bench top simulation discovered a transition in interface stiffness that occurs as the vacuum pressure is increased. The purpose of this study is to retrospectively analyze the previous clinical data to determine if the transition in interface stiffness detected in the controlled bench top experiment exists in the data from the clinical setting study.

METHOD
Subjects: Five unilateral transfemoral amputees participated in the initial data collection.

Apparatus: An inductive proximity sensor was used to measure the distal displacement. The sensor was mounted to the distal end of the socket and tracked the position of a metal target adhered to the distal end of the liner worn by the subjects. The sensor was held in position by a threaded nut embedded in a PVC fitting and secured with an additional threaded nut. The prosthetic sockets incorporated the LimbLogic Vacuum System which was turned on for the elevated vacuum suspension conditions and in “Standby” mode for the suction suspension condition. The LimbLogic communicator was used to wirelessly stream negative pressure data.

Procedures: All patients were fit with a zero ply total surface bearing socket by a certified prosthetist. Subjects were asked to don the prosthetic liner and the metal target was placed on the distal end of the liner using double-sided adhesive tape. The patient was asked to don the socket and seal the interface by reflecting the liner over the brim. With the patient standing, the inductive sensor was threaded into position and the corresponding suspension treatment was applied. The patients were asked to walk in place between parallel bars for 20 seconds. Simultaneous displacement and vacuum pressure responses were collected. Tissue type was assessed by a certified prosthetist on a five point scale: soft, soft-medium, medium, medium-firm, and firm.

Data Analysis: Both the displacement and vacuum pressure response data were processed by calculating the absolute deviation, maximum minus minimum, for each step cycle. For the retrospective analysis of data, linear regression lines were fit to the lower (less than 12 inHg) and higher levels (greater than 12 inHg) of suspension respectively. The corresponding slopes were compared and a Wilcoxon Signed Rank Test used for statistical analysis.

RESULTS
The results indicate that as the vacuum pressure increases, there is a transition point where there is a significant increase in stiffness at the interface. Similar to the controlled benchtop test, the maximum stiffness achieved varied among individual subjects, suggesting differences in soft tissue compliance and the fit of the prosthesis. The patients with a firmer tissue type displayed higher pressure fluctuations than the patients with medium tissue type for a given amount of distal displacement.

DISCUSSION
Overall, the retrospective results provide additional insight than previously reported. The change in interface stiffness for each subject is aligned with clinician-based classification of tissue type and can explain in part the differences across subjects. Socket fit can also account for some of these differences. This was explored in further detail in a controlled benchtop experiment (see other abstract). The benchtop platform provided a more ethical means to investigate the effect of socket fit (potentially mal-fitting) on the sub-atmospheric pressure profile.

CONCLUSION
The study confirmed related benchtop results of a change in interface stiffness as vacuum pressure is increased. Future work is needed to quantify a clinically optimal interface stiffness to promote functional utility and maximize residual limb health.

CLINICAL APPLICATIONS
These results lead toward the development of socket fit parameters to optimize patient care by augmenting subjective feedback from patients and reliance on previous experiences by clinicians.

REFERENCES

American Academy of Orthotists & Prosthetists
42nd Academy Annual Meeting & Scientific Symposium
March 9 – 12, 2016