INTRODUCTION
Elevated vacuum suspension creates sub-atmospheric pressure between the prosthetic socket and the interface material. Monitoring the sub-atmospheric pressure profile during gait may enable a clinically relevant method of assessing socket fit. The underlying principle stems from Boyle’s Law which states that pressure is inversely related to volume in a closed system (a sealed socket system). In other words, if there is a change in vacuum pressure, it must be the result of a change in volume between the liner and socket, and therefore there must be movement of the residual limb within the socket.

Preliminary work compared the change in sub-atmospheric pressure during level-ground gait to an inductive-based proximity sensor mounted to the distal end of the socket of 5 amputee subjects (Gershutz 2010). A strong linear correlation between a decrease in vertical displacement and a decrease in the change in vacuum pressure waveform magnitude was found; however the slope of the regression lines varied across subjects. The variance may be due to different gait styles, different tissue types and residual limb geometries, and different socket fits. The purpose of this study was to investigate the influence of socket fit, residual limb size, and socket design on the correlation between vacuum pressure fluctuation and distal displacement in a controlled environment.

METHOD
Residual Limb Models: Three residual limb models of different sizes were constructed consisting of a rigid plastic core surrounded by a compliant thermoplastic elastomer. A uniform thickness liner was cut into three sections and donned over the model (Figure 1). Removing one of the sections allowed the fit of the socket to be adjusted simulating clinically relevant socket-residual limb volume discrepancies. Two sockets with different sealing locations were fabricated for each residual limb model.

Apparatus: Leveraging the mechanical testing platform for ISO 10328 (Gershutz 2011) (Figure 1), researchers were able to control the magnitude, direction, and frequency of load application. The machine connections were modified for this test to allow tension and compression.

Procedures: A consistent sine-wave force was applied, alternating between ±30 lb. The test was performed for vacuum settings of 5, 10, 15, and 20 inHg and socket fit conditions of a normal fit, tight fit (distal liner section removed), and loose fit (middle liner section removed). Three repetitions of each trial combination were repeated totaling 864 total trials.

Data Analysis: Displacement and vacuum pressure data were processed by calculating the absolute deviation (max-min) for each force cycle.

RESULTS
The results indicate that as the vacuum pressure increases, there is a transition point where a significant increase in stiffness at the interface exists. Socket fit had a significant impact of the maximum interface stiffness as well as the magnitude of the transition in stiffness. Additionally, sealing more proximal on the socket resulted in less movement of the residual limb model within the socket compared to a distal sealing location.

Figure 1: Left: Residual limb model with the divided liner. Right: Adaption of ISO 10328 Configuration 1.

DISCUSSION
Agglomeration of the results suggests the transition in interface stiffness occurs because increased vacuum levels decrease or eliminate (depending on socket fit) separation between the socket and limb model and any compliance at the interface is a result of thermoplastic elastomer deformation.

CONCLUSION
Application of Boyle’s Law to evaluate socket fit appears to provide a clinically relevant method for clinicians. Future work can pair the method leveraged here with clinical studies to quantify limb health in order to define optimal socket fitting parameters.

CLINICAL APPLICATIONS
Leveraging this technique could provide clinicians a tool to optimize socket fit and maximize functional performance and comfort. Ultimately, this work will improve amputee care and quality of life through more quantitative analysis and documentation of socket fit.

REFERENCES