INTRODUCTION
In 2014, 21 million Americans were living with diagnosed diabetes mellitus [1]. Lower extremity complications such as foot deformity, neuropathy, and ulceration are common in diabetic patients, and are common precursors to amputation in diabetic patients, which make up 60% of all non-traumatic amputations performed in the U.S [1][2]. A deeper understanding of diabetes-related changes in tissue mechanics could improve treatment and prevention of ulcers and reduce amputation incidence. Previous research investigating diabetes-related changes in tissue mechanics has been contradictory, and has suffered from testing conditions dissimilar to in vivo loading and neglect of confounding factors like age [2]. This study aims to develop a system to allow in vitro measurement of plantar soft tissue properties under physiologic gait loading and comparison thereof between diabetic and healthy specimens.

METHODS
Fifteen cadaveric specimens per test group (diabetic older, healthy older, and healthy younger, n=45 total) will be loaded in physiologically realistic compression and shear over the stance phase of gait using the robotic gait simulator (RGS) at the VA Puget Sound RR&D Center for Limb Loss and Mobility [3]. The RGS uses an R2000 six-degree of freedom robot to move a force plate (‘ground’) relative to a cadaver foot attached to a custom fixed tibial mount. Linear force actuators prescribe dynamic forces to external tendons, and fuzzy logic controllers adjust the Achilles tendon force, tibialis anterior force, and inferior-superior position of the force plate. The RGS matches the simulated vertical ground reaction force (vGRF) to the in vivo vGRF collected for the same population.

Internal tissue displacement over the stance phase of gait will be measured by ultrasound. A custom mounting device will secure the ultrasound probe to the RGS force plate and allow planar translation of the probe along the force plate (Figure 1) for precise placement over five clinically relevant regions: the hallux, first and third metatarsal heads, lateral midfoot, and calcaneus. Three trials will be performed at each region using two ultrasound modes. B-mode ultrasound will be collected at 1/6th physiologic gait speed. Digital image correlation (DIC) will measure displacement and strain along the axial and lateral axes of the ultrasound images. Force plate load data and DIC displacement data will be used to create stress-strain curves for each tissue at each region. Quantitative shear wave elastography (SWE) will measure the modulus of each tissue as the RGS moves through the stance phase of gait at 1/10th physiologic gait, accommodating slower SWE acquisition speed. Stiffness versus percent stance phase will be plotted for each tissue type and compared between test groups.

DISCUSSION
Preliminary displacement and force have been measured using B-mode images and a three-axis load cell. Displacements were successfully tracked using open source DICe (Sandia Corporation, Albuquerque, NM). Displacements will be validated using a custom ultrasound phantom consisting of layers of polyurethane with differing ratios of particulate material mimicking inhomogeneity and reflection of different plantar soft tissues, but not enough particulate matter to considerably change the known modulus values of the material. Using a load cell mounted in-series with an ultrasound probe, B-mode and SWE will be collected at known forces, and displacement will be measured with DICe to create a stress-strain curve. Elastic moduli will be calculated from these curves and compared with reference values.

The RGS is a complex and finely tuned system. Inertial effects due to the weight of the force plate are currently offset in the RGS control system. The ultrasound mount weight and size may require adjusting these parameters or replacing the force plate with a smaller load measurement system. Finally, while the RGS is precise and repeatable, its tolerance may be too large for collecting planar ultrasound images. Repeatability analyses using the mounting device and a sample specimen will assess ultrasound imaging repeatability. A deeper understanding of healthy and diabetic plantar soft tissue behavior will inform better computational models, could inform ulcer etiology research, and may improve clinical patient care techniques.

REFERENCES