Abstract: Prosthetic socket performance is a critical barrier to progress in rehabilitation, the most common source of patient dissatisfaction and part of a growing socioeconomic problem [1]. It has been shown that skin ulceration can be avoided if the soft-tissue envelope of the residual limb is not loaded, deformed, strained and stressed beyond a patient-specific threshold, duration and loading rate. There were, however, until recently, no devices capable of monitoring the direct loading patterns and functional status of prosthetic devices outside confined laboratory conditions, so quantification of these loading patterns in the real world was not possible [2]. This study uses a new wireless Intelligent Prosthetic Endoskeletal Component System (iPecs™) to measure the direct 3D forces and moments in trans-tibial (TT) prostheses during a course of prolonged continuous strenuous activities of daily living (ADL) performed outside the laboratory. The study aims to characterize the kinetic envelope of total surface bearing prostheses with pin suspension as it compares to that of elevated vacuum suspension prostheses.

Methods: Nine trans-tibial amputees (Age: 61.2±11.9 years, body mass: 92.2±22.3 kg, body height: 162 cm ± 7 cm, Stump length: 16±3 cm) wearing total Surface bearing (TSB-A) sockets with silicon liner (Alpha pin suspension) participated in this study approved by our institutional IRB. All patients were asked to perform the MOVE center strenuous activities protocol (MCSA) (Fig.1) after they were fitted with the iPecs™ [3] device which is applied in series at the socket alignment interface. All patients were also fitted with elevated vacuum sockets and repeated the protocol so that the effect of the different socket interventions on prosthesis kinetics could be evaluated (Fig.1). The protocol consists of twelve consecutive stations that iterate the performance of a number of tasks and subjective pain/comfort assessments (Analogue 1-10 scale [4]). The patient performs consecutively and with no interval the following 12 tasks (16 stations): 1) Getting up from a chair (no arm rests); 2) Walking (5m) and open door inwards; 3) Walking (10m) and open door outwards; 4) Walking (5m) and open door inwards; 5) 200 m walking on running track-in the first 100m a suitcase is carried (4kg) and two obstacles (23cm in height of the 200m walking task and during the effort to overcome an obstacle while carrying a suitcase.

Discussion: The study characterized the kinetic envelope of total surface bearing prostheses with pin suspension and compared it to that of elevated vacuum suspension prostheses. Statistical analysis revealed significant differences (p<0.05) between EV and TSB-A sockets in the Z direction (vertical) of force and in all X,Y and Z directions of moment for the majority of the 16 station course. The study design employed continuous ADL in an outside the laboratory format that could resemble a community outcomes study investigating the relationship between kinetics and functional outcomes of selected prosthetic interventions. To that end, the study demonstrated the ability to monitor forces and moments (which can then be wirelessly streamed for distances up to 1000 feet to a PC via the iPecs data collection module), in real time, for observed research outside the laboratory environments. Post processing of the data remains a challenge with respect to synchronizing the beginning and end of each task. This synchronizing depends on visual and acoustic feedback from video recordings or audio recordings of the whole protocol so that appropriate cues prompt to the exact time instant in the course of a task. Despite this limitation iPecs and this protocol can be vital tools for developing improved outcomes based on enhancing methods for the proper selection & alignment of most commercially available lower limb prostheses.


Figure 1: a) The MCSA protocol with multiple stations-tasks; b) Close up view of patient wearing the iPecs unit and the EV socket.