INTRODUCTION
Poor prosthetic socket performance is a critical limiting factor in rehabilitation progress, and hence part of a growing socioeconomic problem [Ziegler-Graham, 2008]. Residual limb skin ulceration is avoidable if load, deformation, strains and stresses on the limb residual do not exceed a patient-specific threshold, duration and rate. Without monitoring these factors outside of confined laboratory environments, quantification of loading patterns in the real world are nearly impossible [Papaioannou, 2010].

This study uses a wireless Intelligent Prosthetic Endoskeletal Component System (iPecs™) to measure direct 3D forces and moments in trans-tibial (TT) prostheses during a course of prolonged continuous strenuous activities of daily living (ADL), most of which are performed outside the laboratory. The study aims to characterize the kinetic envelope of total surface bearing (TSB) prostheses with pin suspension as it compares to that of elevated vacuum suspension (EVS) prostheses.

METHOD
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 TSB sockets with silicon liner (Alpha pin suspension) participated in this study, approved by our IRB. Subjects were asked to perform the MOVE center prolonged strenuous activities protocol (MCSA) after their prosthesis have been equipped with the iPecs™ [CPI, 2010] device which is applied in series underneath the socket alignment interface. Subjects repeated the protocol with elevated vacuum sockets, for comparison purposes. The MCSA protocol consists of twelve consecutive stations performing tasks while assessing subjective pain/comfort (Visual analogue pain scale [Collins, 1997]): 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 x 15 cm in width) are overcome at the end of the 50m and 150m line; 6) open a door outwards and walking (30m) then open door inwards; 7) Picking up an object from the floor (pencil/keys); 8) Walking up-down 22 stairs without handrail assistance; 9-10) Walking up and down 11 steps with handrail assistance; 11) the patient unassisted lays down on the floor on his back and gets up to the erect position again; 12) Walking (50m) and open door outwards. If pain and/or difficulty of ambulation become very high, an assessment of erythema (skin redness) is carried out. The two conditions (EVS vs. TSB) were compared using Wilcoxon Signed-Ranks tests.

RESULTS
The magnitude of direct vertical forces and sagittal moments of nine TT patients during the 16 consecutive ADL stations (12 tasks) of the MCSA protocol were calculated. Statistical analysis of the forces and moments 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 (after station 11). The highest vertical forces were observed during ascending and descending stairs, at the end of the 200m walk, and during the effort to overcome obstacles, carrying a suitcase.

DISCUSSION
The study quantified the kinetic envelope of total surface bearing prostheses with pin suspension, and compared this parameter to that of elevated vacuum suspension prostheses. 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 were found. The study design included continuous ADL in an outside-the-laboratory format to resemble a community outcomes study, investigating relations between measurable kinetics and functional outcomes of selected prosthetic interventions.

CONCLUSION
The study demonstrated a method of real time monitoring forces and moments (which can be wirelessly streamed over distances of 1000 feet to a PC via the iPecs data collection module) for observed research outside the laboratory environment. Post processing of the various data, particularly the synchronizing at the beginning and end of each task, remains a challenge. Synchronizing was based on visual and acoustic feedback from video or audio recordings of the whole protocol, using appropriate cues to indicate the exact time-instant of a task. Despite this limitation, iPecs and this protocol can be useful tools for improved outcomes based methods for proper selection & alignment of most commercially available lower limb prostheses.

REFERENCES

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