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Advancing the next generation of diagnostic device to sustain residuum health of individuals with limb absence

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Introduction

The well-being of individuals with limb absence depends on their residuum health, particularly the synergy between intrinsic and extrinsic determinants, being indirectly and directly associated with loading, respectively.[1] Clinicians struggle to prevent residuum neuromusculoskeletal dysfunctions and sustain successful coupling with a prosthesis. The efficacy and safety of their interventions are primarily assessed using questionnaires, physical examinations, medical tests, and static images. Unfortunately, interactions between determinants of residuum health are difficult to cross correlate and quantify under real-life conditions. Establishing causal relationships between the bespoke interventions and residuum health is challenging.[2] This study outlines the barriers and facilitators to the developments of the In-Vivo Kinetic System 4.0, diagnostic tool capable of rendering morphometry, deformation and stresses of the residuum's tissues under real-life weightbearing conditions.[3]

Methods

Developments of the integrated, wearable, and non-invasive In-Vivo Kinetic System 4.0 (Figure 1) involved iterative research-evaluation cycles including:

- **Step 1 (Plan)**: Outline the roadmap for development and testing of device, involving 40+ experiments.
- **Step 2 (Do)**: Create physical and digital phantoms of a residuum limb, and design the alpha prototype which integrated measurement of the mechanical constrains applied on the residuum using iPecsLab and morphometry of the residual limb's tissues using our novel Dynamic Anatomical Ultrasonography technique.[4, 5]
- **Step 3 (Study)**: Trial the alpha prototype to establish its proof of utility, efficacy, and safety.
- **Step 4 (Act)**: Prepare randomized clinical trials and investigating commercialization pathways.

Results

The primary facilitator is the urgent need for a better understanding of how to optimize residuum health when fitted with a conventional, endo/ exo-skeletal implant alone or in combination with emerging bionics solutions. A key barrier to the development of the device was the lack of basic knowledge of the mechanical properties of human skin, adipose, and muscle tissues, as well as bone/implant coupling. The discrepancy between technology readiness levels of loading, Dynamic Anatomical Ultrasonography, and modelling elements were estimated to be at 7, 3, and 4, respectively. This complexify the integration of all part within the unique technological platform. Commercialization avenues of the device met limited interest from MedTech investors, because of their perception that the market is too small.

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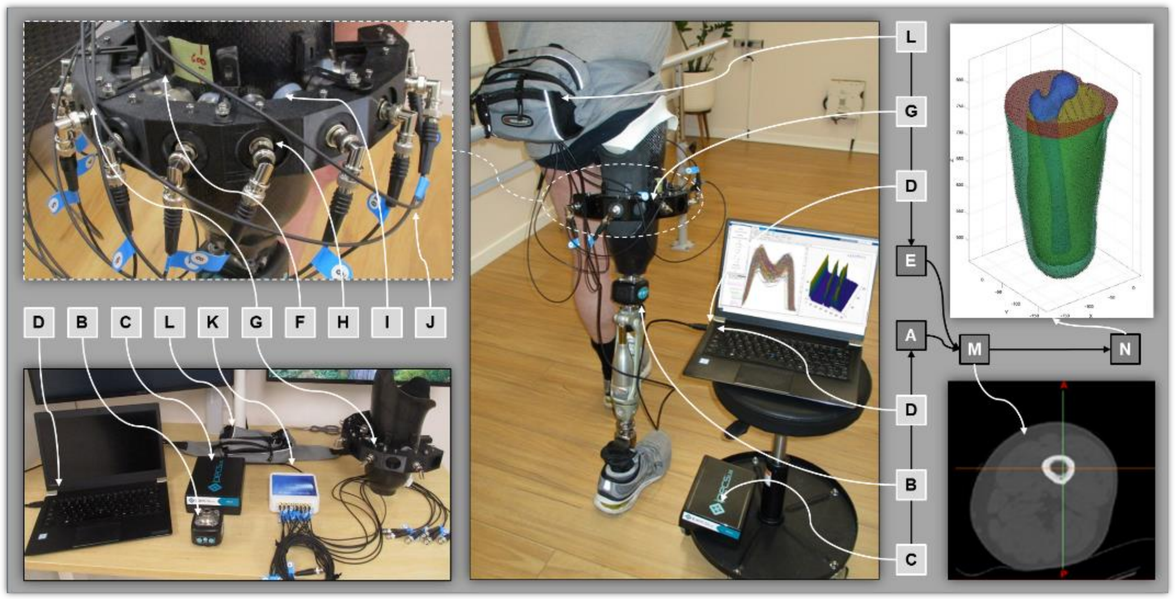

Figure 1. Benchtop (bottom, left) and in-situ (middle) In-vivo Kinetic System 4.0 combining portable kinetic system (A) including tri-axial load cell (B) and wireless receiver (C) connected to laptop (D) as well as Dynamic Anatomical Ultrasonography (E) including bracket (F) to attach a holder (G) housing up to 12 ultrasound transducers (H) fitted with coupling pads (I) and cables (J) wired to US-Mux (K) placed in waist bag (L) and connected to a laptop (D). Data will be integrated with 3D medical imaging (M) to inform the design of a replica computational model of the residuum (N).

Conclusions

The In-Vivo Kinetic System 4.0 has the potential to productively disrupt the current model of rehabilitative and prosthetic care used for current and emerging bionic solutions, provided all its technological elements can be integrated and deemed acceptable to clinicians and end-users. The In-vivo Kinetic System 4.0+ can further facilitate assessment of stress and strain on all residuum tissues and, consequently, improve our understanding of the potential associations between residuum loading and neuromusculoskeletal disfunctions. The diagnostic device can be used for immediate gait retraining and improvements in computer controlled prosthetic knee functions (e.g., adjustments to residuum loading, stresses and strains).

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