2022 Military Health System Research Symposium
Kissimmee, USA
MHSRS-22-06886

Development of a diagnostic device to maintain residuum health of Service Members suffering from limb loss: Barriers and facilitators

Laurent Frossard, PhD [(1)], Christian Langton, PhD, DSc, PhD(Hon) [(1)], Nataliya Perevoshchikova, PhD [(1)], Stefanie Feih, PhD [(1)], Ross Powrie, CPO [(2)], Rod Barrett, PhD [(1)], David Lloyd, PhD [(1)] ,

(1) Griffith Centre of Biomedical and Rehabilitation Engineering (GCORE), Griffith University, Gold Coast, QLD, Australia, (2) Custom Prosthetics, Mudgeeraba, Australia

LEARNING OBJECTIVES

1. Highlight the **need for diagnostic devices** capable of conducting patient-specific differential diagnosis of neuromusculoskeletal disfunctions that can affect the residuum health.
2. Outline **barriers and facilitators** to the engineering developments, clinical implementations and commercialisation pathways encountered during the creation of diagnostic devices.
3. Suggest **when and how to overcome barriers** during the development of diagnostic devices.

BACKGROUND

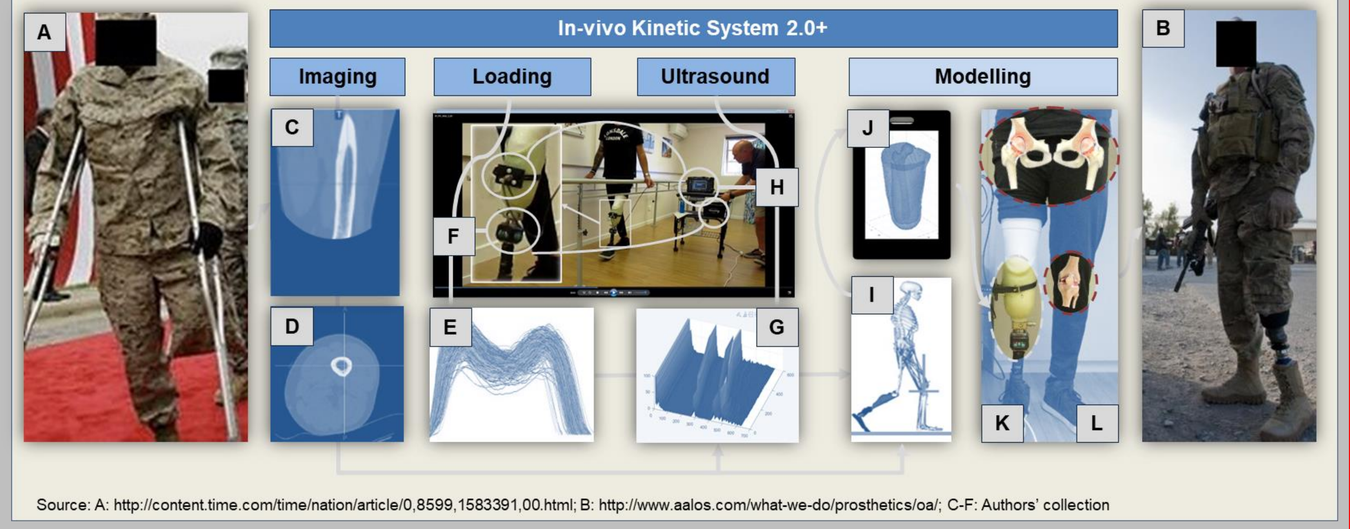
- The quality of life of military Service Members, Veterans and beneficiaries suffering from lower limb loss highly depends on their ability to walk with a prosthetic limb.
- Rehabilitation specialists use a series of separate tools to diagnose specific neuromusculoskeletal disfunctions. However, interfacing these devices to work together and provide a holistic understanding of disfunctions is rarely achieved.
- There is a need for a device capable to conduct patient-specific differential diagnosis of neuromusculoskeletal disfunctions and to holistically establish the cause-effect relationship between prosthetic care interventions and residuum health.
- Since 2016, we have been developing a portable and non-invasive diagnostic device, called the In-vivo Kinetic System 2.0 (Figure 1).
- The purpose of this study is to share the barriers and facilitators to the engineering developments, clinical implementations and commercialisation pathways encountered during the creation of the In-vivo Kinetic System 2.0.

METHODS

- **Step 1 (Plan)** provides a roadmap for the development and testing of this device involving 40+ experiments.
- **Step 2 (Do)** creates phantoms of the residuum and a prototype of the device integrating loading measurements, DAU and computational models.
- **Step 3 (Study)** trials prototypes of the device and determine its proof of utility, efficacy and safety.
- **Step 4 (Act)** prepares registered randomised clinical trials and investigates commercialization pathways of the device.

IN-VIVO KINETIC SYSTEM 2.0

Figure 1. Overview of the innovative orthopaedic, rehabilitation, and prosthetic care pathway for Service Members and Veterans with lower limb amputation (A) relying on **In-vivo Kinetic system 2.0+** *to perform patient-specific differential diagnosis of residuum health and facilitate return to active life and duty (B), integrating medical imaging (C,D), ecological measurements of triaxial loading (E) using a iPecLab (F) and topography of tissues compartments (G) using Dynamic Anatomical Ultrasonography (H) to inform a neuromusculoskeletal model (I) and digital twin of the residuum accessible in real-time with handheld device (J) to predict residuum soft tissue stress and strain and improve design of bespoke 3D printed sockets and prescription of prosthetic components (K) while reducing overloading and risk of osteoarthritis of sound hips and knees (L)*



Source: A: http://content.time.com/time/nation/article/0,8599,1583391,00.html; B: http://www.aalos.com/what-we-do/prosthetics/oa/; C-F: Authors' collection

BARRIERS

- Lack of basic knowledge of mechanical properties for skin, fat and muscle tissues.
- Discrepancy between technology readiness levels for the loading, DAU, and modelling parts.
- Discrepancy between the scope of practice and skills of practitioners who could use this device.

FACILITATORS

- Need for a device capable to conduct patient-specific differential diagnosis of the health residuum.
- Need for a device able to provide evidence of the efficacity and safety of conventional prosthetic care interventions.
- Emergence of new bionics solutions requiring better understanding of the interactions between residual limb and prosthesis.

CONCLUSION

- In-vivo Kinetic System 2.0 can provide unparalleled holistic insights into residuum health and further assist in patient-specific differential diagnosis of residuum health under real world conditions.
- This device can productively disrupt the current model of health care, provided that separated scopes of practice of prosthetic care providers and siloed health care organizations can be overcome.

ACKNOWLEDGMENTS

- FY19 RESTORE Award (No. W81XWH2110215-DM190659).
- Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the DoD.

SPEAKER'S INFORMATION

Laurent Frossard (PhD)
- Professor of Bionics at Griffith university
- L.frossard@griffith.edu.au , +61 (0)4 1379 5086
- https://experts.griffith.edu.au/18825-laurent-frossard