Homeland Defense & Security
Information Analysis Center

Innovative Attachment Systems for Improved Performance of Prosthetics & Exoskeletons

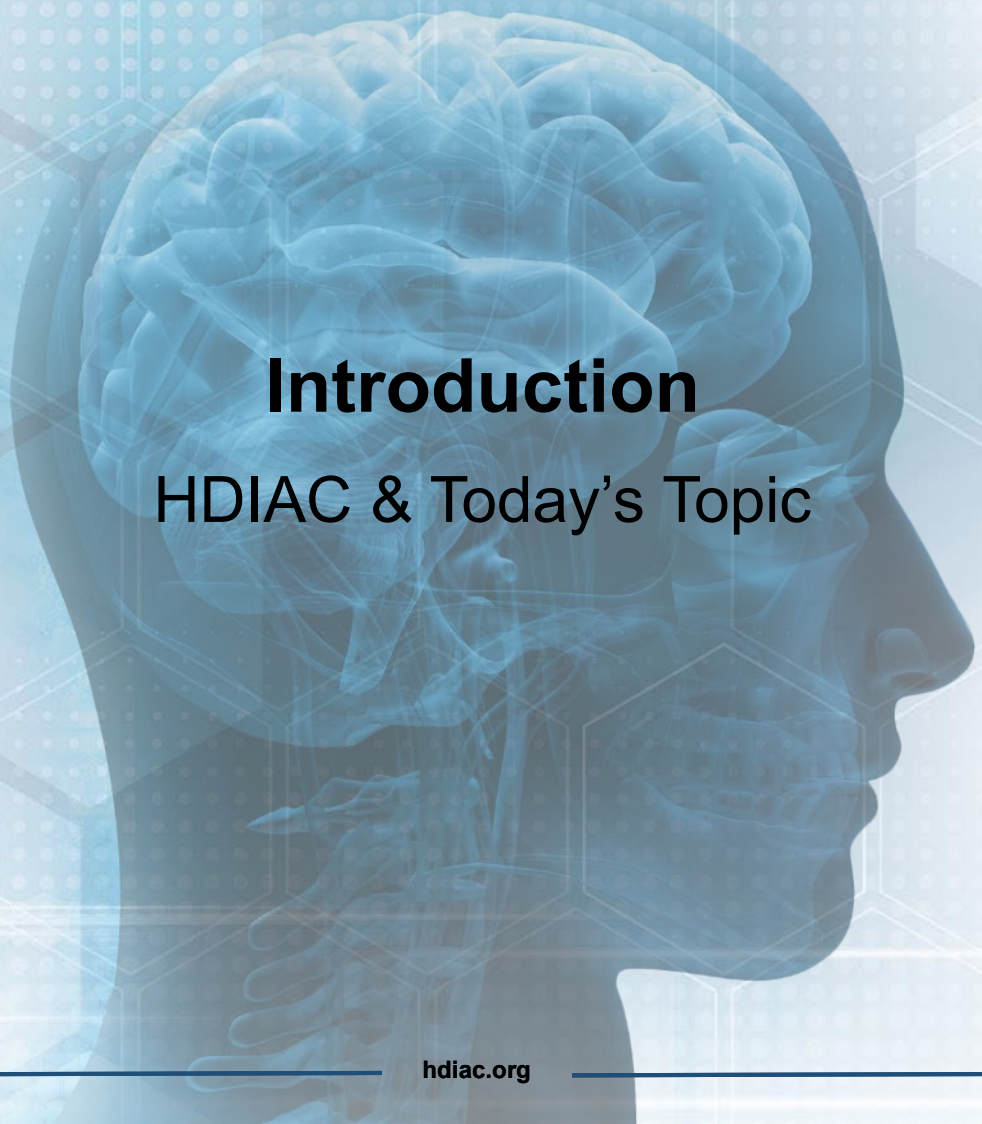
Randall Alley, BSc, CP

biodesigns, inc.

January 30, 2019

The views presented are those of the speaker and do not necessarily represent the views of DoD or its components.

Distribution A: Approved for Public Release; Distribution Unlimited



Introduction

HDIAC & Today's Topic

HDIAC Overview

What is the Homeland Defense & Security Information Analysis Center (HDIAC)?

One of three Department of Defense (DoD) Information Analysis Centers managed by DoDIAC at Fort Belvoir.

HDIAC is responsible for acquiring, analyzing, and disseminating relevant scientific and technical information, in each of its eight focus areas, in support of the DoD and U.S. government research and development (R&D) activities.

HDIAC's Mission

HDIAC's mission is to be the go-to R&D, Science and Technology (S&T), and Research, Development, Test, and Evaluation (RDT&E) leader within the Homeland Defense and Security community.

HDIAC Overview

HDIAC Subject Matter Expert (SME) Network

HDIAC SMEs are experts in their field(s), and, typically, have been published in technical journals and publications.

SMEs are involved in a variety of HDIAC activities

- Authoring HDIAC Journal articles
- Answering HDIAC Technical Inquiries
- Engaging in active discussions in the HDIAC community
- Assisting with HDIAC Core Analysis Tasks
- Presenting webinars

If you are interested in applying to become a SME, please visit HDIAC.org or email info@hdiac.org.

Why this topic? Why now?

- DoD and the Department of Veterans Affairs (VA) have long been leaders in prosthetics development
  - Clear connection between combat and improvements in prosthetics
  - Approximately 1,700 military servicemembers experienced traumatic amputations from injuries in Iraq and Afghanistan since 2002
- Extensive DoD/VA involvement
  - DARPA
  - Extremity Trauma and Amputation Center of Excellence
  - U.S. Army Medical Research and Materiel Command/Congressionally Directed Medical Research Programs
  - Veterans Health Administration facilities
- Major advances supported by DoD/VA
  - LUKE arm system
  - Modular Prosthetic Limb
  - HAPTIX Program
  - Osseointegration
- Exoskeletons
  - Rehabilitation - ReWalk
  - Combat aid - TALOS

Presenter

Randy Alley, BSc, CP

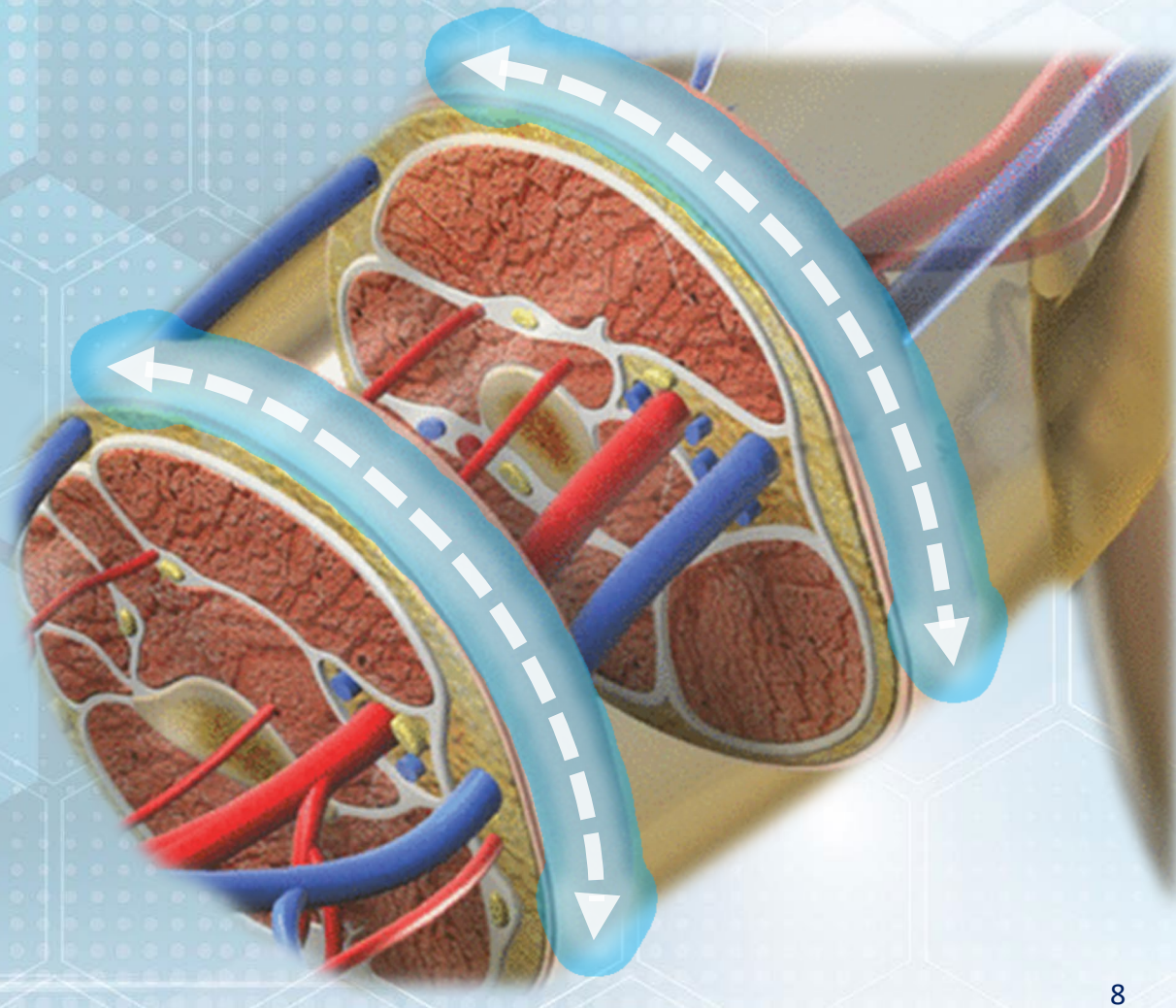
Randy Alley is the CEO and chief prosthetist of biodesigns, Inc.—a full-service clinical facility and research and development center (B.Sc., University of California, Los Angeles). He is the inventor of the patented and patents-pending High-Fidelity™ Interface (socket) System and MOtion-capturing Fast-access Osseostabilizing™ limb exoskeleton for both upper and lower limb applications. Alley was the primary interface consultant working with DEKA Research and Development Corporation on the Defense Advanced Research Projects Agency Luke Arm Project, and he is the PI on biodesigns' DARPA/SBIR Phase II award. Alley is the recipient of a U.S. Army Certificate of Appreciation, NovaCare Chairman's Award, Hanger Clinic Excellence in Innovation Award, the 2010 American Academy of Orthotists and Prosthetists Clinical Creativity Award, and the 2016 IEEE Design Award.

THE HUMAN INTERFACE HAS BEEN AN AFTERTHOUGHT

PERIPHERAL APPROACH

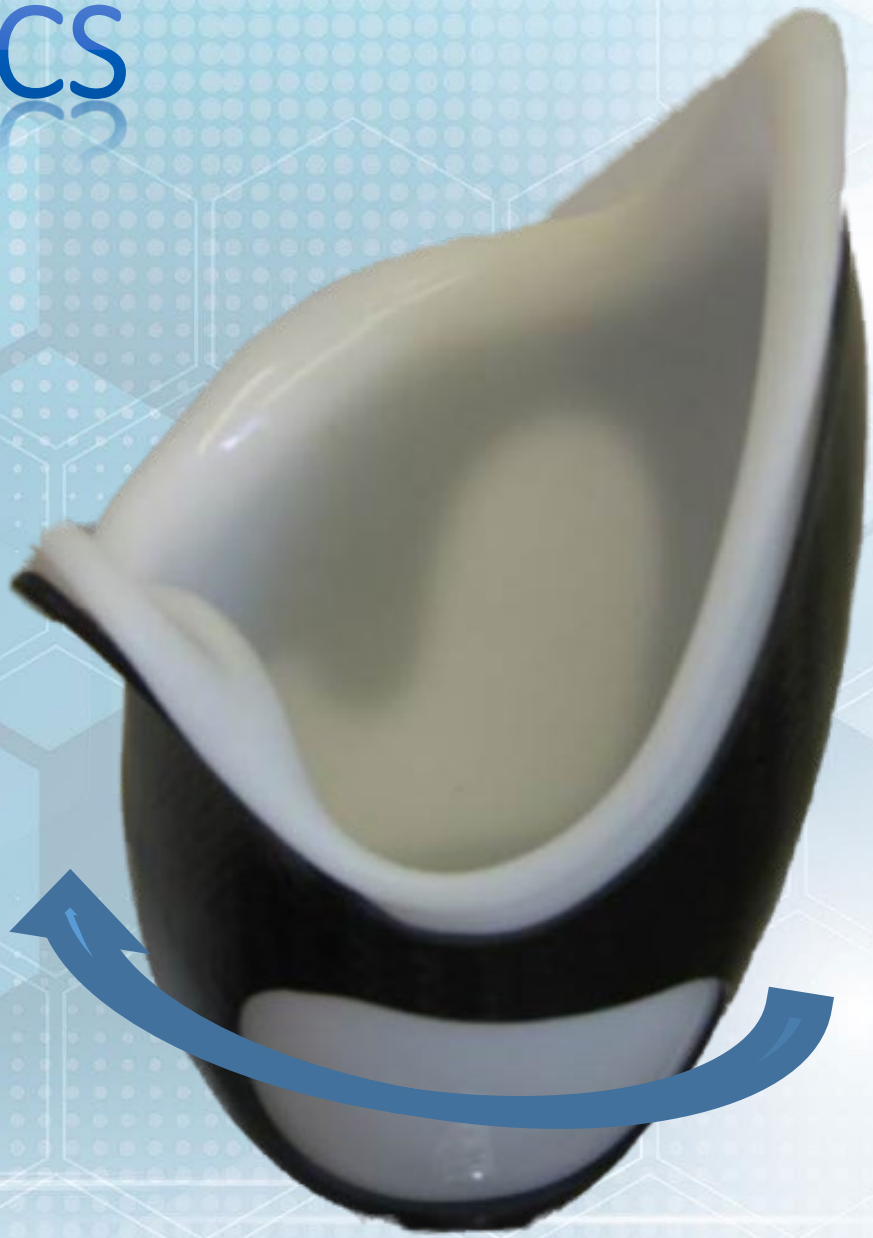
Worldwide industry standard for attaching just about anything to the human limb

- Superficial
- Circumferential
  - Simplistic, inferior biomechanics



PROSTHETICS

The standard approach in prosthetics is simple capture of the limb, without regard to skeletal biomechanics



ORTHOTICS

Orthotics is much the same

ORTHOPEDICS

A traditional fracture management strategy utilizes primitive containment methods, increasing healing times and negatively affecting bone strength

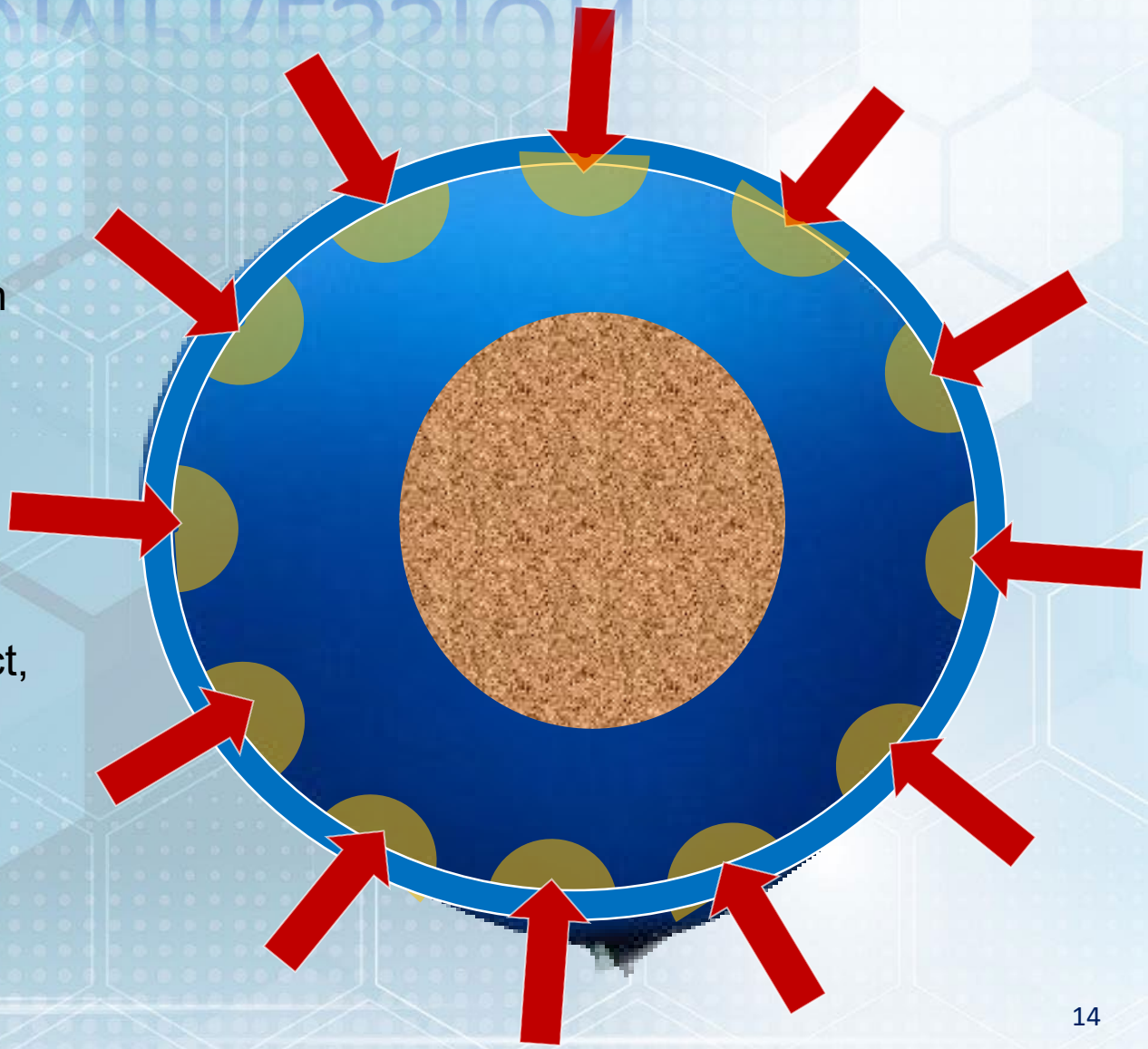
EXOSKELETONS

The standard approach in the exoskeleton and bionics markets is, again, simple capture of the limb, with little regard to skeletal biomechanics.

WEARABLE TECH

GLOBAL COMPRESSION

- Circumferential approach inherently unstable
- Impossible to sufficiently control bone
- Bone moves relative to externally mounted object, resulting in instability



FUNDAMENTALLY FLAWED

The fundamental principles of traditional human attachment are neither biomechanically efficient nor suitable for maximizing function as they *exert too little influence on the underlying bone*

WHEN IT COMES TO ATTACHING THINGS TO THE HUMAN BODY, WE CAN DO BETTER

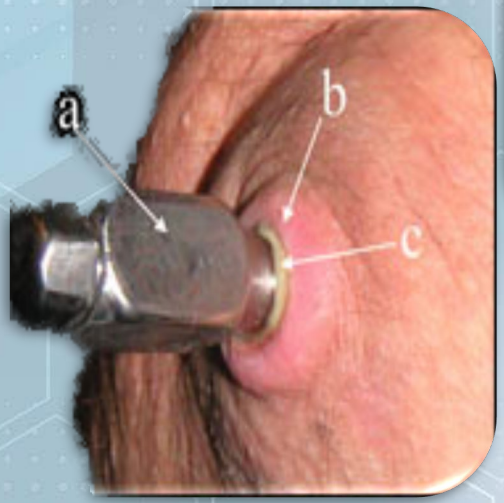
WE MUST CAPTURE, CONTROL AND CONNECT TO THE UNDERLYING BONE

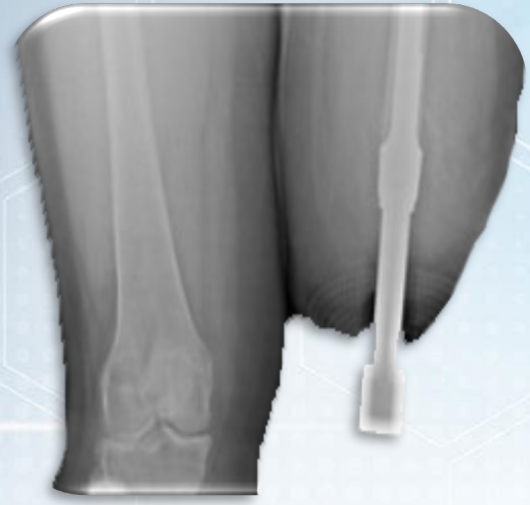
- When looking at the cross section of the limb, it becomes apparent why the long bones are so mobile within the traditional interface

- But how can we capture and control skeletal motion such that it is synchronized with the prosthesis?

OSSEOINTEGRATION

- Direct surgical connection
- Contraindicated for diabetic and highly active individuals
- 100% infection rate-though infection has been "reclassified"
- Expensive
- Constantly evolving
  - Hard to retroactively "update" once done
- Without external compression, perfusion potentially compromised





THE ALTERNATIVE SOLUTION

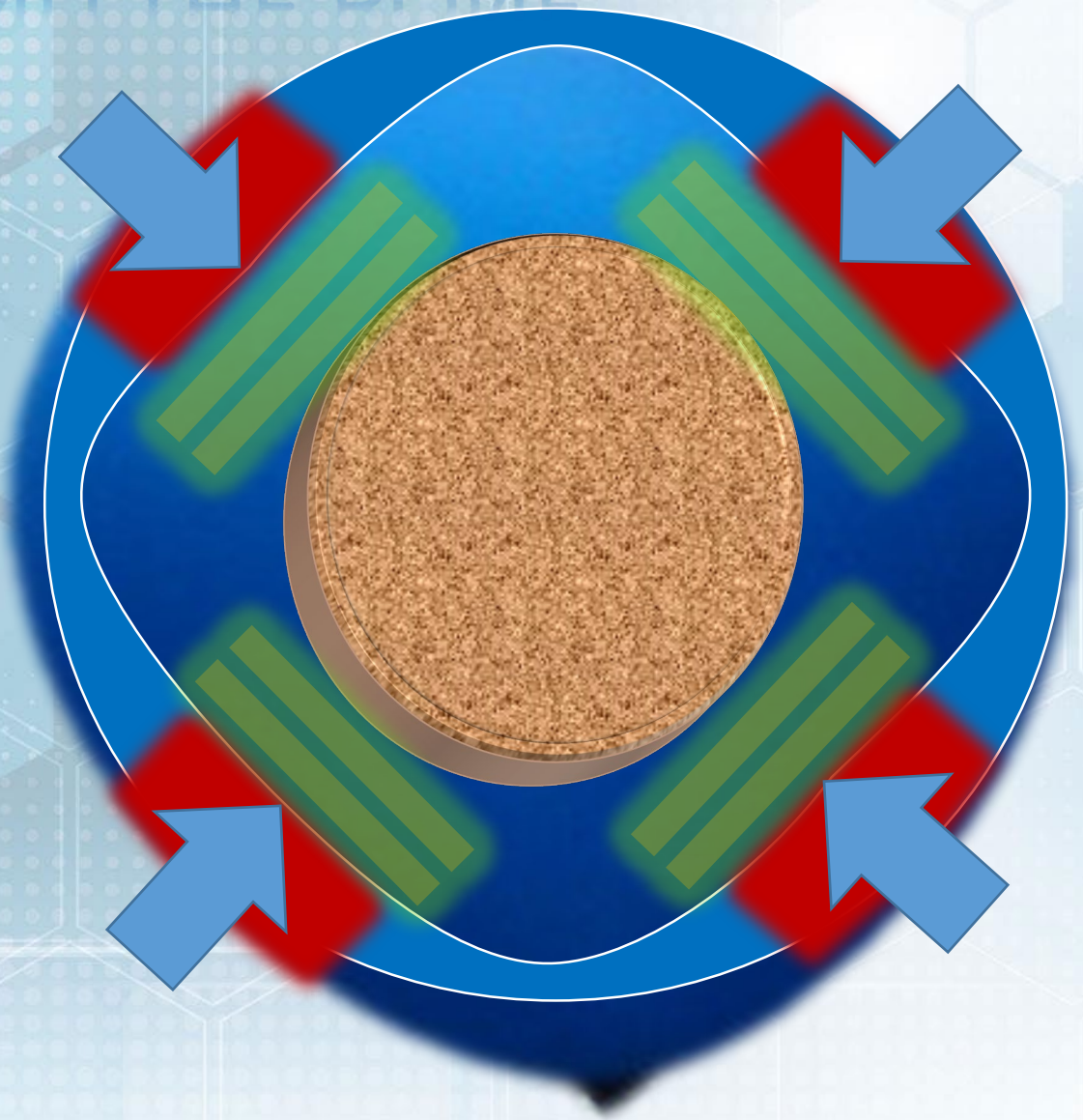
Osseostabilization™

- Non-surgical method of stabilizing and controlling the intrinsic bone within the interface
- Eliminates risks of surgery
- No known contraindications



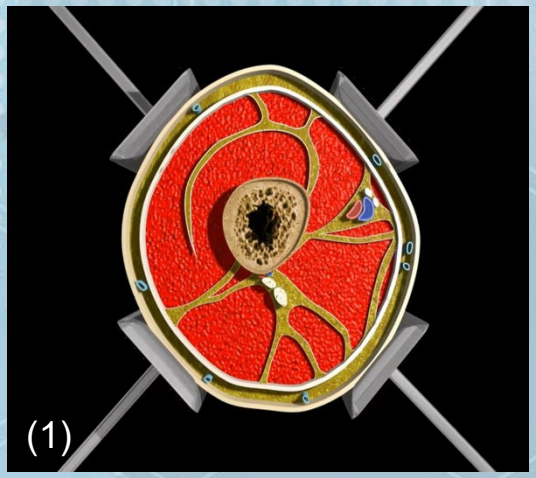
CREATING A DENSE MATRIX OF SOFT TISSUE AROUND THE BONE

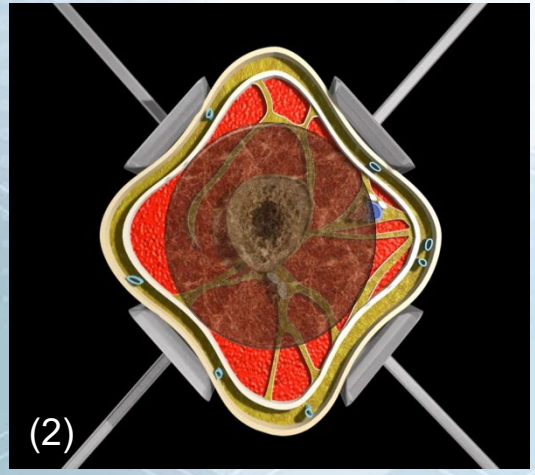
- Maximizes stability
- Maximizes force/energy transfer
- Maximizes range of motion
- Minimizes rotation
- Enhances deep venous return

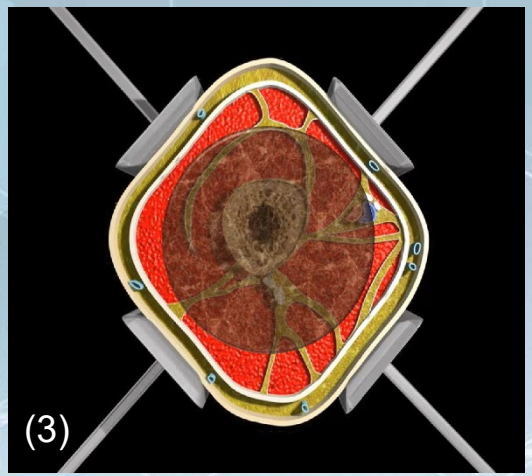


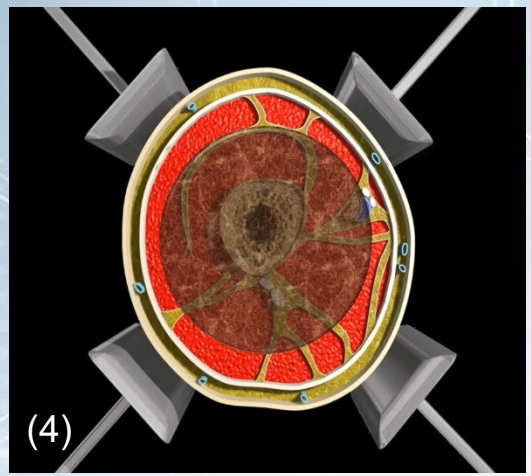
This set of graphics depict how this compression and release works to create a field, or column of compressed tissue around the femur

- This compressed column of tissue, represented by the shaded area, is much more dense than the surrounding soft tissue
- Because the bone is surrounded by a dense medium, its motions are not only restricted within this medium, but the column of dense tissue surrounding it is similarly unable to squeeze through the gap between the compression zones
- These two elements work together to quickly and efficiently transfer skeletal input to prosthetic output
- And in the case of outside influences such as ground reaction forces generated through the gait cycle or impacts derived from other sources or activities, the interface is likewise unable to translate on the limb for the same reasons





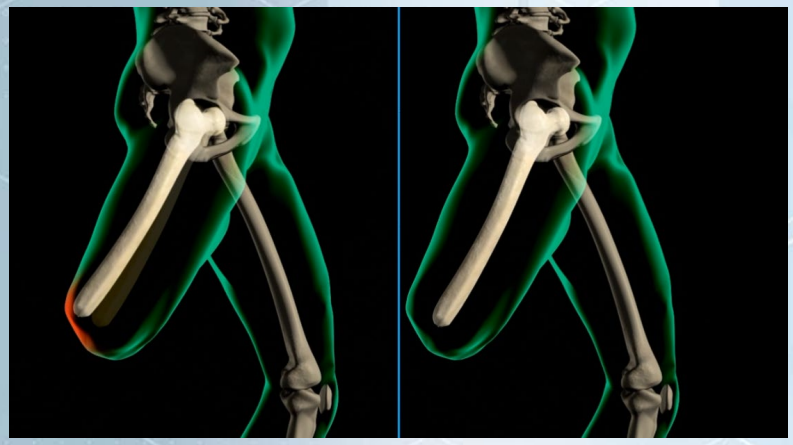


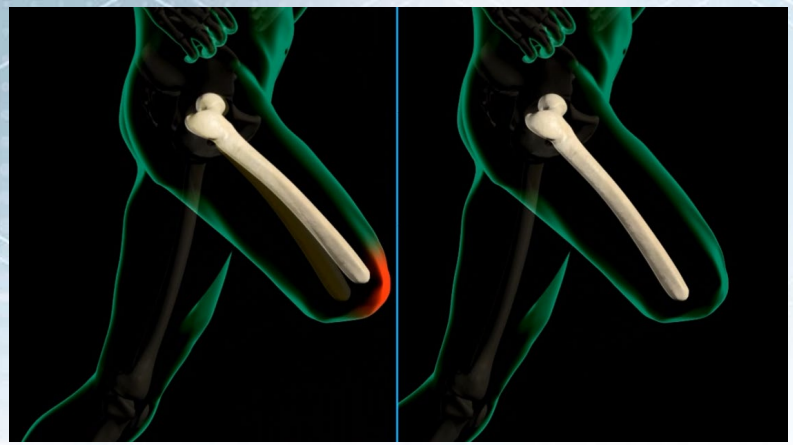


- When the compression levels are optimum, unwanted motion of the femur with respect to its interface is significantly reduced, while adequate blood flow is maintained. In this clip, we simulate how the femur behaves differently in a traditional socket, depicted on the left, as compared to a High-Fidelity or Osseosynchronized interface on the right

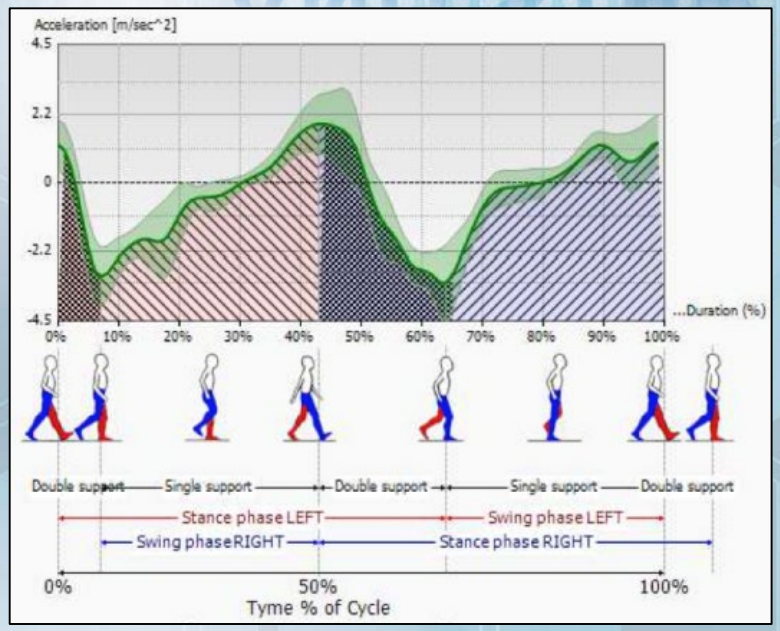
- Note that while there still is some movement of the femur in the HiFi design, it is far less than in the traditional socket

- If you look closely at the running figure on the left, you can see the ghosted image of the HiFi controlled femur in pale yellow as it directly compares to its counterpart in the same limb, exhibiting the difference between a critically damped oscillating system and an under-damped oscillating system respectively

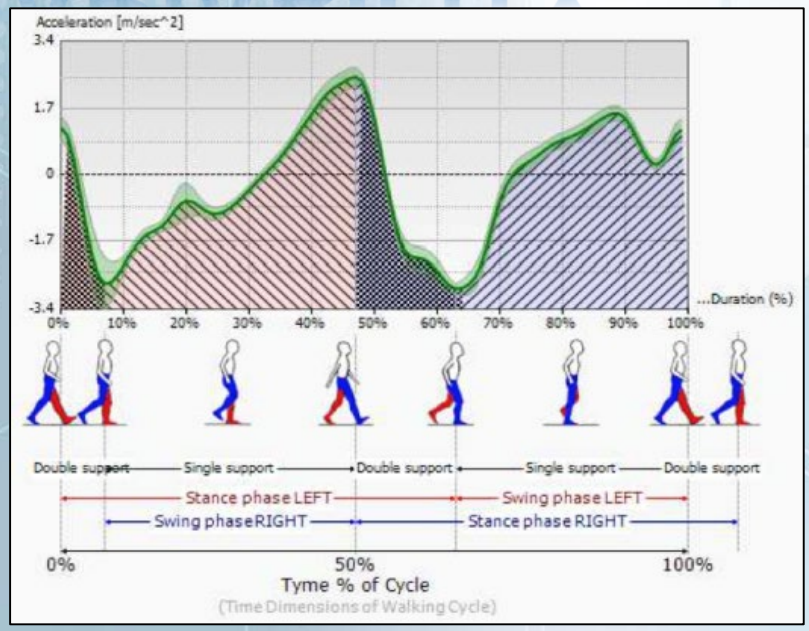




OSSEOSYNCHRONIZATION™ AND STEP VARIABILITY



Subischial traditional elevated vacuum

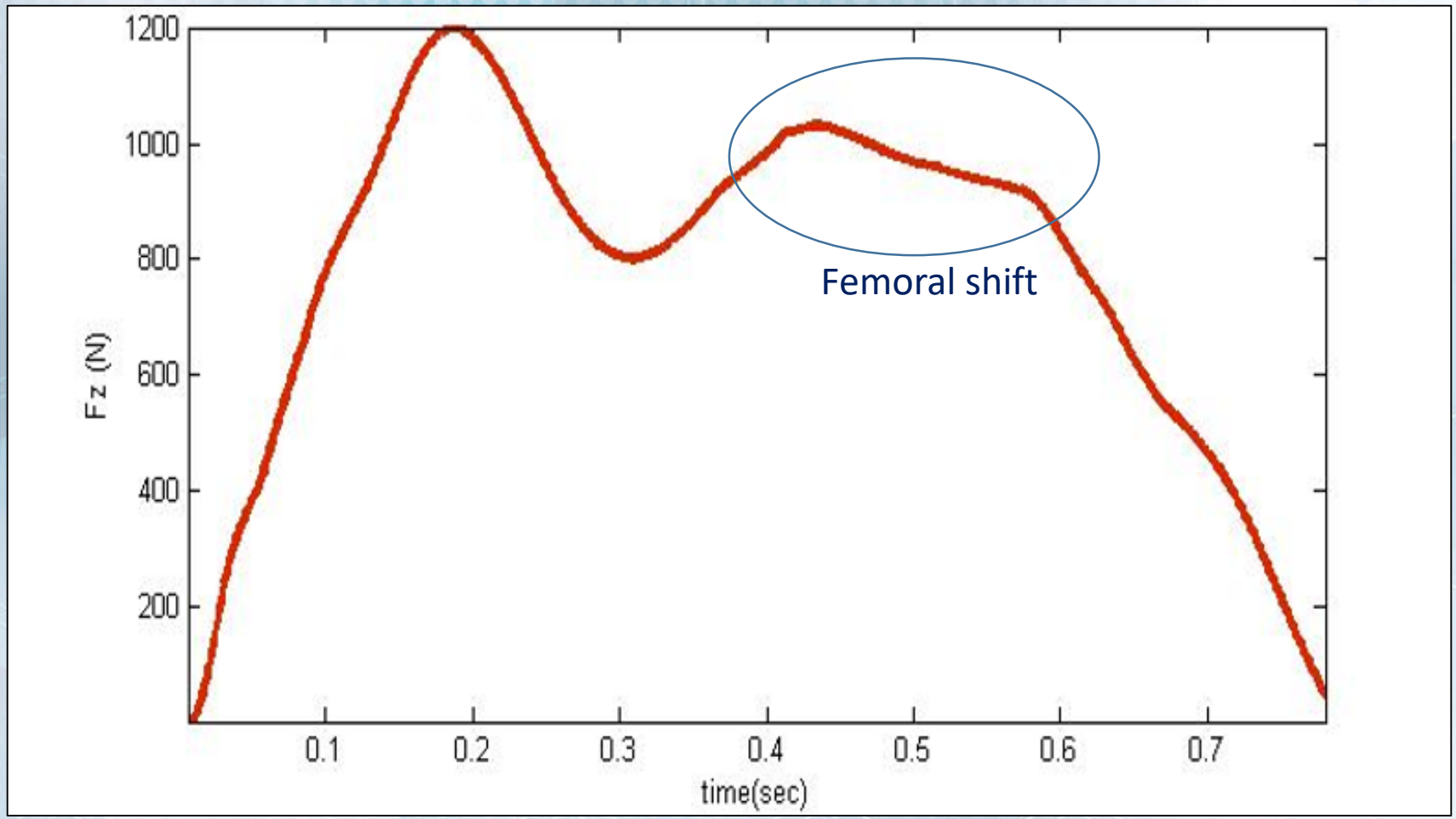


Subischial HiFi expulsion valve

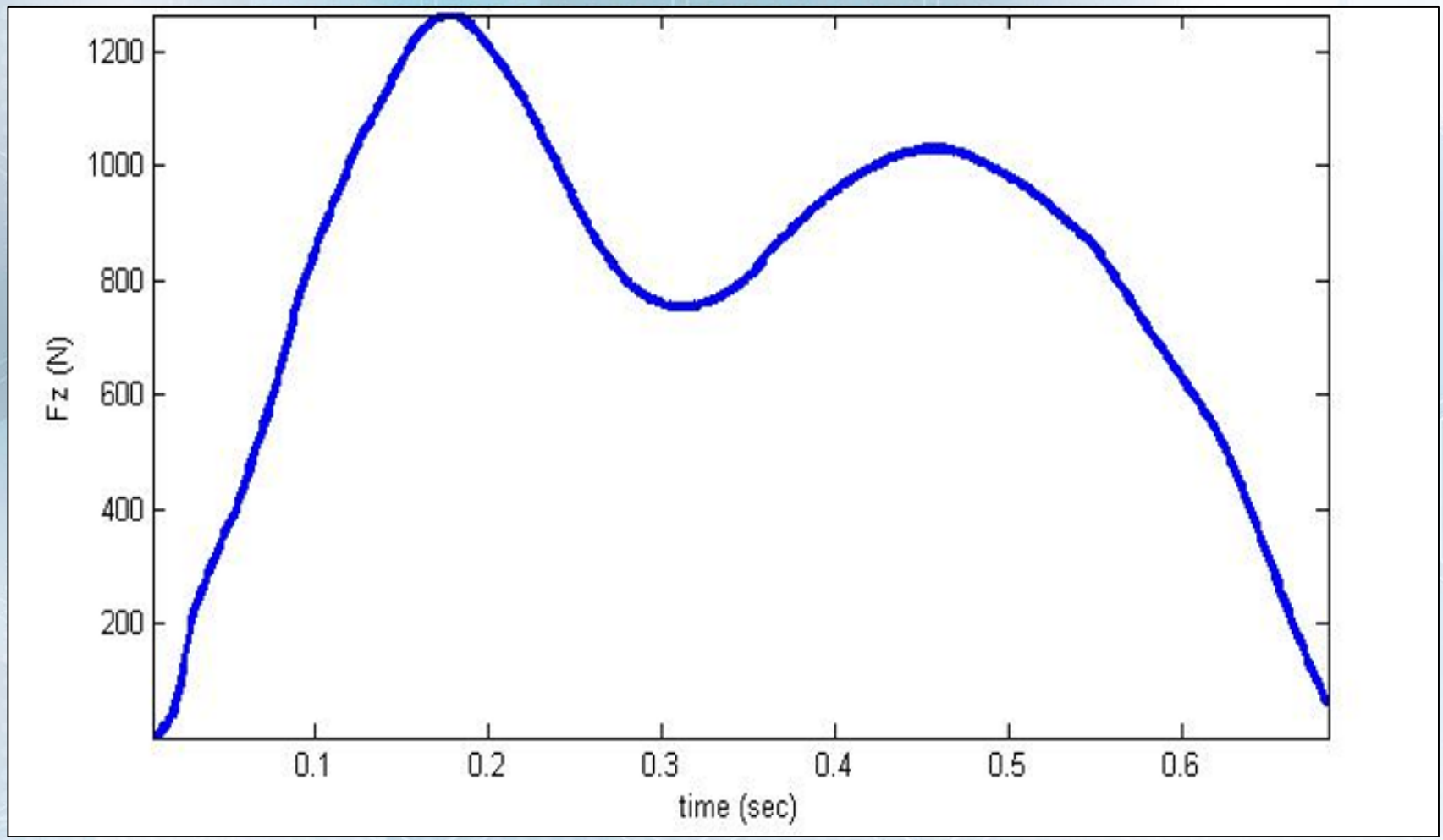
- To illustrate the enhanced proprioception and gait improvements, we've utilized the G-Walk six axis sensor and data logging system to perform a functional gait analysis comparison between a sub-ischial elevated vacuum socket represented by the graph on the left and a sub-ischial High-Fidelity interface with total suction depicted on the right
- The green band shown represents same side step variability or the level of differentiation of the same side step as compared to its predecessors and successors – A wider band represents greater variability

- As you can clearly see from the graphs the HiFi interface exhibited significantly reduced step variability, indicating enhanced positional control
- We believe this is most likely due to the improved proprioception gained from a more direct linkage, which in turn results in more precise step placement

EASTERN MICHIGAN UNIVERSITY STUDY



EASTERN MICHIGAN UNIVERSITY STUDY



REBOOTING THE EXOSKELETON

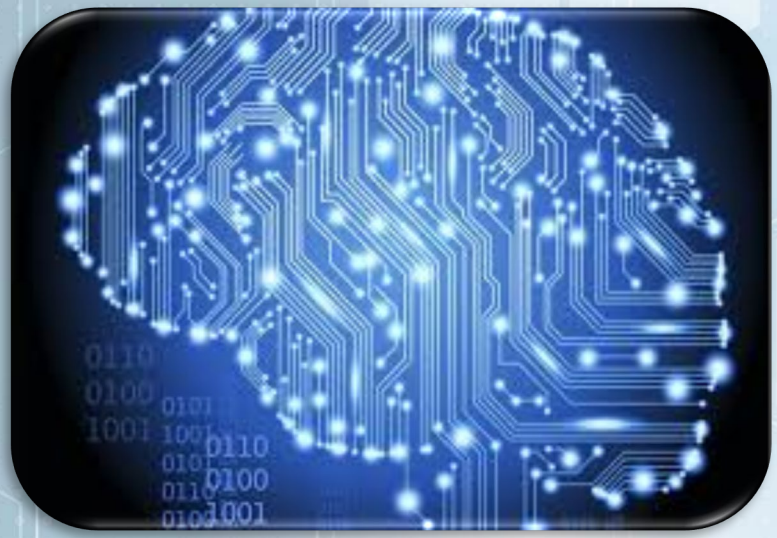
From TALOS Mk5 and Hyper Enabled Operator (HEO) to Rewalk and REX

- The human attachment can be radically improved without surgery
  - Less complex
  - Reduced cost
  - More energy efficient
  - Enhanced weight tolerance
  - Improved acceptance

FUNDAMENTAL GOAL FOR HUMAN ATTACHMENT: "EMBODIMENT"

Achieving suspended disbelief

- Reestablishing the neuromuscular connection through skeletal capture/control
- Ultimate goal is to forget you are wearing a device at all
  - Will lead to a revolution in human-robot integration



Questions?