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The High-Fidelity Interface: Skeletal Stabilization through Alternating Soft Tissue Compression and Release

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ABSTRACT

Traditional interface designs have largely focused on tissue containment of the encapsulated limb and establishing stability via anatomical contouring in the areas of the interface closest to the proximal joint of said limb. Firm control of the shaft of the underlying bone of the encapsulated limb has either been wholly ignored or given only a cursory examination at best. Indeed, for many there still remains a question whether or not the underlying bone can be controlled at all. Limited biomechanical knowledge, a general acceptance of Hydrostatic theory with regard to interface design, a glaring absence in our quantification of window edema and its relation to aperture design and location and the relaxed pace at which we have both developed an interest as well as the associated technology to assess the socket environment in a comprehensive fashion have all inhibited rapid interface advancement. A new theory "Compression-Release Stabilization" (CRS) focuses primarily on control of the underlying bone and forms the foundation of the High-Fidelity Interface (HiFi) described herein. This paper will discuss the theory as well as the results of its application in both upper and lower limb prosthetics and orthotics.

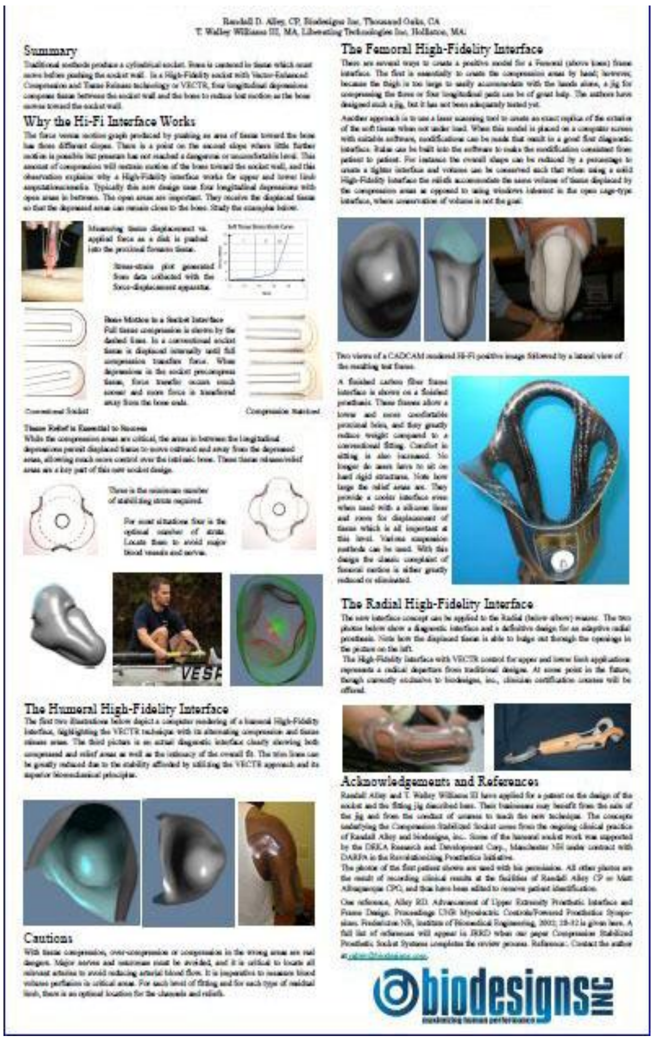
INTRODUCTION

Newton's First law essentially states that an object at rest will remain at rest unless acted upon by sufficient force to create a change in state. With regard to even the latest interface designs from the Symes level to the hip and partial hand to the shoulder, in nearly every case, the underlying bone or bony structures translate significantly within the interface relative to the interfacial boundary during volitional movement and in response to externally applied loads. This unwanted motion is predominantly due to the lack of sufficient counterforce generated by the soft tissue between the moving bone and the socket wall. Because the underlying bone is typically fixed at one end, it swings in such a way as to cause its distal end to strike the interface wall, separated by a very thin layer of highly compressed tissue. In this paper I illustrate the inherent design weakness of traditional sockets [1,2] and why a different model based on alternating soft tissue compression and release applied along the shaft of the underlying bone or strategically about targeted bony structures offers a more efficient way to generate prosthetic motion. Vastly improved stability, enhanced functional range of motion, improved ability to handle (position and carry) or ambulate with greater loads more comfortably, reduced energy expenditure, increased gait speed and stride length, and a perception of the prosthesis feeling more like a part of the wearer were all achieved. Its intimate connection with the limb offers the wearer a feeling of agility and precision that, based on the laws of physics, cannot be equalled with a traditional approach. Finally the patient subjects reported a perception their prosthesis weighed less than their traditional system, even in instances where the prosthesis employing Compression-Release Stabilization weighed more than its traditional counterpart.

The alternating soft tissue compression and release technique places longitudinal compression areas along nearly the entire shaft of the bone or underlying bony structures while the release areas allow for soft tissue, including skeletal muscle, to escape out of the fields of compression. In many cases, primarily in upper limb, this outward flow of tissue is completely unrestricted to allow for increased heat dissipation but also to reduce the overall volume of tissue that lies within the field of compression. With correct aperture design to control a variety of critical variables including the volume of released tissue, the rate of "step-off" from elevated compression to zero compression, exiting skin tension, fluid and venous return, as well as the strategic location of the release areas themselves, window edema is not a concern. Likewise, correctly applied compression to facilitate bone capture and control, if designed and deployed with precision regarding shape, location, extent and compression level, blood perfusion is also not a concern.

Because less tissue remains between the compressed area and the shaft of the bone, additional compression-and therefore skeletal control-is gained. In essence, by "precompressing" the overlying soft tissue prior to volitional movement or applied external force, its density is significantly increased. Subsequently, as the compressed tissue's density increases, so too does its ability-when trapped between the target bone and the interface wall-to provide a counterforce to unwanted skeletal motion [3].

Because it can be understood that preloaded or highly compressed tissue within the interface will not only provide a greater counterforce but will provide it more rapidly, we can apply Newton's Law to assume the prosthetic interface will respond more quickly as well. If we then consider the total area of elevated compression at the boundary of bone to soft tissue and relate it to Archimedes' Principle regarding buoyancy, we can analogize that with any increase in surface area of the compressed region at the bone to tissue boundary (the hull) there is a corresponding decrease in the force (buoyancy) required to initiate prosthetic motion. Thus if we increase both the magnitude and total area of increased density at the bone to tissue boundary, we can readily appreciate the improved biomechanical condition existing within the interface.

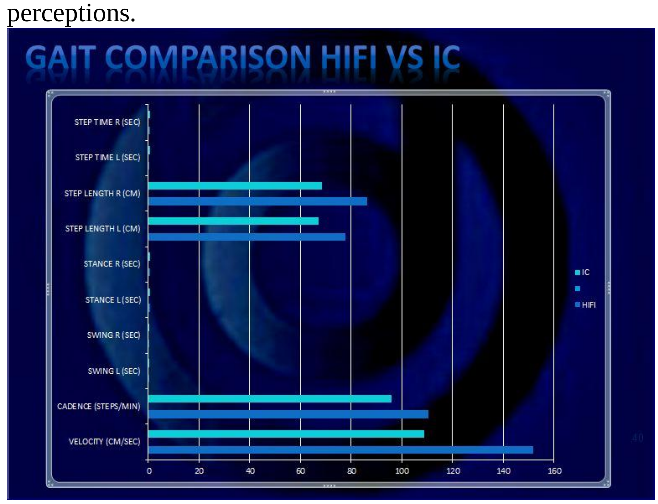


METHOD

A series of assessment tools are currently being developed in anticipation of formal clinical trials in several locations throughout the United States and Europe. The results of informal analysis provided here attempt to simply illustrate trends observed in both upper and lower limb applications. Close to one hundred patients have been fit with the High-Fidelity Interface to date and at the time of this writing.

For the purposes of this preliminary study, emphasis of this paper will focus upon a detailed discussion of the prosthetic application of CRS, including both measured and observed results. A heart rate monitor was used over a fixed distance to assess energy expenditure. The theoretical basis of this measure is the linear relationship that exists between heart rate and energy expenditure (EE) in steady state exercise involving large muscle groups. The method has shown to have high reproducibility within subjects [4]. Distance was measured at the conclusion of a two minute walk test comparing traditional ischial containment to the HiFi interface. A randomized crossover study is proposed in the future at several sites to validate the acquired data.

Gait attributes were assessed utilizing a GAITRite mat [5]. Video assessment of upper and lower limb wearers was also undertaken along with a patient survey regarding the High-Fidelity Femoral Interface and its wearers' subjective perceptions.



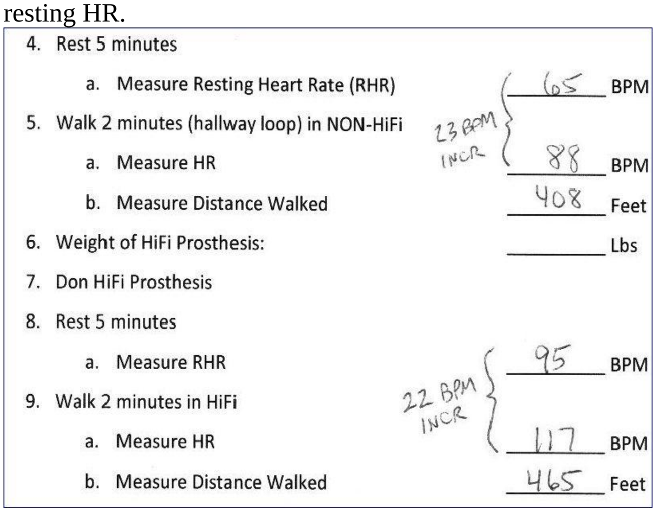
RESULTS

The above table demonstrates a sample data set comparing a traditional ischial containment socket to the High-Fidelity Interface, averaged over three walks on a GAITRite mat for a single individual. The clinical protocol as a condition for licensing this design involves informal analysis of gait parameters and HR, and so much larger patient populations will be the subject of future papers.

Videos to be presented illustrating range of motion of an upper limb wearer involved in the Luke Arm Project under significant load show the increase in both range of motion and comfort.

Finally, patient satisfaction surveys regarding their experiences with the High-Fidelity Interface reveal a greater level of satisfaction with the newer design.

The sample below shows the HR delta between rest and post-exercise to be relatively equal, though the subject in the HiFi walked 57 feet farther in the same two minute interval. It is interesting to note the resting HR prior to the subject's second walk test was significantly higher than his original resting HR.



4. Rest 5 minutes
   a. Measure Resting Heart Rate (RHR) 65 BPM
5. Walk 2 minutes (hallway loop) in NON-HiFi (23 BPM INCR)
   a. Measure HR 88 BPM
   b. Measure Distance Walked 408 Feet
6. Weight of HiFi Prosthesis: ________ Lbs
7. Don HiFi Prosthesis
8. Rest 5 minutes
   a. Measure RHR 95 BPM
9. Walk 2 minutes in HiFi (22 BPM INCR)
   a. Measure HR 117 BPM
   b. Measure Distance Walked 465 Feet

DISCUSSION

The gait data illustrate the potential benefits of Compression-Release Stabilization, and although merely a snapshot of the results, significant data with much larger upper and lower limb patient data sets are planned for the future. The difference between a traditional ischial containment and the HiFi interface with regard to the delta between rest and post-exercise measurement was approximately 4% in favor of the HiFi, while the difference in distance walked given the same time period amounted to a significant increase of approximately 22% for the HiFi.

In no way do these singular cases allow us to draw formative conclusions as to expected results for all patients, but given the simple biomechanical nature of Compression-Release Stabilization and the laws of nature, it is fairly easy to understand why it might improve function for both upper and lower limb wearers in significant ways.

CONCLUDING REMARKS

With regard to upper limb, studies involving range of motion analysis under light and heavy loads, positional accuracy without visual aid, stability and bone motion within the interface are among some of the areas of interest. In lower limb, energy expenditure, preferred gait velocity, step length and overall gait quality will be assessed. In both upper and lower limb cases, heat dissipation and other temperature-related characteristics will be studied. Finally, a quality of life survey will be given to both upper and lower limb wearers of the High-Fidelity interface to assess their subjective impressions.

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