DEVELOPMENT OF A CLINICAL PROTOCOL FOR FITTING A MODIFIABLE FOOT KEEL

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INTRODUCTION

A novel prosthetic foot has been developed that is comprised of an injection molded plastic keel and cover, and designed so that the size and stiffness of the keel can be modified by selectively removing material. It is currently undergoing clinical evaluation in order to develop a suitable fitting protocol and to assess its long-term performance. While clinical practices are well established for static and dynamic alignment of lower limb systems, these generally assume that mechanical properties of the foot are not altered during the process. However, because there is an interaction between keel stiffness and the endpoint of dynamic alignment, a modified clinical protocol is required.

Figure 1a. Niagara Foot Modifiable Keel.
The C-spring, heel and forefoot each have layers of removable material to change the mechanical properties of the keel.

OBJECTIVES

To develop a clinical protocol for dynamic prosthetic alignment and keel modification that optimizes gait in a cohort of transtibial amputee patients by specifying a series of trial prostheses for use in the clinical workflow.

Figure 1b.
Split Heel and Toe Options

METHODS

The single-piece flexible keel (Niagara Prosthetics and Orthotics International, St. Catharines, Canada) is comprised of heel, forefoot, and C-spring (ankle) elastic features that can be modified by the removal of layers of material (Figure 1).

Mechanical testing was first undertaken for keel conditions that included combinations of reduced and non-reduced layers. Based on a previously reported method, testing produced reference data for expected changes in vertical deflection and stiffness during a standardize stance phase of gait [1]. Based on these measurements, a series of trial components was fabricated to span the range of modifications for the keel.

Initial walking trials using these components identified an appropriate modification as a starting point, followed by selective fine-tuning changes in the component stiffness, with corresponding adjustments to the alignment (Figure 2).

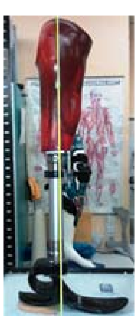

Figure 2. Static Alignment.
Initial static alignment is defined as shown. This is tuned dynamically for each keel during fitting protocol.

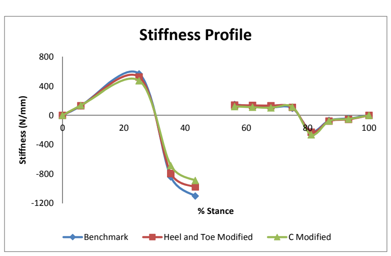

Figure 3. Stiffness Profiles of Modified Keels.

RESULTS

The effect of modification to apparent keel stiffness at specific points in the stance phase is shown in Figure 3. Heel and C-spring modification decreased measured heel stiffnesses by 10-50% compared to the unreduced case. Similarly, Toe and C-spring modification reduced toe stiffness by 7-15%. The mechanical testing suggested four trial components: (1) unmodified, (2) reduced heel, (3) reduced heel and toe, and (4) reduced toe. Their use in the fitting protocol corresponded qualitatively to the expected relationship between component stiffness, patient weight and activity level, but a majority required further modification as optimization was approached.

CONCLUSIONS

The use of four trial components that span stiffness ranges varying by 7-50% can be suitably integrated into the clinical workflow for prosthesis fitting using a modifiable foot keel. However, mechanical characterization is not sufficient to capture the activity level of all patients. As such, a fifth trial component is recommended in which a softened heel and toe are split longitudinally to accommodate activities on uneven terrain (Figure 1b).

REFERENCES AND ACKNOWLEDGEMENT

[1] Haberman, A (2008). Mechanical properties of dynamic energy return prosthetic feet. M.Sc. Thesis, Queen's University, Kingston, ON, Canada. Funding provided through the Donald and Joan McGeachy Chair in Biomedical Engineering.