OPTIMIZING SOCKET COMFORT AND PROSTHETIC ALIGNMENT UTILIZING PORTABLE SOCKET PRESSURE-SENSING TECHNOLOGY.

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INTRODUCTION

Prosthetic sockets and alignment have a large impact and are frequently a source of frustration for prosthetic users and their rehabilitation team. Several factors influence the success of a prosthetic user, including how comfortable the socket is and their ability to ambulate in a controlled manner. It has been shown that an ill-fitting and mal-aligned prosthesis increases the risk of falling significantly[1.] Additionally, proper alignment and a comfortable fit is needed to ensure a positive outcome for an prosthetic user's rehabilitation[2].

The pressure distribution between the residual limb and the socket interface is known to affect the overall socket fit[3]. The pressure distribution between the limb and socket varies throughout the course of a day, or over a period of time as the limb matures or biological changes occur. Because of changes consistently happening, it can be a challenge to properly evaluate socket fit consistently and thus unfavorable for those with limb loss.

Prosthetists have several interventions and dedicate significant time to properly fit and align a prosthetic socket for each patient. . The challenges of understanding and decoupling issues (improper alignment or interface residual limb-socket) [4], decision making based on anecdotal patient feedback and the usual trial-and-error methodology lead to a lengthy process until the final socket is obtained[1,5,6]. This methodology becomes quite problematic when patients are unable to fully communicate what they are feeling or have limited sensation within the residual limb.

The purpose for this case study was to investigate how to improve prosthetic socket fit and optimize prosthetic alignment. The goal was to determine if Adapttech's INSIGHT Technology and quantitative data could help improve overall patient care, alignment and fit-experience during their socket fitting process.

METHOD

The prosthetic clinic (Prosthetics and Orthotic Associates), in partnership with Adapttech Inc, approved this study and informed consent was obtained from the subject prior to participation.

Subject #1: 65 year-old female, right transtibial amputation and 3 years prosthetic use. Subject 1 experienced an amputation due to a failed knee replacement. She presents with a 2" tibial length followed by 4" of excess tissue at the end of her limb. She has experienced significant difficulties with control within her socket due to the excess tissue causing movement and knee instability. She also has a history of lack of sensation in her residual limb.

Subject #2: 40 year-old male, quadramembral amputations, experience severe pain, phantom pain and sensations, significant scar tissue, numbness over skin grafts, tightened skin and fragile skin tissue due to a sepsis infection. Due to significant 1. involvement, the subject had limited endurance, making socket assessment challenging.

Subject 3: 52 year-old male, left transtibial amputation and over 20 years prosthetic experience, who has significant limb numbness due to an artificial artery lying superficial between the tibial-fibular complex causing claudication.

Apparatus: INSIGHT System, a fitting solution for prosthesis; capable of mapping the patient's unique bio-data profiles (such as distributed socket pressure and temperature) over the 3D model of the prosthetic socket's inner surface in real time.

Procedures: Qualitative process using regular patient and clinician interactions within a clinical environment.

Data Analysis: INSIGHT App was used to present pre and post data on socket pressure, distribution of socket pressure and patient satisfaction.

RESULTS

Subject #1: Apprehensions and fear of appointments were eased by the clear information given through the INSIGHT system by way of bio-imaging. Patient-prosthetist dialogue was significantly improved allowing better understanding mutually. Socket fit with adjustable panel design was optimized and alignment improved in faster time compared to previous socket fitting appointments. Fitting time was also reduced from 15 visits to 9 visits.

Subject #2: Although Subject 2 could only stand for a short period of time, using INSIGHT's recording feature, socket fit can be captured, reviewed, and evaluated with ease. Sensors are placed in areas that are numb to help indicate if there's too much pressure – aiding the subject, who as a new user and unable to give good detail as to what he's feeling. INSIGHT helped to alleviate frustration and stress that patients like Mitch experience when attempting to describe what they are feeling within their socket. It allowed for the physical therapist to also learn optimized gait and fitting due to the portable design of the technology.

Subject #3: The intermittent claudication was eliminated due to immediate knowledge of where the artificial artery was because of pressure sensing technology. The subject's extensive prosthetic problems for over 20 years were rectified with one visit using pressure-sensing technology.

CONCLUSION AND SIGNIFICANCE

The most common complaint among prosthesis users is that the socket does not fit properly.

The goal of this case study was to see how INSIGHT Technology may help enhance overall patient care and fit-experience during the socket fitting process by using objective measurements and quantitative data. If fit quality measurements could be established, they might be utilized in clinical practice to track users' socket fit and alignment, as well as determine when a socket/alignment needed to be changed. Results suggest therefore, benchmark data systems will assist both clinicians and payors in patient management by minimizing the number of design fitting interactions required to attain and maintain a good socket fit. This will help the prosthetist progress toward a "right first time" approach to socket fitting by giving a clinical tool to analyze socket fit and alignment during the rehabilitation process.

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DISCLOSURE

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