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A NOVEL RESEARCH AND CLINICAL APPROACH TO USING GEL LINERS FOR COLLECTION OF SURFACE MYOELECTRIC SIGNALS FOR PROSTHETIC CONTROL

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ABSTRACT

For more than two decades, individuals with lower limb amputations have been successfully fitted with gel liners constructed from a variety of materials. Prosthetists have also reported moderate success with gel liners fit to individuals with upper limb amputations who use externally powered prostheses. At the Center for Bionic Medicine, we have explored a novel approach to collecting myoelectric signals from individuals with lower limb or upper limb amputations—using electrodes embedded in gel liners. Initial designs have proven more comfortable and easier to don than traditional suction sockets and have allowed us to eliminate the need for separate connection of pre-amplifiers. We believe this technology will be of benefit to individuals with upper or lower limb amputations and eliminate some of the clinical challenges and reported drawbacks of current myoelectric fittings. The next step is to combine the new liner technology with advanced electronics to control actuated drive units in both upper limb and lower limb prostheses. In this contribution we describe the evolution of this liner technology from initial experiences through current status to future directions.

INTRODUCTION

Suction Sockets

Many prosthetists have used suction suspension as the primary or sole means of suspending transhumeral or transradial prostheses. Traditional suction sockets, where the limb is in direct contact with an undersized socket, have been widely used, particularly in the transhumeral population. Much of the theory behind the design of these sockets comes from experiences fitting individuals with transfemoral amputations. Traditional suction sockets provide all of the benefits of total contact sockets, including distribution of forces over larger surface areas to decrease concentrated areas of pressure, decreased edema, increased control of the prosthesis, and enhanced proprioception of the terminal end of the prosthesis [1, 2]. Additional benefits to upper limb–prosthesis users may be an increased abduction range of motion (ROM) and better cosmesis, both due to lower lateral trim lines. Elimination of the harness is also possible depending upon which input devices are used and whether or not a hybrid system incorporating body-powered components is used. At a minimum, adding suction to the total contact socket concept has enabled many individuals to tolerate the use of transhumeral prostheses by decreasing the amount of pressure in the contralateral axilla [3], thus preventing neuropathies of the contralateral arm and hand [4]. In a case study, Vacek [5] reported that elimination of tight harnessing prevented tingling or sensation loss, and concluded that prosthesis comfort directly affects an individual's tolerance of, and desire to continue to wear, the device.

Quasi-Hydrostatic Fittings

If the socket is appropriately undersized, it offers the ability to achieve a semi- or quasi-hydrostatic socket environment. Stokosa [6] coined the phrase *Total Surface Bearing (TSB)* for transtibial socket design in which "*the entire surface of the residual limb is in total contact with (the) socket while every unit area is under compression to its proportionate tolerable level,*" and points out that there is a difference between TSB and hydrostatic concepts. Kahle [7], comparing transtibial designs, defines hydrostatic design based on the mechanical properties of fluids and Long [8] states that utilizing the hydrostatic interface design promotes tissue elongation, increasing distal padding and producing a residual limb with a firmer tissue consistency. This is especially important for control of the prosthetic socket in levels of amputation where the soft tissue is less more mobile, which occurs when only one bone is present in the soft tissue—for example in transhumeral or transfemoral amputations. Kahle [7] contends that a proximal seal with the humeral epicondyles is essential for achieving a hydrostatic fit when utilizing roll-on gel liner technology in transtibial sockets. Miguelez [9] asserts that a secondary benefit of hydrostatic fit— the lack of movement of transradial sockets during loading—can be attributed to muscle contouring as opposed to soft tissue compression alone. If true, these latter two statements suggest that liners must be designed so as to (i) create a seal at the proximal socket (gleno-humeral joint or humeral epicondyles for transhumeral or transradial limbs, respectively) and (ii) capture more muscle contours.

The method used to don the socket will affect the ability to achieve a hydrostatic fit. In traditional suction sockets, hydrostatic fit has been achieved with the use of a donning aid. This donning method is challenging for

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individuals with unilateral and bilateral amputations as they need to balance their prosthesis while simultaneously donning the device. Additionally, the inner socket is customarily made of a semi-rigid or rigid thermoplastic, which may become uncomfortable as the user attempts to attain the end ranges of shoulder motion (i.e. glenohumeral flexion and abduction). This is due to the weight of the device creating a force couple that places an intolerable pressure on the distal aspect of the humerus.

The first four individuals with transhumeral amputations who underwent targeted muscle reinnervation (TMR) were fit with traditional suction sockets and cited the donning method as one of the major deterrents to wearing the device: an additional difficulty for TMR subjects is the necessity of precisely orienting their limb with respect to the electrode contacts within the prosthesis in order to achieve optimal alignment for myoelectric control.

Gel Liners

Early designs of gel liners were custom-fabricated over a modified positive model. Ossur Kristinsson first developed this technology, which evolved into viable off-the-shelf liners. A majority of residual limbs can be fit well with appropriately sized off-the-shelf liners, although custom-fabricated liners are still utilized for limbs requiring special attention. Most gel liners are fit to individuals with lower limb amputations for reasons of comfort, suspension, and because the increased shear force between the limb and liner (and decreased shear between the liner and socket) protects skin on the residual limb from friction caused by relative movement of limb and socket interface. An additional benefit is the option of applying sub-atmospheric pressure to the limb-socket interface. Some gel-liner manufacturers use terms such as *TSB* and *hydrostatic* in their product information, however, these varied fitting goals are achieved in many different ways and, although some are based on published specifications, are quite generic in their product applications. Attention should be paid to using these liners as hydrostatic fittings as this requires a distal distraction of the residual limb, which creates elongation and a reduction in cross-sectional area. One method of employing this change in soft tissue geometry is with the use of a lanyard added to the end of the liner to pull the limb into the socket. Another technique, more easily implemented in lower limb prostheses, is using a liner with an added distal pin: while the pin is engaged in the locking mechanism, repetitive loading (weight bearing) and unloading will elongate and circumferentially reduce the limb in size and the pin will further engage into the locking mechanism.

Although roll-on gel liners have been historically used in lower limb fittings, there has been some previous use of this technology with upper limb prostheses. Radocy [10], who has a transradial amputation, presented some of the earliest information on, and evaluation of efficacy of, roll-on gel liners with upper limb prostheses. Early in the development of *silicone suction socket (3S)* technology, it was reported that this fit prevents pistoning of the prosthesis and reduces or eliminates perspiration because there is no air layer between the skin and the socket wall [10]. Radocy [10] reported that the combination of a supracondylar socket and silicone liner provided superior suspension, improved performance during rigorous activities, and reduced or eliminated residual limb–to–socket rotation. The reduction in pistoning and rotation is beneficial for both suspension and maintenance of skin integrity; however, lack of perspiration may decrease surface myoelectric signals.

Daly [11] and Salam [12] utilized roll-on gel liners for both transhumeral and transradial fittings using different techniques for myoelectric signal detection.

In each study, when using roll-on gel liners in transhumeral or transradial sockets, individuals were able to achieve increased ROM. In addition, lower trim lines were possible. For transradial subjects, Daly [11] reported an average increase in ROM of 22.33º and an increase of pull force (before losing suspension) of 30 lbf. Daly [11] reported an average ROM from 8.57º to 120º and a pull force of 37 lbf (with two of the trials exceeding 50 lbf) for his transhumeral subjects. Since no comparisons were made between higher trim lines and roll-on gel liners, it is difficult to determine whether the lower trim lines or the gel liners caused the increase in ROM. Miguelez [9] might argue that neither is the determining factor, due to the fact that his transradial socket design has neither lower trim lines than conventional fittings nor does it necessarily utilize gel liners, yet he reports greater range ROM.

Salam [12] cut holes in gel liners to allow skin to protrude and make contact with the electrodes, and Bill Hansen (Liberating Technologies, Inc.) has proposed using gel liners with conductive patches. Both approaches have similar drawbacks: the hole/patch location must be exactly placed and cannot be moved. However, both have the potential benefit that all wires are self-contained. Daly provided for the transmission of myoelectric signals through the gel liners via snap electrodes—a method we commonly employ in a research setting. This technique permits the individual to don the liner (with contacts incorporated) and then snap a wire harness to the electrodes before inserting the liner into the socket. One major drawback with this approach is the need to protect the wire harness. Both Daly and Salam claim that users are able to don the liner so that the electrodes consistently end up in their correct location. This can be accomplished by practice, by referencing anatomical landmarks, or by referencing marks tattooed on the skin [12]. Salam described the ability to have "more proximal placement of electrodes, if needed, without fear of breaking suction" [12]; his conclusion is based on how the electrodes contact the skin and the size of the electrodes and pre-amplifiers. The underlying question to answer is, is one method of socket interface more reliable or repeatable for electrode placement and congruity than another?

DISCUSSION

The evolution of our gel liner design has involved many changes. Much of the earlier work investigated using a stainless steel contact dome and custom-fabricated stainless steel discs (buttons) to create electrode contacts. These configurations would transmit myoelectric signals through the liner and form a junction with a disc magnet that was embedded in the inner wall of the socket and attached to an external wire leading to the pre-amplifier (Figure 1). This method works well in the laboratory setting on able-bodied subjects and for some individuals with transradial and transhumeral amputation, but requires further refinement and investigation. Challenges arise when the prosthesis user experiences significant movement of residual limb soft tissue so that the button disengages from the magnet. This was problematic for subjects with transhumeral amputations who had undergone TMR and had substantial movement of their soft tissue during muscle contractions.

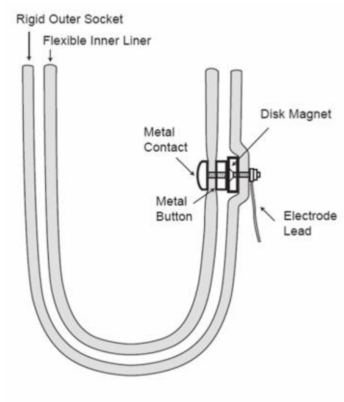

Figure 1: An example of an early iteration of electrode/signal contact interface between gel liner and socket

While investigating new socket interface designs for myoelectric fittings, we became involved in the DARPA Revolutionizing Prosthetics 2009 project. Specifications outlined there steered us toward redesign so that the myoelectric signals were fed into the electronics at the distal aspect of the limb-socket interface. It was necessary to transmit the myoelectric signals along the liner to the distal end through wires or conductive leads. Since the liner was to be inverted and rolled 180° with respect to itself, the signal transmitting material used had to be flexible enough to withstand severe and repetitive flexing. We have investigated using a conductive textile fabric in an attempt to create a liner with signal transmission leads that can undergo the donning and doffing process without serious fatiguing or failure, and would ideally maintain myoelectric signal quality and continuity throughout the useful lifetime of the liner. In order to use this material, custom distal connectors had to be fabricated to receive the leads as they exited the liner. The fabric leads used with these liners are currently being investigated. Various sizes, shapes, and durometers of contacts are being optimized through an experimental process to determine the optimal design thus far; this concept has evolved through numerous designs and has been used in trial fittings. These experimental liner systems have been tested in conjunction with the latest electronic hardware and software developments at the Center for Bionic Medicine (CBM) at the Rehabilitation Institute of Chicago.

FUTURE WORK

Much of the preliminary fitting of these liner systems has been within the research setting at the CBM at the Rehabilitation Institute of Chicago. Refinement of the liner design and interface continue as these systems need to be robust enough for field testing. It is our hope that such testing will provide valuable feedback regarding durability and effectiveness of these liners in a real-world setting.

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