

CLINICAL FITTING OF FOUR PATIENTS USING MYOELECTRIC PROSTHESES AND GEL LINERS WITH MAGNETIC COUPLING FOR TRANSMISSION OF ELECTROMYOGRAPHIC SIGNALS

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Research and development had been undertaken regarding the utilization of gel liners in conjunction with myoelectric fittings. To date; four individuals with various limb presentations and prosthetic components have been fit clinically with prostheses that incorporate gel liners and magnetic couplings that are being used for the transmission of the electromyographic (EMG) signals. The levels of amputation for these individuals include: one long transhumeral, one elbow disarticulation, and two transradial limbs. Different surgical techniques and components have been used for each of these designs based on etiology of amputation, residual limb length and patient preference. Two of the limbs, the long transhumeral and one of the transradial, have undergone targeted muscle reinnervation (TMR), while the other two have not. Three of the prostheses have: electronic wrist rotators, multi-articulating hands, and pattern recognition hardware, but not necessarily in this combination. The common factor between all of these fittings revolves around the utilization of gel liners with the magnetic coupling design.

Myoelectric fittings and sockets for upper limb prostheses have taken on many shapes and designs over the past few decades. As prosthetists attempt to create more comfortable and effective designs; the incorporation of softer interfaces has been evolving. Flexible inner sockets, such as those used in transfemoral fittings, had been proposed by Berger, et. al. in the early 1980s with the Iceland-Sweden-New York (ISNY) design. [1] Although this type of socket design, consisting of flexible thermoplastic inner socket within a fenestrated laminated outer frame, has been much of the standard in transfemoral prosthetic fittings; the popularity of this design still has yet to become a reality for upper limb prosthetic fitting. Since myoelectric (non-hybrid designs) don't require cabling for activation of segments about a joint, many prosthetists strive

to provide sockets/prostheses that are "self-suspended" via the anatomy of the individual, thus eliminating the need for a harness.

Early forms of transradial, self-suspending designs include the Muenster design, with compression from anterior-to-posterior with trimlines that straddle the biceps tendon and cup over the proximal olecranon. This design is primarily used for shorter residual limbs. The Northwestern supracondylar design, with medial and lateral compression above the humeral epicondyles is used for longer residual limbs, and has a lower anterior trimline permitting greater range of motion in the sagittal plane. Another design, one created by Otto Bock, takes advantage of both anterior-posterior and medial-lateral compression and is designed for the medium length limbs. Two other socket configurations for transradial limbs, the Anatomically Contoured and Controlled Interface (ACCI) [2] and Transradial Anatomically Contoured (TRAC) [3] design had been created in the late 1990s and early 2000s. These designs incorporate many of the principles from the aforementioned three designs with added features that are claimed to benefit the wearer by providing increased stability, suspension and comfort. There tends to be debate on the overall benefits of these self-suspending designs. Tighter fitting sockets frequently make sockets more difficult to don and often decrease range of motion and comfort.

Self-suspending designs above the elbow are mainly reserved for individuals with elbow disarticulation amputations who retain their humeral epicondyles. Surgical intervention such as the Marquardt angulation osteotomy has improved suspension and rotational control for levels proximal to the elbow disarticulation. [4] Additionally, there have been more recent attempts at re-establishing humeral epicondyles by implanting hardware to replicate the shape of the amputated distal humerus. Namely, the Humerus-T-

Prosthesis has been used for both suspension and rotational control of a prosthesis with claims to have improved comfort and function for the user. [5] Various methods of osseointegration, invented by Per-Ingvar Branemark in the 1950s and improved upon in recent decades, has become a topic of great discussion as of late and has potential for revolutionizing prosthetic control for individuals with all levels of amputation, including the transhumeral level.

One of the more conventional, non-surgical means of socket alteration for the transhumeral level is based on concepts that J. Thomas Andrew, CP had provided in his review of the “Dynamic” transhumeral socket. [6] This incorporates tighter medial-lateral compression of the arm and soft tissue, with substantial anterior-posterior compression at the proximal socket, surrounding the humeral head. Although this does not provide for self-suspension, it is frequently used in conjunction with “traditional suction sockets”, where the user dons the socket with the use of a donning aid, i.e. Teflon lined bag, and also provides improved control of the prosthesis over former “passive” transhumeral socket designs.

In addition to comfort within the socket, control of the myoelectric prosthesis is paramount. When the user moves through a variety of motions and tasks; traditional sockets with semi-rigid interfaces and/or packaged electrodes don’t always maintain the electrode contact and control necessary to perform the intended operation. Gel liners have been used for several years in conjunction with body powered upper limb prostheses [7] and in combination with myoelectric prostheses. [8,9] Liners with “snap” or MagneSnap™ electrodes are most similar in design to those of this paper, however, it is required that the user manually attach the wires to the liner and electrode. The liner-magnet interface being described in these four prostheses is designed such that the threaded stud of the electrode dome is pierced through the gel liner from inside to out, in the location of one of the desired bi-polar myo-sites, and is secured on the outside of the liner with a martensitic, stainless steel disk. Within the inside wall of the flexible inner socket; a countersunk, ring magnetic is recessed and mounted via a flat-head machine screw that has been inserted through the magnet and flexible inner socket with the electrode lead being secured on the outside of the socket by a washer and hex nut. (Figure 1) With this design, the user dons the liner and then the prosthesis without having to secure any of the leads to the outside of the liner or cautiously feed the liner and leads back into the prosthesis

to prevent damage. As with any liner system, the orientation of the liner is critical and is made easier by the appropriate trimming of the liner, association of stitching and domes with anatomical landmarks such as scars or blemishes, and with practice.

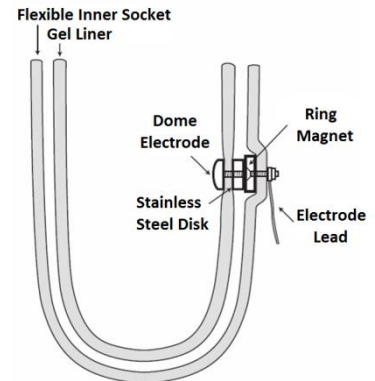


Figure 1

All of the individuals described in this manuscript have given consent to photographs and mention of their cases and prostheses. Patient 1 has a long transhumeral amputation and short transfemoral amputation secondary to trauma. He was fit with his transhumeral myoelectric prosthesis secondary to TMR procedure and involvement in research regarding the efficacy of pattern recognition control subsequent to that procedure. Although involved in research; the prosthesis was fit and provided in the clinical setting. Donning the socket using traditional suction via a donning aid proved difficult. Therefore; it was proposed to attempt fittings with the new design. Being the first individual for whom this gel liner approach was provided; several design considerations were made which have been altered as this approach has evolved. The fitting of this individual includes the customized gel liner with contacts

and stainless steel disks. In addition to the contacts, a small cord had been added to the outside of the liner which aligns the liner with a recessed channel in the flexible inner



Figure 2

socket. This feature was incorporated in order to insure appropriate alignment of the limb and liner as the socket was donned. (Figure 2) Due to the shape and length of the limb, along with all of these contacts and magnets (17 in total), this individual found it difficult to push into the socket past the magnets. A donning bag was then used as a separator between the disks and magnets to permit the limb and liner to be inserted more easily into the socket and was then removed through a traditional valve to provide both a fully seated limb and magnetic contacts between the disks and magnets. The components that were used for this

individual were a Dynamic Arm TMR, Electronic Wrist Rotator, Myobock Hand and Glove, and Greifer Terminal device. Pattern recognition control was used as the method for signal acquisition and processing and proved effective for all three degrees of freedom.

Patient 2 has an elbow disarticulation limb secondary to complications with Complex Regional Pain Syndrome (CRPS). His fitting took several months as he experiences significant pain in his residual limb, requiring a spine stimulator. The first approach to fitting this gentleman was using a test socket alone with harness; progressing to the addition of an endoskeletal elbow and forearm and then gradually adding weight to the device. TMR procedure was discussed, but due to the complexity of the CRPS, was not performed. The new design with gel liner was proposed and utilized due to the sensitivity of the individual's limb and difficulty in donning the socket comfortably. Donning of the liner was difficult, at first, and using the donning bag for securing the limb/liner combination into the socket was necessary early on in the fittings. As the individual became accustomed to the design and fitting, it was no longer necessary to don the device using the aid. Instead; he rolled on the liner and pushed his limb into the socket. Greater challenges for the prosthetic team were the design of the prosthesis. Because of the individual's long residual limb and the weight of the Electronic Wrist Rotator and iLimb Ultra Revolution Hand, it was decided to combine outside locking hinges with an Automatic Forearm Balance mechanism. (Figure 3) Squaring the joints, correctly

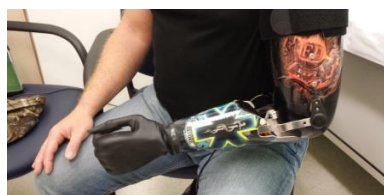


Figure 3 the elbow axis proved difficult.

contouring the proximal forearm section, placement of the pattern recognition hardware and routing of the wiring around the elbow axis proved difficult. Patient 3 sustained a transradial amputation secondary to trauma and subsequently underwent TMR procedure. The time from initial fitting to completion of the device was quite lengthy due to several factors, including: reinnervation of the forearm muscles, pain in the residual limb, contralateral shoulder pain and surgery, and design of the prosthesis that was aesthetically acceptable. The latter concern was secondary to the residual limb being of mid-length and the utilization of pattern recognition hardware, battery, and *bebionic* hand. The liner system used for this gentleman has a pin locking mechanism. Although length

of the overall prosthesis was of concern; the comfort of reduced trimlines and distal suspension advantages outweighed the slightly longer forearm. (Figure 4) This gentleman did not have to abduct and internally rotate his shoulder as much due to the lower trimlines and the use of a flexion wrist unit. The



Figure 4

The major concern for this user is the duration of battery life in the device. Because of this, two 2200 mAh flat, split cell batteries were combined in parallel to increase the overall capacity of the system. This has yet to prove effective in offering a full day use of the system with both Coapt pattern recognition hardware and *bebionics* hand.

Patient 4 had sustained quadrimembral amputations secondary to sepsis. He has bilateral transtibial, left transhumeral and right transradial amputations. Body powered prostheses had been fit to this individual and he subsequently requested a transradial myoelectric device as well. His lower limb prostheses utilize roll on liners that he dons independently. When fitting the transradial test sockets, both traditional self-suspending socket design and pin-locking liner design were attempted. This gentleman preferred the ease and comfort of donning the pin-locking liner and socket. He is able to begin to don the liner with the aid of a stationary platform or wall and using his transhumeral limb; he rolls the liner up onto his humeral section. Donning the pin locking liner with electrodes, disks and magnetic socket connection is quite easy as he has direct control (two sites) with only five disks necessary. Two



Figure 5

Two pairs of disks are for obtaining the bi-polar EMG from wrist flexor and wrist extensor sites, while the fifth contact is the paired reference site. (Figure 5) The hardware being used are an electronic wrist rotator and an iLimb Quantum hand.

In four different prosthetic designs, a customized gel liner and magnetic coupling configuration have been successfully used. Whether it 5, 15, or 17 contacts, the users were able to don the devices and align the limbs such that the EMG signals were transmitted effectively through

the dome electrodes, stainless steel disks, ring magnets, machine screw and wire leads down to the pre-amplifier. Utilization of liners, in this manner, improved comfort, range of motion and ease of donning as compared to traditional self-suspending designs or hardware that require fastening to the liner during donning.

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