

Clinical Evaluation of Implantable Myoelectric Sensors (IMES[®])

James Vandersea, CPO

Background

The purpose of the study is to demonstrate the safety and functionality of implantable myoelectric sensors (IMES[®]) to detect and wirelessly transmit EMG from within residual forearm muscles and to use these signals to simultaneously control three degrees of freedom offered by existing electromechanical prosthetic components.

Method

The goal of this first-in-human feasibility study is to implant three subjects, status post mid length transradial amputation, with up to eight IMES[®] placed in specific muscles controlling wrist rotation, finger extension and flexion and thumb abduction and adduction. Signals from these implants are intended to control the same movements, both independently and simultaneously, in a prosthetic wrist and hand.

The IMES[®] devices are powered by a magnetic field produced by a coil that is wound circumferentially around and laminated into the wall of the prosthetic frame. The coil does two things, one it creates an electromagnetic field charging the IMES[®] electrodes and secondly acts as an antenna receiving the information back from each of the IMES[®] implants.

Each IMES[®] device amplifies, filters, rectifies and integrates the detected signal using parameters set up during initialization.

The main requirements for eligible study subjects include:

Patients must :

- be at least 18 years old
- Have suffered Transradial amputation with one-third or greater residual forearm length
- Have residual forearm anatomy (based on number and size of residual muscles) that will support the implantation and control of at least six IMES[®]
- Have experience using a myoelectric prosthesis
- Have no metal fragments or metal implants in the amputated arm
- Have no active implants (pacemaker, drug infusion device, etc)
- Be willing to come to the hospital for prosthetic training and assessment testing
- Be willingness to wear the IMES[®] prosthesis at home

Eligible subjects will have six to eight IMES[®] surgically implanted. Once subjects recover from surgical implantation of IMES[®] (approximately two weeks) they will begin pre-prosthetic training using a universal, table top prosthesis which allows them to practice IMES[®] control while swelling in the residual limb subsides and before the fitting and fabrication of their custom- fit, take-home prosthesis. subjects will begin six months of prosthetic training. Training includes in clinic sessions supervised by an OT coupled with independent use at home.

Subject 001

This individual suffered a right transradial amputation secondary to trauma caused from an IED blast injury while serving in the armed forces in 2012.

Eight IMES[®] electrodes were implanted into specific muscles on the subject (see x ray below).

Each muscle was chosen according to its natural human anatomical function and paired with an associated prosthetic function.

Muscle Implanted with IMES[®] Assigned Action

Extensor Digitorum Extend all fingers

Flexor Digitorum Profundus Flex all fingers

Extensor Pollicis Longus Abduction of thumb

Flexor Pollicis Longus Adduction of thumb

Pronator Teres Wrist Pronation

Supinator Wrist Supination

Flexor Carpi Ulnaris -not assigned-

Extensor Carpi Radialis -not assigned-

Preliminary Results

After the initial encapsulation period, the subject started to train with the table top training prosthesis. On the first day of training the subject demonstrated his ability to control, both individually and simultaneously, all three degrees of freedom offered by the prosthetic wrist and hand.

AS soon as his new IMES[®] prosthesis was programmed, the subject underwent a series of assessment tests for the purpose of collecting data to compare functional ability both pre-IMES[®] and immediately post IMES[®]. Future assessments will take base on a monthly basis for six

months to determine the change in function with training and experience. Functional outcome tests included the ACMC, SHAP, and BBT.

Subject #001's experience to date demonstrates IMES[®] functioning as intended, i.e. picking up and transmitting EMG information and processing that information to drive a prosthetic device. The subject had reasonable initial control of the prosthesis. It is anticipated that with continued occupational therapy and training, the subject's control will improve. The subject initially reports more natural, intuitive control of the prosthesis.

Subject #001 demonstrates that three degrees of simultaneous control can be attained with existing prosthetic technology.

Discussion

Increase use of the IMES[®] implantable electrodes will help drive future developments in prosthetic technology. Prosthetic companies will have to look at ways to increase prosthetic function, increase the number of simultaneous degrees of freedom.

future work implanting IMES[®] electrodes in addition to procedures like Targeted Muscle Reinnervation surgery, neural integration and or combining IMES[®] electrodes with other technologies like pattern recognition will need to be examined to see if it will increase prosthetic function.

References

1. Weir, R.Fff.; Troyk, P.R. ; DeMichele, G. ; Kuiken, T. Implantable myoelectric sensors (IMES) for upper-extremity prosthesis control- preliminary work Engineering in Medicine and Biology Society, 2003. Proceedings of the 25th Annual International Conference of the IEEE