Submitted Article: *First-in-Man Demonstration of a Fully Implanted Myoelectric Sensors System to Control an Advanced Electromechanical Prosthetic Hand*

Corresponding Author: Dr. Paul F. Pasquina, Paul.F.Pasquina.mil@health.mil

Reviewer Comments and Responses

Reviewer #2:

1) A number of the authors are affiliated with the Alfred Mann Foundation and as a result it would be very helpful if they included a Conflict of Interest statement. Please describe in detail how any potential conflicts of interest have been managed in this trial.

   Response: A signed Conflict of Interest Statement has been completed by all authors affiliated with the Alfred Mann Foundation (see attached document). In addition, a statement of clarification of potential Conflict of Interest has been added to the manuscript (Please see Section 5.1).

2) This study has been approved by the FDA but there must also be an IRB which has approved this protocol. Please provide a statement that the entire research protocol has been approved by an IRB.

   Response: A statement has been provided to this effect. Please see Section 1 (Introduction) in the last sentence of paragraph 4 of that section (pg. 3).

3) Since the study only describes the outcome from the first patient, it would be helpful if the authors included more details about:
   a. The patient (demographic data, co-morbidities, associated injuries, operative procedures performed prior to amputation and since amputation, length of time since amputation, issues related to pain, issues related to neuroma, any evidence of complex regional pain syndromes, medications they are currently taking including narcotics, etc…)
   b. The operation performed (length of time, incisions, complications, etc…)
   c. The postoperative course and any untoward events

   Response: Please see Section 3 (Results), paragraphs 1-3 of this section (pgs. 8-9 of this manuscript) for additions and changes addressing comment #3 and sub-comments 3a-3c.

4) What was the sensitivity and specificity of the signals recorded from each IMES device?

   Response: Please see Section 2.1 (Materials), in paragraph 3 of this section (page 4 of this manuscript).

5) What was the signal to noise ratio?

   Response: Please see Section 3 (Results),the end of paragraph 4 of this section (page 9).

6) How long did it take to position the residual limb in the socket to get the appropriate fit for high resolution signal processing?

Response: Please see Section 3 (Results), the middle of paragraph 4 of this section (page 9).

7) How long was he able to use the device in a single session?

Response: Please see Section 3 (Results), paragraph 8 of this section (page 10).

8) It would be helpful if more quantitative outcome measures were reported in this manuscript including preoperative box and blocks using a standard prosthesis as compared to use of the IMES controlled prosthetic limb postoperatively. This would provide the reader a more detailed understanding of the outcomes achievable with this approach.

Response: While the investigators have been collecting this detailed data, because the current study is under FDA and IRB oversight, detailed results are unavailable at this time; however the authors still believe that this descriptive interim reports of our current study would be beneficial for the readership. (Please see statement in Abstract under Results, as well as an additional statement added to Section 3 [Results] in the first paragraph of this section [pg. 8]).

Reviewer #3:

Comments

1) Several authors are employees of the Alfred Mann Foundation, which manufactures the IMES devices. A conflict of interest disclosure should be included for those authors employed by AMF.

Response: A signed Conflict of Interest Statement has been completed by all authors affiliated with the Alfred Mann Foundation (see attached document). In addition, a statement of clarification of potential Conflict of Interest has been added to the manuscript (Please see Section 5.1).

2) Although FDA protocols prohibit publication of detailed results at this time, it would be helpful to provide readers with additional demonstrations of the system performance. Would it be possible to include videos to illustrate operation of the system?

Response: Videos are available at: http://www.popsci.com/article/technology/video-marine-prosthetic-hand-controlled-his-own-muscles as well as http://www.nbcwashington.com/video/#!/news/health/Meet-the-Man-With-the-Bionic-Hand/242813381, although the authors are unaware of the mechanism by which the J. of Neuroscience Methods might obtain copyright permission.

3) The methods section contains few details about the design and operation of the IMES technology. Many readers will find it helpful to understand at least the basic functions performed by the device in acquiring and conditioning the EMG signal for control. For example, what is the sampling rate? Filter settings? Integration window length? Gain? How does the system handle data dropout (e.g. if a sample is lost during transmission)?

Response: Please see Section 2.1 (Materials), in paragraph 3 of this section (page 4) as well as paragraph 6 of this section (page 5).

Detailed comments

4) Page 3, paragraph 2, last sentence: insert a space between 'individual' and 'superficial'

   Response: Please see Section 1 (Introduction), in the middle of paragraph 3 of this section (pg. 3).

5) Page 6, paragraph 3 states that regional anesthesia is used. Please provide more details on how this was achieved.

   Response: Please see Section 2.2 (Methods), in the middle of paragraph 4 of this section (at the end of pg. 6).

6) Page 7, paragraph 3: What happens to the devices and participants upon completion of the study? Will the devices be removed or left in?

   Response: Please see Section 2.2 (Methods), at the end of the last paragraph of this section (paragraph 8, pg. 8).

7) Page 9, paragraph 4 states that 'no pattern recognition system is currently commercially available'. I believe there is at least one company marketing a pattern recognition system for myoelectric control. See http://www.coaptengineering.com/

   Response: Please see Section 4 (Discussion), at the end of paragraph 2 of this section (pg. 11).