Psychophysical testing of visual prosthetic devices: a call to establish a multi-national joint task force

2014 J. Neural Eng. 11 020301

(http://iopscience.iop.org/1741-2552/11/2/020301)

IOP Publishing Journal of Neural Engineering
J. Neural Eng. **11** (2014) 020301 (2pp) doi:10.1088/1741-2560/11/2/020301

Preface

Psychophysical testing of visual prosthetic devices: a call to establish a multi-national joint task force

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Recent advances in the field of visual prostheses, as showcased in this special feature of *Journal of Neural Engineering*, have led to promising results from clinical trials of a number of devices. However, as noted by these groups there are many challenges involved in assessing vision of people with profound vision loss. As such, it is important that there is consistency in the methodology and reporting standards for clinical trials of visual prostheses and, indeed, the broader vision restoration research field.

Two visual prosthesis research groups, the Boston Retinal Implant Project (BRIP) and Bionic Vision Australia (BVA), have agreed to work cooperatively to establish a multi-national Joint Task Force. The aim of this Task Force will be to develop a consensus statement to guide the methods used to conduct and report psychophysical and clinical results of humans who receive visual prosthetic devices. The overarching goal is to ensure maximum benefit to the implant recipients, not only in the outcomes of the visual prosthesis itself, but also in enabling them to obtain accurate information about this research with ease. The aspiration to develop a Joint Task Force was first promulgated at the inaugural 'The Eye and the Chip' meeting in September 2000. This meeting was established to promote the development of the visual prosthetic field by applying the principles of inclusiveness, openness, and collegiality among the growing body of researchers in this field. These same principles underlie the intent of this Joint Task Force to enhance the quality of psychophysical research within our community.

Despite prior efforts, a critical mass of interested parties could not congeal. Renewed interest for developing joint guidelines has developed recently because of a growing awareness of the challenges of obtaining reliable measurements of visual function in patients who are severely visually impaired (in whom testing is inherently noisy), and of the importance of comparing outcomes amongst the many research teams that have entered this field, all of which are using different devices implanted at various locations within the visual system and different methods of assessing efficacy. Researchers at the BRIP and BVA believe that use of common methods for testing and for reporting results would benefit all scientists and clinicians in the field, the agencies that regulate human testing, corporations that are invested in the success of this field, and, most importantly, potential patients.

The Task Force will be formed with the intent of developing substantive recommendations to provide a measure of consistency and quality control within the field. The guidelines will offer recommendations for the assessment of the: (1) baseline (pre-implant) visual status of potential patients (including specification of the disease diagnosis and impact on visual functioning) and (2) post-operative visual function. The guidelines will be available to the public, research groups and companies. Any groups that choose to adopt the recommendations would be encouraged to include a formal statement of compliance in their presentations and publications. The Task Force will develop these guidelines with the understanding that the ability to perform experiments in the suggested manner might be limited by the particular engineering design and functionality of different prosthesis devices. It is not the intent of the Task Force to write strict test protocols for all parties to follow, but instead to work cooperatively as a research field to develop guidelines

[1] JFR and LNA are representatives for the Boston Retinal Implant Project and Bionic Vision Australia, respectively, and have contributed equally to this preface.

about the types of tests that should be implemented, and how they could be reported in a similar format between groups.

The opportunity to participate on the Task Force is open to all researchers, clinicians and other specialists who work in the fields of sensory prostheses (both visual and cochlear implants), molecular therapy, stem cells, optogenetics or other fields that share a similar goal of restoring vision to the blind. Decisions about the guidelines will be made democratically, with precautions to prevent any one group or company from having a more dominant voice than any other. One or more smaller working groups may be established to delve more deeply into specific issues, like the ethics of testing or governance structure, and to develop specific wording for recommendations that would be voted on by the entire Task Force group. Ultimately, the various recommendations, once approved democratically, will serve as the consensus document for the Multi-National Joint Task Force. The full list of members of the Task Force and the rules of governance will be published to promote transparency.

The Joint Task force will post its guidelines with all signatories on a dedicated page within the website of the Henry Ford Department of Ophthalmology (Detroit). This site was chosen in recognition of the consistent support that Phillip Hessburg MD and the Board of Directors of the Detroit Institute of Ophthalmology, which has recently merged with the Henry Ford Department of Ophthalmology, have so generously and selflessly provided to our field over the past 14 years. This website will also contain a list of all human psychophysical testing that has been performed in the visual prosthetic field, with designations for those studies that were performed in accordance with the guidelines of the Multi-National Task Force, which will assume responsibility for the accuracy of the material.

For those who wish to join this Task Force or have further questions, Dr Rizzo and Dr Ayton can be contacted at the email addresses listed above.

The founding members of the Task Force anticipate that this digital resource will prove valuable to anyone who has interest in learning more about the achievements in our field, especially our prospective patients, to whom we dedicate our work.