Vision Research 108 (2015) 77–84

Contents lists available at ScienceDirect

Vision Research

journal homepage: www.elsevier.com/locate/visres

Assessing the utility of visual acuity measures in visual prostheses

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ARTICLE INFO

Article history:
Received 7 October 2014
Received in revised form 14 January 2015
Available online 29 January 2015

Keywords:
Visual acuity
Retinal prosthesis
Pixelized vision
Head scanning

ABSTRACT

There are presently several ongoing clinical trials to provide usable sight to profoundly visually impaired patients by means of electrical stimulation of the retina. Some of the blind patients implanted with retinal prosthesis reported un-patterned perception and yet benefit from the device in many activities of daily living, seemingly because they adopt active scanning strategies.

The aim of the present work is to evaluate if and under what conditions a measured visual acuity level is truly an indication that the brain perceived a patterned image from the electrical stimulation of the visual prosthesis. Sighted subjects used a pixelized simulator in which they perceived either a low resolution sub-sampling of the original image ("normal mode" – patterned vision) or an image that was solely a function of the brightness and size of the original image ("brightness mode" – no patterned vision).

Results show that subjects were able to adopt a head scanning strategy that enabled acuity beyond the resolution set by a static view of the stimulus. In brightness mode, i.e. without patterned vision, most subjects achieved a measurable acuity level better than the limit set by the geometrical resolution of the entire array but worse than the limit set by the distance between neighboring simulated pixels. In normal mode all subject achieved acuity level that is better than the geometrical resolution of the simulated pixels. Thus, visual acuity levels comparable with the electrodes/pixels resolution implies that the patient perceives an image with spatial patterns.

1. Introduction

Therapeutic procedures require an objective method to assess the efficacy of the treatment. Visual acuity tests are considered the principle quantitative measure to assess the efficacy of ophthalmologic treatments and procedures designed to improve or restore vision (Rosenfeld et al., 2006) and to evaluate the cost-effectiveness (Kobelt, Lundström, & Stenevi, 2002). Recently, the effort to develop methods to restore vision in totally blind individuals has made important strides, to the extent that a comprehensive review of visual prostheses declared that most of the future obstacles have now been identified (Eiber, Lovell, & Suaning, 2013). The need to assess the objective efficacy and subjective benefit provided by these techniques has raised anew the question of how best to quantify visual functionalities. Results from clinical trials of retinal prosthesis show a great variability in the percept from the electrical stimulation of the degenerated retina.

In classic Visual Acuity (VA) tests a subject or a patient is required to report the identity of different patterns presented in various sizes. Each size corresponds to a spatial frequency, and the resulting visual acuity is defined by the smallest shape that can be correctly identified by the observer. The most common shapes used for visual acuity tests are letters from the alphabet, such as used in the Snellen chart and in the ETDRS test (Dobson et al., 2009). Non-alphabetic charts and methods were introduced to assess visual acuity for infants and kindergarten children (Ferris et al., 1982). Visual acuity tests based on a closed-set of shapes were also introduced. These tests include the Tumbling E and Landolt C. In those tests, respectively, a letter E or letter C is presented in different orientations and the subject is required to identify the direction of the optotype. In sighted individuals it has been shown that the visual acuity test results reflect the perceptual acuity which is better than the resolution acuity (Heinrich & Bach, 2013). One of the goals of this study was to investigate whether this is true regarding visual prostheses as well, i.e. does the visual acuity score measured in artificial vision reflect an acuity that is superior to the resolution acuity of the sensor.

Presently, there are several ongoing clinical trials to ascertain the feasibility of providing usable sight to totally blind patients

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http://dx.doi.org/10.1016/j.visres.2015.01.006
0042-6989/

by means of electrical stimulation of the retina. Such therapy is designed for patients who are completely blind due to a progressive retinal degeneration. Sight restoration is done by electrical stimulation of the retina based on the view acquired either by an external video camera (Hornig et al., 2008) or an implanted array of photodiodes (Zrenner et al., 2011). The concept of restoring sensory functionality by means of electrical stimulation is partially driven by the huge success of the cochlear implant that has restored hearing to approximately a quarter of a million individuals worldwide, including numerous children that were born deaf (Papsin & Gordon, 2007).

As of today, there is no standardized procedure to quantify the benefit obtained from visual prostheses. It is recommended by the US regulatory agencies that visual acuity is a primary effectiveness endpoint and would be the desired measure. However, it is recognized that standard acuity eye charts are far beyond the ability of today's prosthesis recipients (Cohen, 2007). Thus, the FDA (2013) in section 7D (Effectiveness Outcomes) in its Guidance for Retinal Prostheses recommends that "Primary effectiveness endpoints of visual performance should provide quantitative documentation of implanted subjects' performance in support of device effectiveness. Depending on the patient population and the nature of the underlying condition, the effectiveness endpoints can be selected from the list of assessments below." This list includes the following measures of Visual Function: Low Vision Letter Acuity, Grating Acuity, Spatial Mapping of Stimulated Visual Phosphene Fields, Form Vision Assessment, Assessments of Functional Vision and Patient Reported Outcomes, Orientation and Mobility, Activities of Daily Living, and Patient Reported Outcomes questionnaires. Indeed, outcomes, other than visual acuity are being published as outcome measures for visual prostheses (e.g. Kotecha et al., 2014; Nau et al., 2014).

In most European countries and in the United States, a legally blind person is defined as someone who has 1/10th of the normal visual acuity, that is, when a person cannot identify the largest letter on the Snellen chart. Current vision tests that evaluate patients with acuity worse than this acuity, i.e. worse than 6/60 (20/200), are limited and not standardized. There are limited quantifiable visual tests aimed at visual levels between total blindness, i.e., no light perception, and legal blindness. Often, for patients in this range, termed ultra-low vision and the range for all current artificial vision devices, clinicians use methods such as light perception with projection and counting fingers. An effort has been made to quantify VA in patients with severe visual impairment who would normally be evaluated with finger counting and found they could reproducibly quantify VA (Lange et al., 2009; Schulze-Bonsel et al., 2006). Others have noted that within the population of low visual functioning there is poor agreement between the Snellen and ETDRS charts. Often in clinical practice Snellen charts are used while in clinical trials ETDRS charts are utilized (Falkenstein et al., 2008). Recently, Bailey et al. (2012) suggested using The Berkeley Rudimentary Vision Test for low vision visual acuity testing. It consists of three pairs of hinged cards that test using single tumbling E optotypes, various grating acuity targets, and white field projection and black white discrimination. This test is commercially available (e.g. http://precision-vision.com/). Bach et al. (2010) have recently developed a new simple test battery to provide a basic quantitative assessment of visual function in the very-low-vision range. This battery of tests has also been used to evaluate tactile vision substitution, for example tactile stimulation of the tongue (Nau, Bach, & Fisher, 2013). The ability to quantify visual acuity for severe low vision will be of a great use in assessing the results of a variety of modern therapies aimed at the severely impaired patients.

Can the extended range of these modified visual acuity tests be used to quantify the vision provided by a visual implant? There is no doubt that the vision provided by the current visual prostheses is different from that of normal human vision. Nevertheless, even crude and artificial vision yields a valuable benefit to blind patients that do not have an alternative treatment (Ahuja et al., 2011). The traditional visual acuity measurements assume that the patient has a spatial map of the image, i.e., can perceive patterns or shapes. Preliminary outcomes of retinal prostheses' clinical trials have shown that some of the participants cannot identify patterns or shapes. However, participants do benefit by their newly acquired ability to locate objects and detect motion in their daily activities. Yet there is no accepted method to quantify this acquired vision (Cohen, 2007). Due to the different pathologies of diseases that cause blindness, the outcome of a visual prosthesis is patient specific and thus, while some patients are able to identify patterns and can score on the extended visual acuity test, other patients can only locate objects or detect motion (Caspi et al., 2009; Humayun et al., 2012; Stingl et al., 2013).

In order to gain a better understanding of the potential benefits of low resolution visual prostheses and to assess different image processing algorithms, visual prosthesis simulators are used. Generally, in a visual prosthesis simulator, also known as pixelized vision simulator, a real-time, low-resolution image of the view is presented on LCD goggles to a normally sighted user. The image of the scene is captured by a head mounted camera, digitalized by a computer, and a sub-sampled low resolution ("pixelized") image is presented on a commercial eyewear video display (Fig. 1).

A variety of tasks have been evaluated using pixelized vision simulator. Thompson et al. (2003) investigated the minimum requirements for face recognition and Fornos et al. (2005) used a visual prosthesis simulator to compare the scanning benefit and shape of individual pixels, square vs. Gaussian, in enabling reading. Hallum et al. (2005) explored the effect of pixelized vision on various eye movements, i.e. smooth pursuit, saccades, and fixation. Wang, Yang, and Dagnelie (2008a) investigated the effect of retinal location of the projected pixelized image on smooth pursuit initiation and stability. Dagnelie et al. (2007) and Wang, Yang, and Dagnelie (2008b) assessed virtual maze navigation and real mobility performance with simulated prosthetic vision. Parikh et al. (2013) compared various computer algorithms, including saliency-based cueing algorithms, using a visual prosthesis simulator.

Clinical trials of visual prosthetics showed that some patients cannot perceive shapes. Published reports from 30 patients implanted with the Argus II prosthesis (Humayun et al., 2012) showed that only 23% can discriminate the orientation of a grating while 57% could discriminate motion and 96% of the patients were able to localize objects. Results from the 8 patients implanted with the Alpha IMS clinical trial (Stingl et al., 2013) showed that only 2/8 were able to score on the Landolt C test, 5/8 discriminate

Fig. 1. An image of the pixelized vision simulator which consists of a USB camera and miniature LCD monitors mounted on goggles.