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Research
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Visual Prostheses: Technological and Socioeconomic Challenges

John B. Troy

ABSTRACT Visual prostheses are now entering the clinical marketplace. Such prostheses were originally targeted for patients suffering from blindness through retinitis pigmentosa (RP). However, in late July of this year, for the first time a patient was given a retinal implant in order to treat dry age-related macular degeneration. Retinal implants are suitable solutions for diseases that attack photoreceptors but spare most of the remaining retinal neurons. For eye diseases that result in loss of retinal output, implants that interface with more central structures in the visual system are needed. The standard site for central visual prostheses under development is the visual cortex. This perspective discusses the technical and socioeconomic challenges faced by visual prostheses.

KEYWORDS neuroprostheses, vision, eye disease, restoration of function, rehabilitation

1 Visual prosthesis development

1.1 The beginning

Technology intended to restore vision to blind people dates back to the late 1960s, when G. S. Brindley and W. S. Lewin of the University of Cambridge in the United Kingdom tested a visual cortical prosthesis on a 52-year old female blind patient. Brindley and Lewin sought to create visual sensations in this patient by electrically stimulating that part of the cerebral cortex known to represent visual information in sighted people. At that time, the occipital lobe of the human brain was known to be a center for the higher processing of visual signals, and it was known that electrical stimulation of this part of the visual system could evoke visual sensations called phosphenes; that is, the perception of spots of light, localized within the visual field. It was also known that such phosphenes could be evoked after years of blindness. The results obtained with the first visual prosthesis were so encouraging that Brindley and Lewin predicted in the conclusions section of their paper that improvements to their prototype should "permit blind patients not only to avoid obstacles when walking, but to read print or handwriting, perhaps at speeds comparable with those habitual among sighted people."

1.2 Waxing and waning

The field of visual prostheses has waxed and waned over the decades since this pioneering effort, and its history might thus serve as a case study in how challenging the development of medical technology can be. The failure of Brindley and Lewin to deliver on the bold prediction made in their conclusions section had a dampening effect on enthusiasm for the field, and we should learn from this. A developer of medical technology needs to tread a fine line between promoting a product enthusiastically in order to garner the financial support needed to bring it to market and avoiding the damaging effect of overstating its likely short-term impact. One needs to become adept at defining realistic milestones and, at the same time, portraying the larger significant long-term impact. The investment community is attuned to the course of technological development. The patient population is hungry for therapies and is therefore both more susceptible to accepting overstated claims and less forgiving when the outcomes fall short of expectations. Today, nearly half a century later, the visual capacities that Brindley and Lewin predicted would be soon provided by a visual prosthesis seem distant. Current visual prostheses fall far short of providing the level of visual performance proposed, and many technical challenges, unappreciated by Brindley and Lewin, remain to be addressed.

1.3 Recent developments

We are currently experiencing an upswing in interest in visual prostheses, following some major recent successes. Retinal implants, developed by Second Sight in the US and Retinal Implant AG in Germany, are now available as clinical products. Initially targeted to patients rendered blind through retinitis pigmentosa (RP), in July of 2015, a retinal implant was for the first time given to a patient suffering from dry age-related macular degeneration (AMD): 80-year old Ray

Biomedical Engineering Department, Northwestern University, Evanston, IL 60208-3107, USA
E-mail: j-troy@northwestern.edu
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Flynn, at the Manchester Royal Eye Hospital in the United Kingdom. Both RP and AMD are eye diseases that lead to blindness through the loss of photoreceptors. The incidence of the former disease is significantly lower than AMD and affects a younger group of patients. It made good sense therefore to target patients with RP as the initial recipients for a retinal implant, leaving those with AMD to follow. Certainly, for investors, the potential for a technology to be applied to the population of AMD patients is enticing, since this population is already large and is sure to grow significantly in coming decades as the populations of developed countries age. Indeed, the potential to apply new technologies to AMD patients may be essential. The cost of developing technology to interface with the central nervous system, of which the retina is a displaced part, is immense and unthinkable from a commercial perspective without the prospect of it being of use to a substantial patient population.

2 Retinal and visual cortical prostheses

There are a number of reasons why retinal prostheses have reached the clinic ahead of visual prostheses that interface with the visual cortex or other areas of the visual system. Anyone considered a candidate for a visual prosthesis today must be blind in both eyes and must hope for just partial restoration of monocular vision. Partial restoration can be accomplished with a single retinal implant, while a visual cortical prosthesis would likely require two implants, one for each hemisphere, since the left visual field is represented in the right visual cortex and the right visual field is represented in the left visual cortex. Another advantage of the retinal implant is that the full visual field is exposed across the retinal surface. For the visual cortical prosthesis, a significant fraction of the visual field is not represented on the brain surface but is instead buried in sulci (infoldings of the cerebral cortex), making it more difficult to access for electrical stimulation. A third advantage of the retinal implant follows from the fact that these implants are more resistant to tissue rejection than cortical implants are. Adverse tissue responses are greater when an implant damages blood vessels. The retina has two blood supplies: the choroid and the retinal circulation. Both varieties of retinal prosthesis—the subretinal implant, which is positioned where degenerated photoreceptors once resided, and the epiretinal implant, which is situated adjacent to the retina's inner limiting membrane—make no contact with blood vessels. In contrast, visual cortical prostheses that employ penetrating electrodes invade the rich capillary bed and larger blood vessels that feed the cerebral cortex. Hence cortical implants are more prone to generate a significant adverse tissue response.

A number of the technological challenges that affect visual prostheses are the same as those affecting many other brain implants: for example, how to minimize damage to tissue and electrodes through implantation and electrical stimulation; how to protect electronics from the electrolyte environment of the brain; how to better match the mechanical properties of the implant, which is generally rigid, with the mechanical properties of the brain, which is soft; how to transfer power to and signals to and from the implant; how to ensure that the implant does not interfere with the flow of nutrients to brain cells; how to minimize the heating of tissue during stimulation; and so forth. There are also some challenges that are specific to visual prostheses. Accomplishing Brindley and Lewin's goal of creating a visual prosthesis permitting a patient to read at a speed comparable to a sighted person would require considerably more electrodes than are available in current retinal prostheses. In fact, accomplishing this goal will likely require the development of electrodes made of novel materials, which have yet to obtain regulatory sanction. A number of investigators have studied materials with a superior charge-transfer capacity to standard platinum electrodes and, as electrode-tip size decreases in order to achieve the goal of higher electrode density, one or more of these materials is likely to be essential.

It is with regard to the goal of attaining good reading performance that the advantage shifts from the retinal prosthesis to the visual cortical prosthesis. The fact that the representation of central vision is magnified in the visual cortex relative to peripheral vision means that good acuity is attainable with reasonable electrode spacing. For the retinal implant, the task of stimulating the central retina is daunting. The retinal ganglion cells—the output cells—are packed tightly, stacked and displaced from the fovea. It is hard to imagine how these important drivers of central vision, essential for the detailed viewing of objects and for reading, can be effectively driven with a retinal prosthesis.

Visual cortical prostheses have one other important advantage: They offer a solution to restoring vision to those rendered blind through the loss of retinal ganglion cells—such as would occur in the event of eye loss or with the disease glaucoma, which is the leading cause of incurable blindness in the world and the cause of blindness for Brindley and Lewin's patient. However, technical challenges are perhaps not the major obstacles to the development of visual prostheses. There are many social and economic factors that potentially stand in the way of success and it is prudent to consider them also.

2.1 Economic considerations

The economics of visual prostheses raises concern about the distribution of medical care. It is perhaps too early in the development cycle to put a price on the cost of a visual prosthesis, but one imagines that the same kinds of concern that have been raised for the implementation of cochlear and deep brain stimulation (DBS) implants will apply. Both of these technologies have seen an uneven distribution of application across the world's population, reflecting in a large part the uneven distribution of medical care generally. Europe, North America, and developed Asia and Oceania have been early beneficiaries. Rapidly developing countries like China are also benefiting, often first from donation units with the expectation that a commercial market will follow. Within the developed world, inequity in delivery also exists. In a study of more than 500 000 Medicare beneficiaries with Parkinson's disease in the US, it was found that men were more likely to receive DBS implants than women and that white patients