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Ilya Petrou, MD | Professor Eberhard Zrenner

Restoring sight to the blind

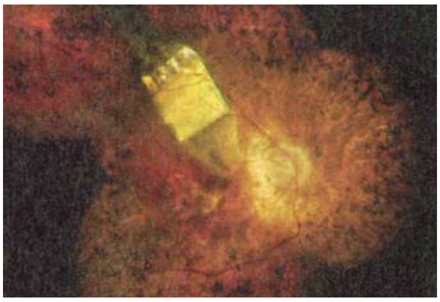
Evaluating the efficacy of a retinal prosthesis

The high incidence of neurodegenerative retinal diseases that lead to visual impairment and blindness has given rise to new technological and biological advances in the field of ophthalmology. Electronic retinal prostheses are among the most eagerly anticipated, yet complex devices to be developed. The expertise of retinal specialists, surgeons and engineers has been combined to thoroughly research the effect of electrical stimulation on retinal neurons, to develop micro-electronic chips, investigate new encapsulation methods that are bio-compatible and to develop methods of powering the subretinal devices.

Unveiling the results

Professor Eberhart Zrenner, MD, led a clinical study with the SUBRET consortium to examine the efficacy and safety of subretinal implants and presented his results for the first time at the 2006 annual meeting of the Association for Research in Vision and Ophthalmology (ARVO) in Fort Lauderdale, Florida, USA, earlier this year.

Two blind subjects, both suffering from retinitis pigmentosa (RP) had a 3 x 3 x 0.1 mm subretinal chip implanted next to the foveal rim. The chips contained 1,500 microphotodiodes (pixels), in addition to amplifiers and electrodes of 50 x 50 µm spaced 70 µm apart. An array of 4 x 4 identical electrodes, spaced 280 µm apart, were also implanted to provide direct stimulation. Each pixel is capable of producing a visual field of 12° and is designed to allow mobility and object recognition. The chip and direct stimulation array were positioned on a small subretinal polyimid foil and were powered using a subretinal transchoroidal, retroauricular transdermal line, ending in a radio-controlled, battery-driven receiver box.



Retina implant inside the eye

In order to present temporal or spatial patterns, the charge injection delivered by the electrodes was simultaneous or successive. Both patients reported homogeneously appearing, small, yellowish or greyish phosphenes for each individual electrode stimulation. When all electrodes were switched on, the patients were able to distinguish spatial patterns such as lines, angles and bright squares. When four electrodes in a line were activated, one patient reported "match-sized bright yellowish rods with round corners and bright indentations on both sides." Horizontal from vertical lines were clearly distinguishable and the patient was able to correctly describe the alignment and direction of dot movement when three or four neighbouring electrodes were switched on sequentially at one second intervals. The electrical thresholds assessed by chronaxy measurements of each electrode and perceptual correlates remained relatively stable.

Postoperative results showed that the implants were well tolerated, with no adverse events being reported and optical coherence tomography (OCT) images revealed stable retinal attachment in both patients. The implant was removed in one patient after four weeks, as per the study plan, while the other patient chose to leave the prosthesis implanted.

What does this meant for the patient?

The retinal prostheses can achieve a spatial resolution of 1° visual angle. This could represent a significant improvement in quality of life for patients by allowing them to orient themselves in space and to recognize and distinguish larger objects. The prostheses look to have a promising future, since the study revealed that the crucial elements of implantability, biocompatibility and spatial resolution were all successfully tested with positive results.

Having initiated the project back in 1995 and, during that time, co-founding the implant manufacturing company, Retina Implant AG, Dr Zrenner is now beginning to see the impact his research is having on the lives of others.

Can it be used for other conditions?

Retinitis pigmentosa is just one of the neurodegenerative retinal diseases for which these prostheses are geared. It is a hereditary progressive degeneration of the retina, which affects night vision as well as peripheral vision, slowly creating tunnel vision. The hallmark of the disease is the presence of dark pigmented spots on the retina, increasingly impairing vision as the disease progresses. The prostheses could also be employed for retinopathies such as cone-rod dystrophies or choroideremia.

Macular degeneration may be another area that would benefit from this approach. The condition is on the rise and is projected to become the single leading cause of legal blindness in a decade from now, occurring in as many as 5.5% of people over 65 years of age. Novel technological inventions such as subretinal prostheses are therefore necessary to counterbalance this rise in macular degenerative diseases, which more often than not will result in partial or complete blindness.

"From the positive results attained in this study, a chronic subretinal stimulation with the use of small electrodes enables a blind patient to successfully discriminate patterns of small, bright, steadily appearing dots. These consistent results were reliably repeated over weeks and demonstrated a still intact subretinal microelectrode array, showing promise for restored sight in blind patients suffering from retinitis pigmentosa," Dr. Zrenner affirmed.

Professor Eberhart Zrenner, MD is Director and Chairman of the Department for Pathophysiology of Vision and Neuro-Ophthalmology, University Eye Hospital of Tuebingen, Germany. He may be reached by E-mail: ezrenner@uni-tuebingen.de