The novel Learning Retinal Implant System™ from IMI

Blind and visually impaired people suffering from degenerative retinal conditions are offered the hope to "see" again using the advanced technology being developed by IMI in its pioneering neurostimulation device – a platform transferable to other fields also

Intelligent Medical Implants

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INTELLIGENT MEDICAL IMPLANTS (IMI) is developing the Learning Retinal Implant System™ to restore functional vision in blind people suffering from degenerative retinal diseases such as retinitis pigmentosa (RP). The Learning Retinal Implant System is the first product of a broad neurostimulation platform. While the company's initial focus is previously incurable blindness, its platform enables development of several neurostimulation devices that will allow patients to compensate for other disabling neurological deficits, such as chronic pain, incontinence, stroke and eating disorders.

Retinitis pigmentosa and age-related macular degeneration (AMD) are the most common causes of vision loss by hereditary degenerative retinal diseases in people over 50. RP and AMD have been considered irreversible conditions; there is no treatment to cure or arrest these diseases. Several million persons are affected worldwide, with about 20% of them having no remaining sight. With the Learning Retinal Implant System, a previously blind person will be able to move independently in an unknown environment without the need for a guide dog or cane.

The Learning Retinal Implant System works by recording images of the environment with a digital camera, processing these images into electronic signals and sending them via wireless transmission to an ingenious receiver implanted in the eye. The receiver translates the signals into electric currents that are applied through microelectrodes to the surface of the retina ("epiretinal approach"), thereby activating the underlying ganglion cells to elicit visual perceptions in the brain.

One of the key properties of the Learning Retinal Implant System is its ability to learn and adjust what the patient sees based upon his/her feedback to optimise the patient's functional vision. To be truly beneficial, the Learning Retinal Implant System must first enable a blind person to regain his/her ability to move independently in his/her home or in an unknown area. Consequently, the initial target market for the Learning Retinal Implant System is retinal-blinded individuals who have almost no light perception. Successful implantation of the Learning Retinal Implant System and rehabilitation may allow patients to "see" again by restoring limited visual acuity, thus enabling the user to lead an autonomous life.

Specifically, an implant (retinal stimulator) is surgically placed into the eye of a blind person, who wears a pair of glasses containing an integrated minicamera and transmitter components for wireless signal and energy transmission (visual interface; see Figure 1). Via a cable, the glasses are connected to the pocket processor worn at the patient's waist. This device replaces the information-processing function of the normally healthy retina. Image data are transformed to stimulation data, and several adjustable parameters allow for the optimisation of the visual perception for the specific patient.

The implant (retinal encoder) consists of a flexible microcircuit board that will ultimately contain hundreds of electrodes. The size and flexible nature of the implant mean that it is tolerable to the tender retina. Integrated into the glasses, the wireless energy and signal transmission system provides power to the implant. An infrared transmitter is used to send the stimulation data to the implant. The pocket processor maps visual patterns received from the mini-camera and transforms these patterns into impulse sequences using adaptable image-preprocessing filters and adjustable algorithms. These impulses are then sent via the implant to the retinal nerve cells. The use of a high-speed digital signal processor allows the provision of "intelligent information" to the implant (and the nerve cells) by using tunable software to approximate the information-

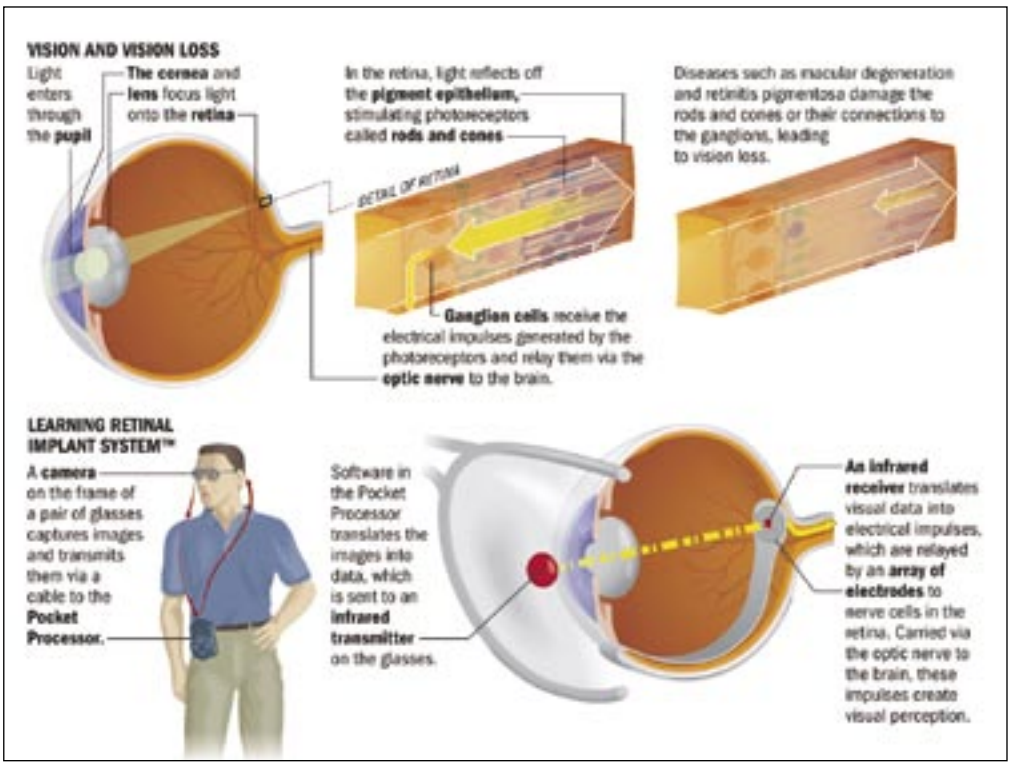

Figure 1. The Learning Retinal Implant System will be the first device to treat currently incurable retinal diseases

processing normally carried out by the real retina.

The first of its kind acute clinical study involving 20 RP patients showed a 95% success rate. This was the largest study worldwide to investigate systematically the ability of the retina to be stimulated electrically. Twenty blind patients with RP took part at four European medical centres. Of these 20 patients, 19 (95%) reported visual perception triggered by the electrical stimulation. During the study, part of the visual prosthesis was inserted into the eye for less than one hour. Tests were conducted to determine whether, and under what conditions, visual perception can be triggered via electrical stimulation of the retina. Both the visual perceptions described by the blind participants and the stimulation parameters required to trigger visual perception appear to be very suitable for the realisation of a visual prosthesis that can be implanted over the long term.

Competitive advantages

IMI is not a "one-product-only" company. Its novel platform enables development of numerous groundbreaking neurostimulation devices.

IMI already has demonstrated in a human study that its Learning Retinal Implant System is by far the most effective device in this field.

CE Mark approval is expected in the first quarter of 2007, with PMA approval in the USA expected about one year later.

The company's first product alone could benefit several million persons who now have no hope of having their sight restored. ■

"There is no treatment to cure retinitis pigmentosa or arrest its progress. Persons affected with this degenerative disease have previously experienced sight and are fully aware of their great loss"
John Wyatt PhD
Consultant to IMI and Professor of Electrical Engineering
Massachusetts Institute of Technology
Cambridge, Massachusetts, USA

"There is no sign of an effective therapy for RP on the horizon. The best hope today is a retinal implant. IMI's Learning Retinal Implant System should be considered a leader in this field"
George A Williams MD
Chairman
Retina Ophthalmic Tech
Assessment Comm
American Academy of Ophthalmology (AAO)

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