General Information on the Retinal Implant Project
- Technique and Clinical Study -

For the past fifteen years, a consortium of Germany based eye hospitals and research institutes has been developing the technical prerequisites for a subretinal implant. In the long run, a large number of blind people is expected to benefit from this electronic prosthesis („retinal chip“), offering an artificial replacement for lost vision due to hereditary retinal degenerations (e.g. retinitis pigmentosa, choroideremia). The research was initiated by and supervised by University Eye Hospital Tuebingen (Prof. Dr. med. E. Zrenner). The expertise of know-how knowledge gained during this research, thereafter protected by worldwide property rights, was entrusted to medical engineering company Retina Implant AG, Reutlingen, currently responsible for production, clinical admission, and worldwide distribution of the retinal implant. In 2005, within the scope of a clinical pilot study, the first retinal chips were, as planned, successfully implanted on a temporal basis. In the currently running second clinical study, the patient is allowed to carry the retinal chip, as long as he tolerates it and has a benefit from it.

How does the chip work?

Core of the implant is a microchip of approx. 3 mm in diameter and 70 µm thickness, with an array of roughly 1,500 pixel fields. Each pixel is a size of 70µm x 70µm. Photocells, an amplifying circuit, and a stimulation electrode is attached to each pixel field. The photocells absorb the light entering the eye, transforming it into electrical signals. These signals steer an externally supplied energy, stimulating the intact retinal nerve cells electrically. The nerve impulses generated by the retinal cells are transmitted via the optic nerve to the visual cortex, hence creating visual impression. For this reason an unimpaired, evenly functioning optic nerve is an absolute requirement for the implant’s operational reliability. In the ongoing implant generation, the energy supply is provided by a subcutaneously implanted inductor, which is already a standard procedure in cochlear implants.

How and where is the chip implanted?

Implantation of the chip is comparable to vitreous or retinal surgery, and resembles standard procedures performed in cases of complicated retinal detachment or lesions. Surgery takes place for several hours (about 6-8h) under general anaesthesia.

The chip is designed to be capable of taking over the function of the light sensitive cells (photoreceptors) which have perished in degenerative retinal diseases. The implant is placed onto that retinal spot where light sensitive cells are present in healthy persons, thus making use of the natural information processing channels.

What degree of vision can be achieved by the chip?

Due to its technical properties, the chip is able to produce sufficient visual acuity to enable blind persons to regain autonomous mobility and to recognise objects and persons within a visual field of 12 degrees.

How do participants in the first study benefit from the chip?

This study is a pioneering in this field, hence, the advantages the chip may offer to the first participants are difficult to assess. Study's success is dependant on a large variety of factors. It may also be expected for patients to report atypical, prior not experienced visual impressions, as generated by the subretinal implant. The knowledge gained by this study will set the future direction for the implant's further development and refinement, to which end the pilot study patients' participation is essential. To safeguard patient welfare, participants are constantly supervised by a professional team before, during, and after the study. In opposite to the pilot trial, the implant can be activated in daily life by the patient himself.

Who will be able to participate in the study?

Eligible for the pilot study are:

- adults suffering from **hereditary retinal degenerations** (retinitis pigmentosa, choroideremia, cone-rod dystrophy),
- completely blind patients (at least in one eye), having either no light perception or residual light perception to permit orientation and with a latter visual experience of at least 12 years.

Who can not be considered for the study?

Unfortunately, the retinal implant is not suited for patients suffering from:

- retinal circulation disorders (vascular obliteration, thrombosis)
- diabetic retinopathy (in diabetes)
- ROP (retinopathy of the premature)
- retinal detachment
- glaucoma
- blindness due to stroke
- optic nerve injuries, e.g. due to accident
- patients with general diseases prohibiting anaesthesia for several hours

Also, at the present time the subretinal implant is not applicable in patients with age-related macular degeneration.

What is the present state of the project?

Consented by the local Ethics Committee, the first clinical pilot study with implant prototypes has been running since autumn 2005. Results so far have been positive and promising. The implantations of the pilot trial were successful and demonstrate good healing process with no serious complications. In the meantime the Ethics Committee consented to execution of the second clinical study. The ample findings gained by the electric stimulation were valuable and decisive in understanding retinal responsiveness, thus indicating the most favourable electronic calibration for the chip's further development. Triggering electric stimulation enabled patients to perceive light in particular forms and patterns. Visual perception triggered by the chip enabled patients to recognise and localise light sources (window, lamp), which is important for autonomous orientation. In many cases patients recognise and localise objects of the daily life,

as for example tableware. Other objects as e.g. obstacles in road traffic were identified by some patients. Some patients could even read letters. Despite the strain of operation and often long lasting test procedures, all patients valued their participation in the study as a positive and exciting experience. At the end of the study, all of the patients demonstrated willingness to remain with their decision and to participate in the study once again.

Contact

Should you be interested in participating in the study and consider yourself suited, please contact:

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Retina Implant AG

The medical engineering company Retina Implant was founded in spring 2003. The next project goal is to obtain the licence for the chip as medical product in Europe and USA within the scope of clinical studies. These are the essential preconditions to manufacture and distribute the chip system worldwide, and to enable blind person's spatial orientation without external help.

For general or technical project information you may also contact the Retina Implant GmbH. Please find below further contact details or please find http://www.retina-implant.de website for additional information.

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