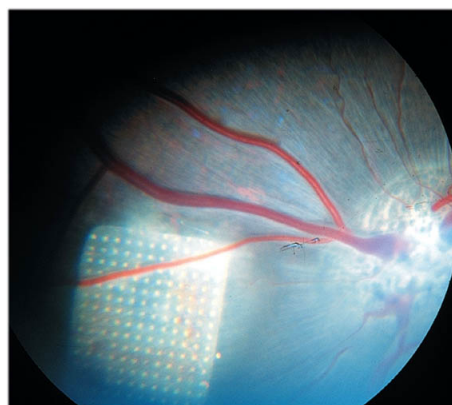
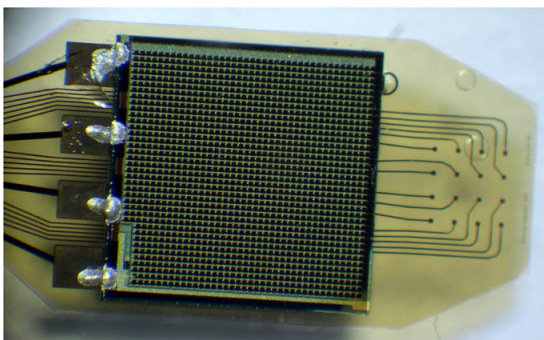


General Information on the Retinal Implant Project - Technique and Clinical Study -

For the past ten years, a consortium of German 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 University Eye Hospital Tuebingen (Prof. Dr. E. Zrenner) has been playing a significant part in all research involved and still is. The know-how gained by this research and protected by worldwide property rights was transferred to the medical engineering company Retina Implant GmbH, Reutlingen, now 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 inserted temporarily in blind persons; after refinement, future generations of implants are to be implanted permanently.

How does the chip work?

Core of the implant is a microchip of approx. 3 mm in diameter and 50 µm thickness, with an array of roughly 1,500 pixels (see figure below on the left). Each pixel has a size of 70µm x 70µm. To each pixel field photocells, an amplifying circuit, and a stimulation electrode are attached. The photocells absorb the light entering the eye, transforming it into electrical signals. These signals steer an externally supplied energy, which stimulates the intact retinal nerve cells electrically. The nerve impulses generated by the retinal cells are transmitted via the optic nerve to the visual cortex, creating visual impressions there. This is why an unimpaired, normally functioning optic nerve is an unconditional requirement for the implant's operational reliability. In the first study, energy supply will be provided externally by a small stimulation box, placed in the patient's pocket. In future chip generations, it is aspired to implant the energy supply subcutaneously, already a standard procedure in cochlear implants.



How and where does the chip get implanted?

Implantation of the chip is by any large comparable to vitreous or retinal surgery, like the standard procedures performed in cases of complicated retinal detachment or lesions. Surgery takes place under general anaesthesia and lasts several hours.

The chip is capable of taking over the function of the light sensitive cells (photoreceptors) which have perished in degenerative retinal diseases. The implant is being placed onto the retina in an area in which in healthy persons light sensitive cells are present, thus making use of the natural channels of information processing. The figure on page 1 (right) shows the implant's location on the retina.

What degree of vision can be attained by means of 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?

By this study we are breaking new ground. Hence, the advantages it may offer its early participants are difficult to assess, as the study's success will depend on a variety of factors. It might be possible that patients regain some indefinable degree of visual perception or may be able to report completely new visual impressions, which have not been experienced by anybody before. The knowledge gained in this study will substantially influence the implant's further development and refinement, and the pilot study patients' willingness to cooperate to this end is essential and much appreciated. To safeguard their welfare, participants are constantly supervised by a professional team before, during, and after the study.

Who will be able to participate in the study?

Eligible for the pilot study are

- adults suffering from hereditary retinal degenerations
- completely blind patients (at least one eye) with a former visual experience of at least 12 years (visual acuity more than 20/400), currently having no light perception or residual light perception not permitting orientation

What is the present state of the project?

Having obtained the local Ethics Committee consent, the first clinical pilot study with implant prototypes has been started in autumn 2005. In this study, vision is measured prior to implantation and after implantation, with the implant being removed after 30 days. Participation in the pilot study is no exclusion criteria to benefit from advanced chip technology at a later point in time. Functional testing prior to and after implantation as well as all surgical procedures take

place at the University Eye Hospital Tuebingen. Preliminary results are positive and promising. Should you be interested in participating in the study, please contact Dr. med. Barbara Wilhelm (telephone number ++49- (0) 70 71-29 8 48 98, fax ++49- (0) 70 71 - 29 50 21 or per E-Mail barbara.wilhelm@med.uni-tuebingen.de). Principal Investigator of the pilot trial is Prof. Dr. E. Zrenner, University Eye Hospital, Schleichstr. 12, D-72076 Tübingen. For general or technical project information please contact the Retina Implant GmbH (address see below) or go to <http://www.retina-implant.de> to find constantly updated information.

Retina Implant GmbH

The medical engineering company Retina Implant was founded early in 2003. Its next step will be to get the chip licensed as medical product in Europe and USA, which is to be achieved by clinical studies. This approval is an essential precondition to manufacture and distribute the chip system worldwide, enabling blind persons spatial orientation without external help.

Contact data:

Dr. Walter-Gerhard Wrobel (CEO)

Reinhard Rubow, (CFO, Managing Head Personell and Administration)

Retina Implant GmbH, Gerhard-Kindler-Str. 8, D - 72 770 Reutlingen, Germany

Tel. +49 – (0) 71 21 - 36 40 3-0 Fax +49 – (0) 71 21 - 36 40 3-115

E-Mail: info@retina-implant.de