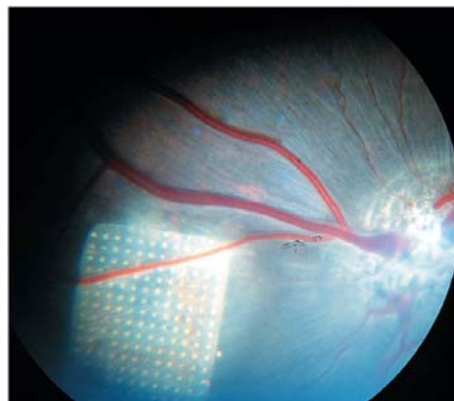
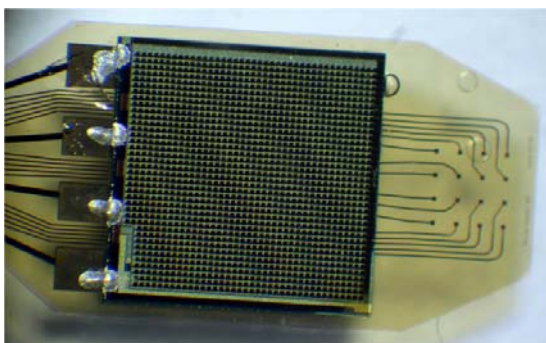


## General Information on the Retinal Implant Project - Technique and Clinical Study -

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). From the beginning, the University Eye Hospital Tuebingen (Prof. Dr. E. Zrenner) has been playing a decisive role in all research involved. 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 will 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 pixel fields (see figure below on the left). Each pixel has a size of 70µm x 70µm. Photocells, an amplifying circuit, and a stimulation electrode are 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, creating visual impression there. This is why an unimpaired, regularly 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 is the chip 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 for 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 placed onto that retinal spot where light sensitive cells are present in healthy persons, thus making use of the natural information processing channels. The figure on page 1 (right) shows the implant's location on the retina.

### **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°.

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

By this study we are breaking new ground. Hence, the advantages the chip may offer to the first participants are difficult to assess, as the study's success will depend on a variety of factors. Patients might be able to report completely new visual impressions generated by the subretinal implant, which have not been experienced by anybody before. The knowledge gained by this study will set the future direction of the implant's further development and refinement, to which end the pilot study patients' participation is essential. 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** (retinitis pigmentosa, choroideremia, cone-rod dystrophy),
- completely blind patients (at least in one eye) having no light perception or residual light perception not permitting orientation and with a former visual experience of a least 12 years.

### **Who cannot 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)
- 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 present 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. Vision has been measured before and after implantation,

with the implant being removed after 30 days. In July 2007 the Ethics Committee has approved an extended and prolonged study protocol including recruitment of 6 additional patients starting in autumn 2007. This protocol implies that the implant remains in the retina for 4 months instead of 30 days.

Participation in the pilot study does not prohibit a future implantation of 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.

Results so far are positive and promising: The first patients were implanted successfully and with good healing process; there were no serious complications. 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 due to the chip itself enabled them to recognise and localise light sources (window, lamp), which is important for autonomous orientation. Partly, bright objects (e.g. plates) set against a dark background were perceived and localised. 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 them declared that they would renew their decision to participate in the study anytime.

### **Contact**

Should you be interested in participating in the study and consider yourself suited, please contact PD 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](mailto:barbara.wilhelm@med.uni-tuebingen.de)). Director of the clinical pilot study is Prof. Dr. Eberhart Zrenner, Schleichstr. 12-16, D – 72076 Tuebingen. For general or technical project information you may also contact the Retina Implant GmbH (address see below) or go to <http://www.retina-implant.de> for current information.

### **Retina Implant GmbH**

The medical engineering company Retina Implant was founded in spring 2003. Its next goal is to get the chip licensed 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, enabling blind persons spatial orientation without external help.

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