

## Extraocular Surgical Approach for Sub Retinal Implant Placement in Blind Patients: Cochlear Implant Lessons

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### Abstract

In inherited retinal illnesses, photoreceptors gradually deteriorate, frequently leading to blindness without accessible medication. Recently discovered sub retinal implants can replace photoreceptor functions in certain conditions. Cochlear implants are heavily utilised in the extraocular surgery for retina implants. However, a brand-new surgical technique that allowed for the safe handling of the picture sensor array had to be created. The Retina Implant Alpha IMS was inserted into the orbit through a retro auricular incision through a sub periosteal tunnel above the zygoma using a specially made trocar. It consists of a sub retinal micro photodiode array and cable connected to a cochlear-implant-like ceramic housing. In all patients, the implant housing was secured in a bone bed within a tight sub periosteal pocket. Effectiveness and short-term patient safety were the main objectives. In the first phase of the multicentre experiment, nine patients received the sub retinal visual implant in one eye. In every instance, a pull-through technique and steady positioning of the micro photodiode array were possible without compromising the device's functionality. There were no difficulties throughout the operation. A sub retinal device with a transcutaneous extracorporeal power source can be safely implanted extraocular using the minimally invasive suprazygomatic tunnelling technique and a sub periosteal pocket fixation of the implant housing.

### Introduction

Cochlear implants (CI) restore hearing by using an electronic device to replace the peripheral acoustic receptor. Thus, since the early 1990s, a number of groups have been working to restore vision to blind individuals by replacing the photoreceptive function with technological means. In the majority of inherited retinal illnesses, photoreceptors gradually deteriorate, frequently leading to blindness in middle life and with no cure. The remaining visual route is still mostly useful. For the treatment of inherited retinal degenerations, several types of electronic retinal implants have either received commercial product approval, including Argus II (Second Sight, Sylmar, CA) or Retina Implant Alpha IMS (Retina Implant AG, Reutlingen, Germany). All of these implants are made up of an electrode array for stimulating retinal neurons, usually those in the inner retina, and a light-capturing unit (an external camera or an intraocular photodiode array) [1].

Our method of restoring vision involved placing a microelectronic light-sensitive device in the sub-retinal space that could convert light after it had been amplified into electrical signals for controlling bipolar cells, although several researchers favour the epiretinal technique with camera outside. This strategy makes use of the eye's organic eye movement, which results in more organic visual perception. However, because of the specific position in the sub retinal space-which is not a common location for ophthalmological surgery-the implantation approach seems more difficult. Additionally, a receiver coil and electronic circuits in implant housing similar to cochlear implants positioned in the retro auricular area are used to convey the energy supply and parameter settings. Since the power and signal supply cables had to be pushed forward to the orbital area instead of the cochlea, the retina implant (RI) extraocular surgical approach had to be freshly designed [2].

The extraocular component of the multidisciplinary strategy for the implantation of a sub retinal RI developed by the Tübingen group is described here. This surgical technique was developed during a Tübingen pilot research and further improved during a subsequent clinical trial, which resulted in the 2013 CE-approval of the Alpha IMS (Retina Implant AG, Germany) device. Nine patients had implants in the initial phase of this research, which was the first time this procedure was used. Cone-rod dystrophy was identified in one case and retinitis

pigmentosa in eight other patients. Effectiveness and patient short-term safety (defined as no permanent impairment to function or structures that were functional prior to surgery) were the primary. Currently, this approach has been used to perform surgery on 29 patients across 7 centres without any complications [3].

### Materials and Methods

Retina Implant Alpha IMS was implanted in one eye of nine patients (four females and five men) between the ages of 35 and 62 in 2010 and 2011 at the Center for Ophthalmology, University of Tübingen, Germany. All subjects provided written informed consent in accordance with the Helsinki Declaration prior to inclusion. Between May 2010 and January 2012, the study was authorised by the regional ethics council and conducted in accordance with EN ISO 14155 and the German Medical Product Law (MPG) [4]. All nine patients had a congenital retinal illness that was in its final stages, leaving them either entirely blind (8 patients) or just partially able to see light (no light perception, 1 patient). Prior to the microchip implantation, all patients had cataract surgery on the study eye and were given an artificial intraocular lens. There was only one implanted eye. If the two eyes' residual light perception varied, the worse eye was chosen for implantation. See for more information. Each patient had good overall health. The patients did not disclose any significant general illnesses or pertinent medical histories. A general anaesthesia had no known contraindications [5].

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The electromagnetic receiver coil and amplifier electronics found in the implant body are in charge of processing energy and signal. The Pulsar cochlear implant device, previously used by MED-EL Company, Innsbruck, Austria, has a ceramic housing comparable to that. The photosensitive chip is attached to the housing by a lengthy connection. The plate of the reference electrode is connected to the implant by a second, short cable. The implant's active sensor is a sub-retinal chip made up of 1500 separate photodiode-amplifier-electrode units. These units each convert local luminance data into an amplified electrical current used to stimulate nearby bipolar cells [6].

The chip is about 3 mm 3 mm and 70 m thin; it is attached to a strip of polyimide foil that exits the sub retinal region in the upper temporal periphery through the choroid and sclera and is about 20 m thick. The power supply line, which travels through an orbital loop and ends at the sub dermal coil positioned retro-auricular, is connected to the foil. Here, a handheld control unit's battery pack powers an external transmitter coil, which in turn transmits energy and control signals via the skin to the implant [7]. This battery pack includes two knobs for controlling the amplifiers' strength and amplification, which affects how bright and contrasty the perception is overall and how it responds to different lighting circumstances. After training, the patient makes this adjustment. An image in grey scales resembling an old black and white TV is produced by the chip by giving the inner retina a "point-by-point electrical image" of the acquired brightness information. Retina Implant Alpha IMS, as demonstrated in the clinical trial, can convert blindness into low vision or very low vision in a subset of people with hereditary retinal disorders. The method of sub retinal implantation and the functional aspects of the chip were previously published [8].

## Discussion

A retinal prosthesis with an extraocular implant retro auricular ceramic housing for power supply and control signals can be implanted utilising the surgical technique created for this investigation, in our opinion. In every case, surgery went smoothly and resulted in a stable fixation of the implant for the duration of the study. For cochlear implants, a method of placing the device in a periost pocket behind the temporalis muscle is well established. A less invasive approach was used since the retina implant was placed below the pinna. The pinna's helix, the ear canal, and the zygomatic process served as the main points of orientation and allowed for the anticipation of the linea temporalis, which is the caudal extension of the temporalis muscle. Due to the limited surgical access, only by suturing the periost without extra fixation over the implant housing was it possible to close the sub periosteal pocket very tightly and precisely fit the implant body [9].

The delicate implant structures must be handled carefully during surgery, it would seem. The implant's intra- and extraocular components have to be implanted as a whole through the post-auricular incision because they are made as a single piece. Additionally, the photosensitive chip needed to be dragged posterior-anterior through the little sub periosteal tunnel before being fastened to the orbital rim. The procedure for the second point of fixation involved creating an indentation precisely the same size as the implant cable. Extrusion is prevented while minor motions are permitted [10]. At the mastoid margin, similar fixation is frequently employed for CI-cable. By introducing a specifically made trocar in an anterior-posterior orientation from the orbital rim to the retro auricular incision, it was possible to pass the chip through the infratemporal tunnel. On the route under the temporalis muscle, this hollow trocar housed the photosensitive chip and the reference electrode. To prevent the overlying muscle from being penetrated, the trocar must be inserted

as forcefully and closely to the infratemporal fossa bone as feasible. Otherwise, there is a chance that the implant cable and reference electrode will be positioned incorrectly and that the temporalis muscle will shift permanently [11].

A side effect of implant activation with the reference electrode positioned under the temporal muscle is pulsating surrounding the electrode. The reference electrode is currently situated close to the ceramic coil to prevent this. None of the recent patients (who were not a part of the group described here) afterwards had any pulse in the area of the temporal muscle. In one example with an unusually anterior implant site, the only postoperative complication was a superficial hematoma that healed without any long-term effects. This served as another justification for placing the implant body behind the pinna, where the subcutaneous layer seemed to be the most sensible choice. After the period of wound healing, patients had surprisingly minimal aggravation and did not feel uneasy with the presence of the device [12].

## Conclusions

A sub retinal device with a transcutaneous extracorporeal energy source can be safely implanted extraocular using the minimally invasive suprazygomatic tunnelling technique and a sub periosteal pocket fixation of the implant housing. The extraocular portion of the implant process was carried out traumatically in every case, maintaining the integrity of the photosensitive chip. Implant migration was not seen during the implantation period. In the meantime, seven additional centres in the on-going multicentre trial using the Alpha IMS device have successfully adopted and employed the extraocular method that was created and detailed here.

## Conflict of Interest

None

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