

# Implantation and Explantation of a Wireless Epiretinal Retina Implant Device: Observations during the EPIRET3 Prospective Clinical Trial

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**PURPOSE.** Visual sensations in patients with blindness and retinal degenerations may be restored by electrical stimulation of retinal neurons with implantable microelectrode arrays. A prospective trial was initiated to evaluate the safety and efficacy of a wireless intraocular retinal implant (EPIRET3) in six volunteers with blindness and RP.

**METHODS.** The implant is a remotely controlled, fully intraocular wireless device consisting of a receiver and a stimulator module. The stimulator is placed on the retinal surface. Data and energy are transmitted via an inductive link from outside the eye to the implant. Surgery included removal of the lens, vitrectomy, and implantation of the EPIRET3 device through a corneal incision. The clinical outcome after implantation and explantation of the device was determined. The implant was removed after 4 weeks, according to the study protocol.

**RESULTS.** Implantation was successful in all six patients. While the anterior part was fixed with transscleral sutures, the stimulating foil was placed onto the posterior pole and fixed with retinal tacks. The implant was well tolerated, causing temporary moderate postoperative inflammation, whereas the position of the implant remained stable until surgical removal. In all cases explantation of the device was performed successfully. Adverse events were a sterile hypopyon effectively treated with steroids and antibiotics in one case and a retinal break in a second case during explantation requiring silicone oil surgery.

**CONCLUSIONS.** The EPIRET3 system can be successfully implanted and explanted in patients with blindness and RP. The surgical steps are feasible, and the postoperative follow-up

disclosed an acceptable range of adverse events. (*Invest Ophthalmol Vis Sci.* 2009;50:3003–3008) DOI:10.1167/iovs.08.2752

Although major progress has been achieved in the treatment of retinal disorders, the hereditary dystrophies of retinal photoreceptors are still untreatable and eventually lead to blindness. It is estimated that in the Western countries approximately 5% to 7% of newly diagnosed blindness is attributable to retinitis pigmentosa (RP), a heterogeneous group of receptor dystrophies caused by mutations in key enzymes of the visual cycle or major cell-signaling pathways.<sup>1–3</sup>

It has been proposed that electrical stimulation of remaining neurons in the visual system may restore vision in patients with blindness.<sup>4</sup> Research groups worldwide are investigating the use of implantable devices for the electrical stimulation of the retina, the optic nerve, or the brain.<sup>5–7</sup> Several groups have demonstrated that, in subjects with blindness and RP, phosphenes can be elicited by stimulation of the retina.<sup>8–10</sup>

One of the major problems with the devices currently under investigation is the sufficient transfer of data and energy from an external device to the implanted stimulator. This transfer is usually achieved by a cable connecting an external power supply with the implant inside the eye. Other major concerns are (1) the positioning of the stimulating electrodes as close as possible to retinal neurons, (2) the safety limits of the electrical current applied to the tissue, (3) the avoidance of adverse electrochemical processes at the interface between the electrode material and neural tissue, and (4) the transfer of enough information into the visual system to provide useful visual perception.

The EPIRET3 retinal prosthesis is designed and fabricated as a remotely controlled wireless device implanted completely within the eye. No cable connections crossing the eye's wall are used for energy and data transfer. Instead, energy and data are provided via an inductive link placed in front of the eye. The safety and efficacy of this device has been evaluated in a prospective clinical trial in patients with blindness and RP. We report on the clinical and safety results determined in that trial.

## METHODS

### Study Design

Six legally blind adult patients who had RP were enrolled in a prospective exploratory two-center trial to evaluate the safety and efficacy of the EPIRET3 retinal implant during a 4-week implantation period. Endpoints of the study were defined as the observation of visual sensations induced by the implant, adverse events during or after implantation or explantation, and morphologic and functional changes in the study eye. The study protocol was approved by the local ethics committee at both trial centers, and the study was approved and registered by the German Regulatory Authority (Trial Number DE/CA21/A/07/Dr.Schmidt IOL/EPIRET III). The study was performed according to GCP guidelines, the German Medical Product Law, and

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**TABLE 1.** Inclusion Criteria for the EPIRET3 Prospective Clinical Trial

Age between 18 and 80
Diagnosis of RP confirmed clinically and by ERG
Visual acuity in the better eye less than 1/50
Absence of any other severe ocular disease, such as glaucoma or uveitis
No history of intraocular surgery except cataract surgery
No participation in another clinical trial
No other severe systemic or mental disease
No other active implant such as cardiac pacemaker or cochlear implant
No pregnancy
Ability to read obtained in childhood
Ability to understand the goals of the study
Written informed consent

the Declaration of Helsinki. Written informed consent was obtained from each patient. The inclusion criteria are given in Table 1. The study eye was defined as the worse eye.

### Study Interventions

The EPIRET3 device was implanted in the study eye after removal of the lens or, if present, after removal of an artificial intraocular lens and the vitreous. An 11-mm corneoscleral incision was necessary to place the receiver module safely in the posterior chamber. To ensure a stable position after removal of capsular remnants after cataract surgery, two transscleral 10-0 sutures are used. The microcable that leaves the receiver module in a defined angle was led through an incision in the posterior capsule. It was flexible enough to be maneuvered into the vitreous cavity, but at the same time stiff enough to follow the retinal curvature without any further movement after fixation of the stimulator. After the incision was closed, the stimulator was positioned and fixed on the retinal surface in the area of the posterior pole with two retinal tacks. Activation of the implant to record visual sensations was planned at postoperative days 7, 14, and 27. At day 28 the implant was removed by opening the closed oval hole of the stimulator with microscissors. The receiver module was rotated in the anterior chamber, and, after a new opening was created at the initial corneoscleral

incision site, the device was gently extracted from the eye. According to plan, the tacks were not removed.

### Examinations

Morphologic and functional data of the study eye were obtained before the study began and during a follow-up of 6 months. These examinations included visual acuity, Goldmann perimetry, slit lamp examinations of the anterior and posterior segment, intraocular pressure, fluorescein angiography, Ganzfeld electroretinogram, and multifocal electroretinogram.

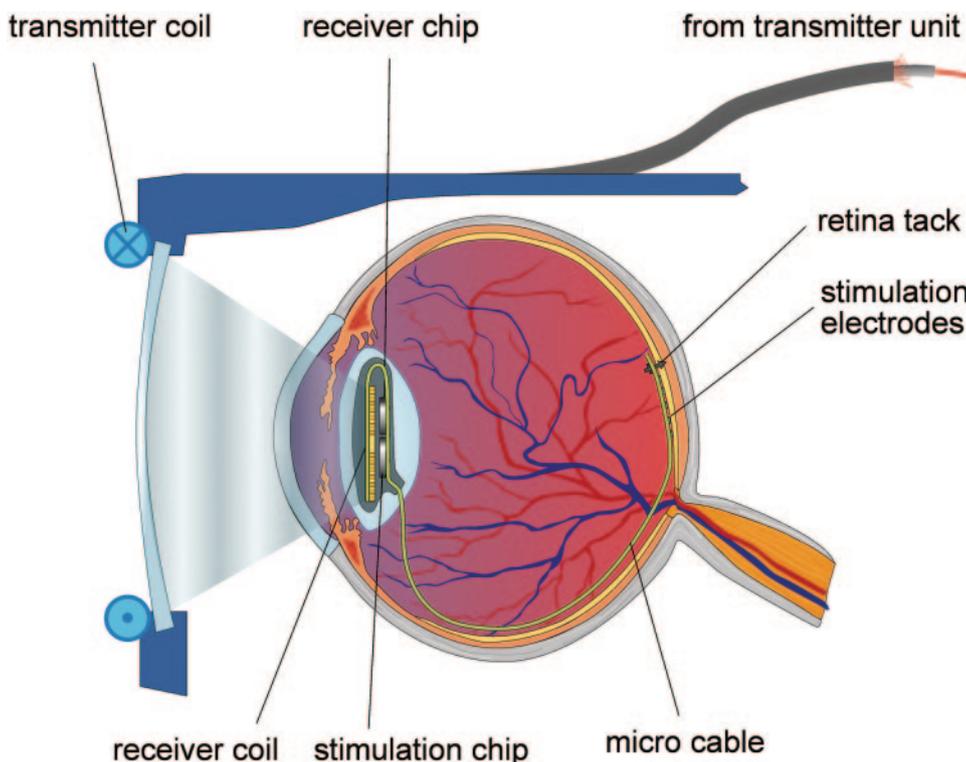
### Technology

The EPIRET3 system consists of an extraocular and an intraocular component (Fig. 1). The extraocular component includes a computer system, a transmitter unit and a transmitter coil attached to a holder placed in front of the eye. The intraocular device consists of a receiver coil, all necessary electronics, and 25 3-D stimulation electrodes (height, 25  $\mu\text{m}$ ; diameter, 100  $\mu\text{m}$ ; Fig. 2).<sup>11</sup>

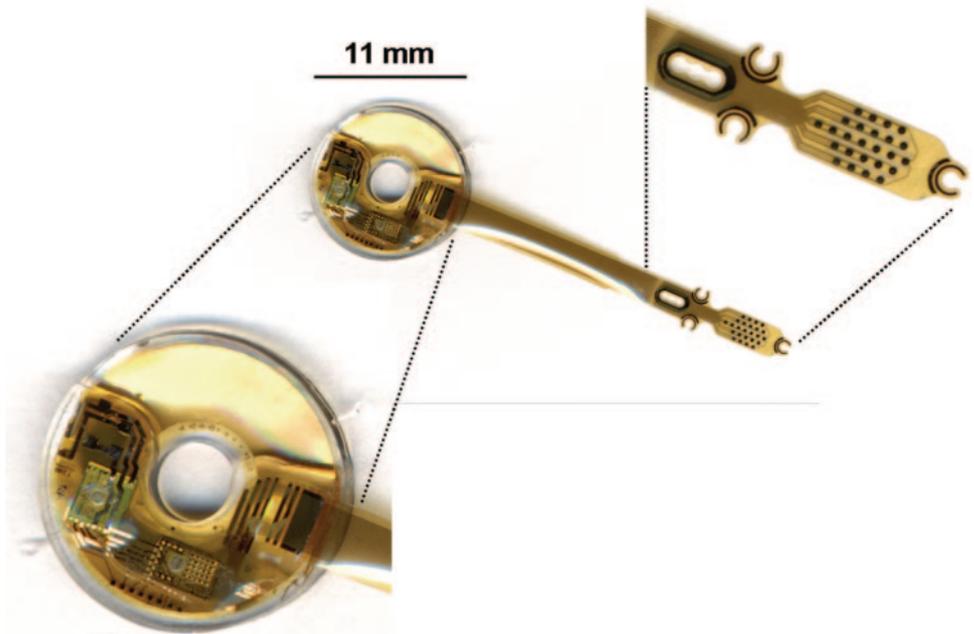
The computer generates stimulus pulse sequences based on temporospatial patterns. Stimulation data and control signals are sent to the transmitter unit through a wireless RF link. The receiver coil inside the eye acquires the electromagnetic signals and passes them to a receiver microchip. A stimulator chip generates the stimulation pulses and activates the selected electrodes with bipolar current. The intraocular part is a flexible 10- $\mu\text{m}$  polyimide foil (length, 40 mm; width, 3 mm) serving as a substrate for the electrical components. A planar coil, metal wiring, and the electrodes are formed by microelectroplating of gold. The electrodes are covered with a thin film of iridium oxide yielding a charge-delivery-capacity of up to 95  $\text{mC}/\text{cm}^2$ .<sup>12</sup> The whole implant is coated with parylene C, and the active surface of the stimulation electrodes is opened by plasma etching.

### Encapsulation

The implant is encapsulated with a two-component silicone material that is used for the fabrication of intraocular lenses. The process was developed as a two-step molding process using disposable polycarbonate molds. The encapsulated implant is sterilized by ethylene oxide.



**FIGURE 1.** Concept of the EPIRET3 system. A transmitter coil sends data and energy to the receiver unit of the implant, which is located in the posterior chamber of the eye. The receiver unit is connected with the stimulator unit carrying an array of 25 3D IrOx electrodes by a flexible microcable. The stimulator is placed safely onto the retinal surface and fixed with retinal tacks.



**FIGURE 2.** EPIRET3 device with magnified views of the receiver module (*left*) with the microcircuits mounted to the polyimide basic structure and the micromachined coil placed underneath the electronic components and the IrOx electrode array for electrical stimulation (*right*). The C-shaped openings and the triple hole are used for the insertion of retinal tacks to enable a stable fixation onto the retinal surface. The total length of the system is 40 mm.

## RESULTS

The main clinical characteristics of the six patients before surgery are given in detail in Table 2. Postoperative findings are demonstrated in Figure 3 after implantation and in Figure 4 after explantation.

### Patient AC-01

**Implantation.** A previously implanted artificial intraocular lens was removed, and the retinal device was implanted uneventfully after complete vitrectomy. The stimulator was placed slightly inferior to the fovea and fixed with retinal tacks. The eye was filled with air. After surgery, a mild transient inflammatory response in the anterior chamber was noticed. No implant-related adverse events were observed.

**Explantation and Follow-up.** At day 28 the implant was removed without complication. The tacks were left in place and the eye was filled with SF6 20%. The follow-up period of 6 months was uneventful.

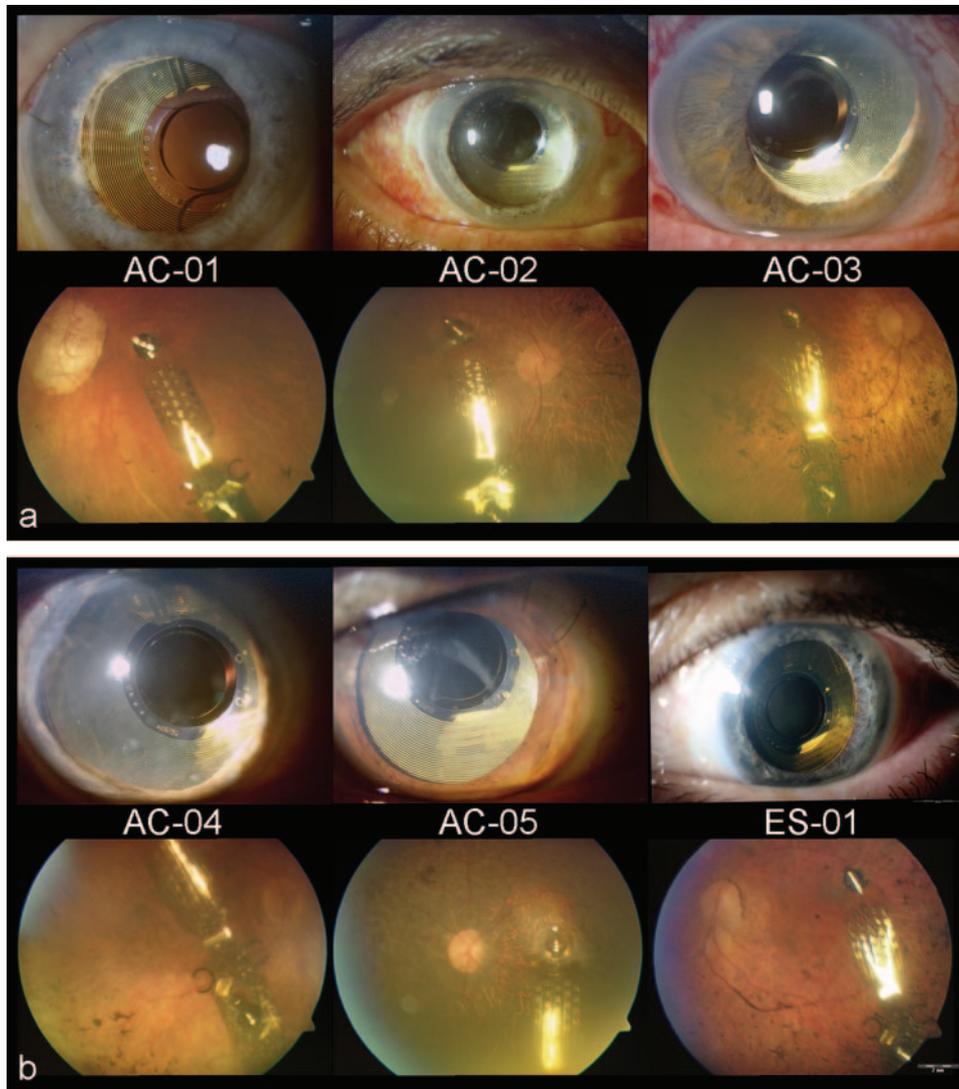
### Patient AC-02

**Implantation.** The EPIRET3 device was implanted after removal of the lens by phacoemulsification, posterior capsule opening, and complete vitrectomy. The receiver module was positioned within the sulcus ciliaris, and the stimulator was placed directly on the retinal center and fixed with two retinal tacks. The eye was filled with air. After surgery, a significant inflammatory reaction was observed on day 3 with a 1.5-mm painless hypopyon without chemosis. Anterior chamber samples obtained on that day were culture negative. The patient was treated systemically with steroids and antibiotics. The hypopyon resolved completely at day 5.

**TABLE 2.** Summary of Preoperative Findings

Patient Code	Study Eye				Fellow Eye	
	Visual Acuity	IOP (mm Hg)	ERG mfERG	Anterior Segment Fundus	Visual Acuity	Duration of Legal Blindness (y)
AC-01	LP	15	NR	Posterior chamber IOL Optic atrophy, narrow vessels, central RPE	LP	3
AC-02	LP	15	NR	Cataract Pale optic disk, narrow vessels, central RPE atrophy, bone specule pigments	LP	2
AC-03	No LP	12	NR	Cataract Pale optic disk, narrow vessels, bone specule pigments	No LP	3
AC-04	LP	11	NR	Posterior chamber IOL, posterior synechiae, posterior capsula opacifications	LP	8
AC-05	HM	10	NR	Narrow vessels, bone specule pigments Cataract	HM	4
ES-01	LP	12	NR	Narrow vessels, bone specule pigments Cataract Narrow vessels, bone specule pigments	LP	7

LP, perception; HM, hand movements; NR, not recordable.

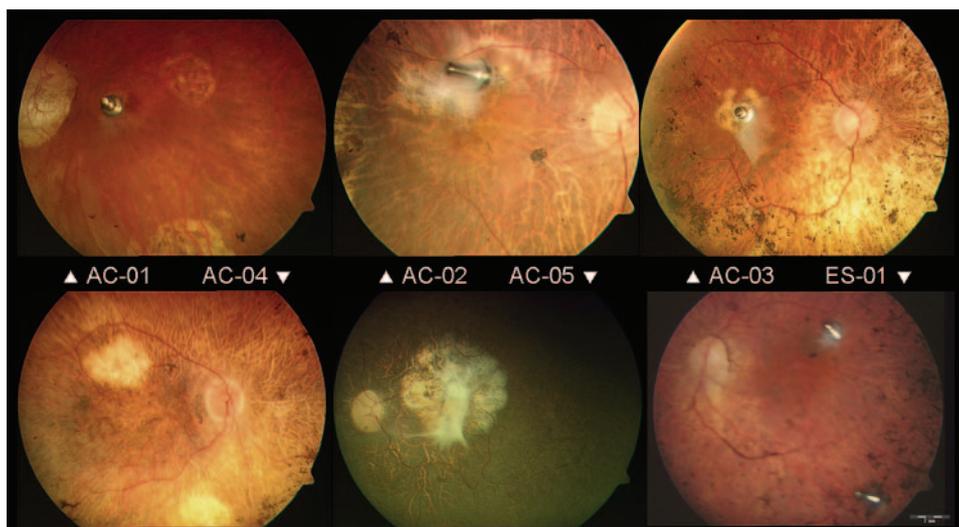


**FIGURE 3.** (a) Anterior segment and fundus of each of the six patients AC-01 to -05 and ES-01 4 weeks after implantation of the EPIRET3 device. Anterior segment shows the receiver module placed behind the iris in the posterior chamber. (b) Fundus photographs demonstrate the position of the microelectrode array fixed onto the retinal surface by retinal tacks.

**Explantation and Follow-up.** At day 28, the implant was removed without problem. The tacks remained and the eye was filled with SF6 20%. Six months after explantation, funduscopy showed complete retinal attachment with moderate gliosis formation at one tack.

**Patient AC-03**

**Implantation.** The lens was removed by standard phacoemulsification, followed by opening of the posterior capsule. The stimulator was placed slightly inferior to the retinal center



**FIGURE 4.** Patients AC-01 to -05 and ES-01 6 months after explantation of the device. Fundus photography of AC-05 shows the posterior pole with residual proliferative reaction after silicone oil removal.

TABLE 3. Summary of Clinical Findings before Explantation 4 Weeks after Implantation

Patient Code	Visual Acuity	IOP (mm Hg)	Anterior Segment	Posterior Segment
AC-01	LP	19	Cornea clear, AC deep, clear, pupil round, implant in PC, well centered	Stimulator at posterior pole, electrode array on retinal surface, two tacks, retina attached
AC-02	LP	21	Cornea clear, AC deep, cells+, pupil round, implant in PC, well centered	Stimulator at posterior pole, electrode array on retinal surface, two tacks, retina attached
AC-03	No LP	14	Cornea clear, AC deep, pupil oval, Implant in PC, well centered	Stimulator at posterior pole, electrode array on retinal surface, two tacks, retina attached
AC-04	LP	12	Cornea clear, AC deep, cells +, pupil in mydriasis, Implant in PC, well centered	Stimulator at posterior pole, electrode array on retinal surface, two tacks, retina attached
AC-05	HM	18	Cornea clear, AC deep, pupil round, Implant in PC, well centered	Stimulator at posterior pole, electrode array on retinal surface, two tacks, retina attached, gliotic membrane around central tack
ES-01	LP	14	Cornea clear, AC deep, pupil round, implant in PC, well centered	Stimulator at posterior pole, electrode array on retinal surface, two tacks, retina attached

LP, light perception; HM, hand movements; AC, anterior chamber; PC, posterior chamber.

and fixed with two tacks. The eye was filled with air. Postoperative examination showed a minor transient inflammatory reaction.

**Explantation and Follow-up.** At day 28 the implant was removed without any complications. The tacks remained and the eye was filled with SF6 20%. A mild epiretinal membrane at one of the remaining tacks could be seen.

#### Patient AC-04

**Implantation.** An artificial intraocular lens had to be removed after opening of broad posterior synechiae together with the capsule. The implant was inserted and fixed transsclerally with two 10-0 prolene sutures. The stimulator was inserted without any problems and was fixed with two retinal tacks over the posterior pole. The eye was filled with air. After surgery, no problems were noted.

**Explantation and Follow-up.** The explantation procedure was uneventful. The tacks were removed because they were found to be loosely inserted, and the eye was filled with SF6 20%. The follow-up did not show any adverse reactions.

#### Patient AC-05

**Implantation.** The lens was removed by standard phacoemulsification and, after complete vitrectomy and opening of the posterior chamber, the implant was inserted and fixed over the posterior pole with two tacks. Air was used as an endotamponade. On the first postoperative day, the eye was hypotonous due to permanent finger manipulations by the patient. The anterior chamber was flat. We injected sodium hyaluronate into the anterior chamber and ensured that the sutures were tight. The patient was again educated to avoid touching

the eye. Slit lamp examination revealed moderate levels of flare and AC cells. Under topical and systemic steroids and antibiotics, the inflammatory response resolved. At the central tack, an epiretinal proliferation was observed before explantation.

**Explantation and Follow-up.** During explantation, we found the central tack loose but adherent to the epiretinal membrane so we had the impression that we should remove the tack. The stimulator was removed, but removal of the tack and the membrane caused a central retinal defect. The procedure was finalized with heavy liquid fill, endolaser, and decaline/silicone oil exchange. After surgery, visual acuity dropped from hand movements to light perception. After oil removal at 3 months, the retina remained attached, and visual acuity increased to hand movements again.

#### Patient ES-01

**Implantation.** The lens was removed by phacoemulsification, and the implant was inserted after complete vitrectomy and fixed to the retina with two tacks. After surgery, no adverse events were seen.

**Explantation and Follow-up.** The explantation was uneventful at day 28. The tacks remained and the postoperative course showed no complications.

The clinical data before explantation and at the last examination 6 months after implantation are given in Tables 3 and 4.

## DISCUSSION

We have demonstrated that the implantation of the wireless EPIRET3 device in all six patients included in the trial was feasible. As expected after such a major procedure, transient

TABLE 4. Summary of Clinical Findings 6 Months after Explantation

Patient Code	Visual Acuity	IOP (mm Hg)	Anterior Segment	Posterior Segment
AC-01	LP	12	Cornea clear, aphakia, AC deep, pupil round	Retina attached, two tacks in place, no proliferation
AC-02	LP	12	Cornea clear, aphakia, AC deep, pupil round	Retina attached, one tack in place, some proliferation around tack
AC-03	No LP	15	Cornea clear, aphakia, AC deep, pupil oval	Retina attached, two tacks in place, some proliferation around one tack
AC-04	LP	14	Cornea clear, aphakia, AC deep, pupil round in mydriasis	Retina attached, both tacks removed, no proliferations
AC-05	HM	20	Cornea clear, aphakia, AC deep, pupil with open inferior iridectomy	Retina attached, both tacks removed, residual proliferation
ES-01	LP	14	Cornea clear, aphakia, AC deep, pupil round	Retina attached, two tacks in place, some proliferation around one tack

Abbreviations as in Table 3.

inflammatory responses occurred but were treatable with local antibiotics and steroids. The hypopyon in patient 2 was first thought to be an indicator of endophthalmitis but anterior chamber samples taken the same day did not show a positive culture. However, we treated the patient with systemic steroids and antibiotics, and the hypopyon resolved completely within 2 days. In patient 5, during removal of the implant, a thick epiretinal membrane was found in the tack area at the retinal center, and during removal of the membrane a macular hole became evident. We filled the eye with silicone oil to achieve a stable situation. Despite these two adverse events, the complication profile of the surgery of complex wireless retina implant systems, such as the EPIRET3 system, was acceptable, and the procedures were well tolerated. Both, the implantation and explantation were completed within 2 hours of operating room time.

The EPIRET3 device consists of a wireless technology to transfer data and energy from the external power source to the implant. Thus, a cable connection through the wall of the eye is avoided, which considerably shortens surgical time and prevents the possibility of intraocular infections or mechanical stress over the long term. Other implants currently under investigation require wire connections between the outer world and the visual system: The ARGUS II device implanted by Yanai et al.<sup>9</sup> has a cable connection from the implanted intraocular microelectrode array to the SC space behind the ear linked to a modified cochlear implant data- and energy-transfer device. The system implanted by the German Subret Group employs a cable connection from the subretinal space to the skin behind the ear where a direct cable connector is applied.<sup>13</sup> The Artificial Silicone Retina (ASR) Chip developed by Chow et al.<sup>14</sup> is a passive subretinal microphotodiode implant that transforms photon energy from the light falling on the retina into electric power stimulating retinal neurons. Temporary visual improvements were noted in retinal areas far away from the implant, possibly due to neuroprotective effects (Chow AY, et al. *IOVS* 2003;44:ARVO E-Abstract 4205). The epiretinal system implanted by Richard et al. (*IOVS* 2002;43:ARVO E-Abstract 666) used an inductive link from outside the eye to the episcleral area. From the episcleral area, data and energy were transferred by a cable connection through the wall of the eye. In contrast, the EPIRET3 system detailed herein is the first retinal prosthesis implanted in the human eye that does not require any cable connection crossing the globe's wall.

Placing the electrodes to the neurons as near as possible is mandatory to ensure specific local activation of neurons with minimum electric energy. The EPIRET3 implant allows for direct epiretinal montage of the 3-D shaped electrodes by fixing the electrode array with two retinal tacks close to the inner retinal surface. Animal experiments have shown that tack fixation is sufficient to achieve close contact between the target tissue and the implant without any significant adverse fibrovascular response.<sup>15,16</sup> Retinal tacks have been used for the repair of complicated retinal detachments.<sup>17,18</sup> In such cases, glial reactions were observed adjacent to the tack. However, it is not clear to what extent such reactions will occur in cases in which the retina is attached. In our trial, three of the six eyes showed mild to moderate epiretinal changes, and another eye showed a thicker membrane. We have the impression that epiretinal membranes occur in tacked areas where the tack is not very tightly inserted.

Obviously, longer follow-up periods in humans are necessary to determine long-term adverse tissue reactions. However, a follow-up exceeding 28 days is prohibited by German Law, since the implant is an investigational device fabricated in an academic, nonindustrial environment. Based on the data of the EPIRET3 trial, a second-generation wireless implant system will

be developed together with companies in this field. This implant will have a considerably higher number of electrodes and more signal processing power, to provide useful artificial vision for people with blindness.

During three follow-up examinations after implantation, stimulation experiments were performed to elicit visual sensations. In all cases, the implant activated from the external power and data unit. Details of the stimulation experiments such as stimulus thresholds and the type of percepts will be given in a separate publication.

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