

Electrical Stimulation Therapy for Retinal Degeneration

Initial reactions from patients indicate major interest in this mode of therapy.

**BY WALTER G. WROBEL, MD, PhD; GUIDO BLAESS, PhD; CARMEN EIPPER;
ALEX HARSCHER, PhD; AND ANUSCH HEKMAT, PhD**

Retinal diseases are currently the subject of much research in ophthalmology. Whereas drug medication is available for age-related degenerative diseases such as wet age-related macular degeneration, none have been approved for those of genetic origin, such as retinitis pigmentosa (RP). Approximately 1 in 4000 people are affected by RP, making it the most common hereditary eye disease. A degenerative disease, RP reduces the visual field over a course of years, usually starting from the periphery, and results in tunnel vision; in the final stages, visual function often disappears completely.

Although retinal implants have been developed for the management of RP, such systems are applicable only once the loss of vision has progressed significantly. There is still no generally accepted and scientifically recognized therapeutic option for the prevention of RP.

ELECTRICAL STIMULATION THERAPY

The idea of using electrical current therapeutically is as old as our knowledge of electricity itself. The initial impulse for this idea came from basic research with retinal implants in recent years, which indicated, among other things, that electrical stimulation of the retina liberates growth factors which may be able to delay retinal degeneration.

After a clinical study at the University Eye Hospital of Tuebingen showed that the visual field can be improved by means of electrostimulation,¹ and indications of improvement in vision and other parameters were also found, a corresponding system of therapy was developed.



Figure 1. A typical visual field (tunnel vision) in RP. The arrows show an improvement of approximately 20%.

The challenge was to design a system that would require only a single adjustment by an expert with normal vision and then, after being installed, that could give even patients with severely diminished vision the ability to use the system independently under a physician's supervision in the surroundings of their own homes.

A NEW CLINICAL APPROACH

Based on the work of its parent company, Retina Implant AG, Okuvision GmbH (Reutlingen, Germany) ascertained that pulsed electrical stimulation of the retina above a certain intensity would result in the perception of electrically triggered light phenomena (so-called

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phosphenes). Studies of patients with retinal degeneration have shown that the threshold differs widely from patient to patient but tends to rise as retinal degeneration progresses.² This observation led to the idea of electrical stimulation with a fixed percentage of individual threshold values, thus ensuring that stimulation could be administered with equal intensity to every patient in the groups compared.

The loss of photoreceptor function typical of retinal degeneration leads to morphologic changes that have descriptively been termed a "hunger of the retinal ganglion cells for stimulation." For that reason, a positive effect of electrical stimulation is to be expected only when the stimulation does in fact lead to a release of phosphenes. Studies to date have not taken the individuality of the patients into account.

CLINICAL TRIAL RESULTS

Twenty-four patients at various stages of RP were treated during the aforementioned prospective, randomized, sham-controlled clinical study, in which most measurements were double-masked but all were at least single-masked. All those tested had measurable remnants of vision and visual fields.³

After the individual phosphene threshold in each case was determined, the patients were randomized and divided into three groups. The first (sham) group was treated without electric current, the second with 67% of the individual phosphene threshold, and the third group with 150% of the individual phosphene threshold.

Final evaluation showed an improvement in vision of approximately 0.05 logMAR in both the sham and the second group, but an improvement of approximately 0.10 logMAR in the third group. This means that approximately one line more can be read on a vision-testing chart. Because of the small case number, these values were not statistically significant ($P = .22$).

Study of the visual fields showed no change in the sham and second groups, but a highly statistically significant improvement ($P < .001$) of approximately 20% was observed in the third group (Figure 1). The visual field is to be regarded as particularly essential for patient mobility because it permits the patient to at least orient him-

self or herself independently both indoors and outdoors. Future studies are needed to optimize the treatment parameters even further. In our opinion, however, the results to date justify the development of a specialized system of therapy.

SUMMARY

Okuvision's electrical stimulation therapy system received CE approval in 2010 based on the clinical data detailed above. The treatment parameters will require further testing and optimization in additional, more comprehensive clinical studies. With a bit of practice, the new stimulation system can be used under the direction of a physician both by medical staff assistants and the patients themselves. The system also helps lay the groundwork for carrying out multicenter studies in this medical area. Initial reactions from patients indicate major interest. ■

Walter G. Wrobel, MD, PhD, is President of Okuvision GmbH. He can be reached at + 49 7121 36403-111; or via fax at + 49 7121 36403-115.

Guido Blaess, PhD, is Product Manager for Okuvision GmbH.

Carmen Eipper is a manufacturing technician with Retina Implant AG.

Alex Harscher, PhD, is Vice President of Operations at Retina Implant AG.

Anusch Hekmat, PhD, is Vice President of Quality/Regulatory at Retina Implant AG and Okuvision GmbH.



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