New perspectives for retinitis pigmentosa

Patient information on transcorneal electrostimulation (TES)
TES can help maintain eyesight

In retinitis pigmentosa (RP), the field of vision gradually shrinks as the photoreceptors of the retina are lost. Previously, there was no satisfactory therapy that could halt the gradual restriction of the field of vision, or even reverse it.

Transcorneal electrostimulation (TES) from Okuvision now offers the chance to positively affect the course of this disease.

TES is one of the first outpatient therapies for RP whose efficiency has been proven through clinical studies.\textsuperscript{1,2}

- The current results of the study have been classed as reliable according to expert committees of doctors and representatives of the patient organisation Pro Retina Germany.
- Approximately 200 patients have already used TES through clinical trials, also over longer periods.
TES therapy using OkuStim®

TES has been shown to increase the release of neuroprotective growth factors, which have a cell-preserving effect in the retina. Using clinical trial data, the OkuStim® system was designed to reproduce the benefits of TES to promote the best possible retention of visual fields.

1 **Pilot study:**
The pilot study carried out at the University Eye Clinic at Tübingen (UKT) showed that TES is safe and has positive effects on the course of the disease for retinitis pigmentosa patients.¹

2 **Long-term study:**
The second study, “EST II”, carried out by the UKT (up until August 2013), confirmed the safety of OkuStim® therapy over a 52-week application, and indicated a slowing of the progression of the disease.²

3 **Open-label study:**
The “TESOLA” surveillance study took place in 12 European centres from Oslo to Florence – the OkuStim® treatment showed an improvement in the stimulated eye with regard to the field of vision in the majority of cases. The patient survey predominantly revealed a high level of patient satisfaction and almost exclusively an improved or at least consistent capability regarding object recognition and other everyday tasks. The safety of the OkuStim® treatment has been clearly confirmed.³
The OkuStim® system

Eyes are stimulated using a weak electrical current delivered by the OkuStim® device. This occurs through the OkuEl® electrodes, which are held on the eyes using the OkuSpex® frame.

**OkuStim® device**
The doctor saves the exact treatment parameters on the USB stick for the OkuStim® device. All of the necessary information on the operating state and any possible warnings are shown on the display. In addition, the Okustim® device provides a range of acoustic signals to guide those with visual impairment.

**OkuEl® clip-on electrodes**
Disposable OkuEl® electrodes with hair-fine, 100 μm thin electrode filaments are placed below the pupil on the surface of the eye. They can hardly be felt by the patient and, with a little practice, can also be placed in the holders of the OkuSpex® frame by visually impaired patients.

**OkuSpex® frame**
The OkuSpex® frame is used for positioning the electrodes on the eye and for supplying the therapeutic current. The frame can be individually tailored to the shape of the face and head size.
Determining the personal treatment parameters by the doctor

The OkuSpex® frame is tailored to the shape of the patient’s face and the counter electrodes are stuck to the skin.

1

OkuEl® electrodes are placed in the OkuSpex® frame

2
The doctor determines the patient’s threshold values to establish their unique treatment parameters.

Then the treatment parameters for further treatment are saved on the USB stick.
The course of the therapy

1. The electrodes are placed in the holder of the OkuSpex® frame.

2. The counter electrodes are stuck to the skin and the OkuSpex® frame is put on.

3. Therapy starts by pressing the start button. The OkuStim® device reads the treatment parameters saved by the doctor on the USB stick. The stimulation takes place with the eyes closed.
For safe treatment, the OkuStim® device continually monitors the flow of current and resistance during the therapy session. The therapy can be stopped at any time by pressing the pause button.

At the end of the therapy session set by the doctor (generally 30 minutes), the OkuStim® device stops automatically.
A therapy system made in Germany

The OkuStim® system is made in Germany assuring you of the highest quality. This is because our products, which are predominantly made by hand, are developed and manufactured exclusively by qualified specialists in Germany.

Our extensive quality control allows us to fully trace each step of production and processing, from the raw part from the supplier to its use in the finished product by the customer.

All process sequences are carried out and checked in a controlled manner using work and test instructions so that
our customers receive only technically perfect products. Our comprehensive technical documentation guarantees traceability for many years and consistent product quality.

In addition, the quality management system is tested through annual audits by TÜV-Rheinland Germany in accordance with the standards and guidelines relevant for manufacturers of medical devices.
How does transcorneal electrostimulation work?
Current research results prove that activation of several so-called neuroprotective growth factors in the retina – by means of electrical simulation – has a cell-retaining effect on retinal cells that are dying off.

How is the OkuStim® system used?
The operation of the system is simple and tailored to the needs of patients with limited eyesight. The system consists of three components: The OkuStim® device, the OkuSpex® frame and OkuEl® electrodes. The OkuEl® electrodes are designed for single use. Details can be found on pages 4 and 5, as well as 8 and 9.

How often is the OkuStim® system used?
Based on clinical tests, we currently recommend a stimulation session of 30 minutes per week. You should continue to attend regular eye examinations to monitor your response to the treatment.

Is it painful or unpleasant to use?
Generally, the use of OkuStim® is painless. During stimulation, we recommend using artificial tears, if necessary, should patients react to the electrode filaments, or should mechanical irritation or reddening occur.
Can the OkuStim® system be used for other retinal diseases?
Data and results collected so far are only relevant to retinitis pigmentosa. Tests of the effect on other eye diseases such as age related macula degeneration (AMD) and Stargardt disease will occur in future studies.

The treatment of other hereditary retinal dystrophies such as cone-rod dystrophy, Choroideremia or Usher syndrome must be discussed in each individual case with the attending doctor.
Can the OkuStim® system also be used by children and pregnant women?
The manufacturer cannot recommend the use of the OkuStim® system by children or pregnant women because this has not as yet been tested in clinical studies.

How can the OkuStim® system be obtained?
According to the doctor’s assessment, therapy can either take place in hospital or at the patient’s home. A doctor’s prescription is required for both the OkuStim® system and the electrodes for home use. Patients who are already using the system are currently supplied directly by Okuvision with consumables on presentation of a prescription.

For new patients, we recommend finding a clinical centre that already has experience in setting up treatment parameters, and having an eye examination with them. It is up to the doctor whether a patient is suitable for treatment. If you are interested in therapy using the OkuStim® system, please contact a centre near you. You can find an overview of current centres and Low Vision Partners at www.okuvision.de/en

Will the cost of the OkuStim® therapy be reimbursed by the national health insurance?
The patient bears the costs of the OkuStim® treatment. Depending on the health care system of the particular country and the individual scope of insurance an assumption of the costs of the treatment may be met in individual cases. For example, in Germany the Federal Joint Committee (G-BA: the highest decision-making body of joint health scientists and health funds) sees significant potential in the
Okustim® therapy. However, this does not justify any claim of reimbursement, as the process is lengthy and may take years.

Is the OkuStim® system safe and efficient?
Yes, but not all patients benefit equally from the OkuStim® treatment. A differentiation must be made between so-called “high and low responders”. Possible reasons may be the different genetic causes that lead to this retinal dystrophy. A positive influence on the field of vision or at least a slowing down in the progression has only been identified in “high responders”.

1 Schatz et al.: Transcorneal Electrical Stimulation for Patients with Retinitis pigmentosa: A Prospective, Randomized, Sham-Controlled Exploratory Study – IOVS, June 2011, 52nd. year, no. 7
2 EST2, University Eye Clinic at Tübingen, Germany (data on file) – 2011 to 2013; Results not yet published
3 TESOLA, an evaluation at the University of Tübingen, Institute of Clinical Epidemiology and Applied Biometrics, Prof. Martus (data on file) – 2012–2014; results not yet published
Your point of contact

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