Transcorneal Electrical Stimulation in Retinitis Pigmentosa with the RI OkuStim system

Information for Physicians
New Perspectives in Retinitis Pigmentosa
for a Window of Hope

As a result of retinitis pigmentosa (RP), the visual field often continuously decreases due to a loss of photoreceptors in the retina. To-date no satisfactory therapy for stopping this loss of vision has been found. The quality of life of the patients is massively compromised.

Retina Implant’s RI OkuStim system now offers a trialed therapy which can slow the course of disease in RP-patients who still have a residual visual function. For patients without such a remaining visual function, on the other hand, we will gladly provide information about the possibilities offered by the subretinal RETINA IMPLANT Alpha AMS.

„If the RI OkuStim can slow down the progression of the disease, then I want to seize that chance.“

Irene F. (49), Hamburg

The RI OkuStim – the Therapy Option for Retinitis Pigmentosa

Up to now there has been no scientifically and clinically tested therapy for retinitis pigmentosa. Retinitis pigmentosa is officially classified as a rare retinal disease. It usually means a long wait until blindness eventually sets in. Patients in the early stages of RP, especially those who would otherwise be fit for work, could profit from the RI OkuStim system. Offer your patients the chance now to slow down the gradual progression of the disease.
Retinitis Pigmentosa

Course of the Disease

For those affected, retinitis pigmentosa (RP) means a slow loss of visual field in most cases eventually leading to blindness. Our dedicated team of scientists and engineers carry out research and development with the aim of opening a window for RP-patients – a window of hope.

Analyses carried out by Massof et al. have shown an exponential reduction of the visual field with an average time constant of approximately 4.5 years. During this time, the remaining visual field of an RP-patient decreases in each case by 50%.

The first symptoms (usually night-blindness) can appear in a person’s teens. Large parts of eye-sight are affected early on. The ensuing consequences may be professional limitation and psychical strain. The course of the disease often ends with complete blindness.

Illustration how RP can be perceived from the perspective of an RP-patient.
Study Results Concerning Safety and Efficacy

The following studies have shown the safety and efficacy which patients can expect from Transcorneal Electrical Stimulation (TES) with the RI OkuStim system.

Pilot Study: expansion of the visual field

The results of the pilot study show the potential of a therapy with TES (Transcorneal Electrical Stimulation). The sham-controlled, prospective clinical study with 24 RP patients showed significant improvement of the visual field after 6 weeks of stimulation (p < 0.05). 150% of the individual phosphene threshold was used during stimulation. The phosphene threshold is the individual intensity of electric current which generates perceptible light flashes within the eye.\(^2\)

Long-Term Study: increased cellular activity in the retina

A further long-term clinical study resulted in significant improvement in the patient groups which underwent stimulation, as shown by electrophysiological evaluation. The study indicates an increase of cellular activity in the retina.

Light-adapted single-flash ERG b-wave analyses showed highly significant improvement (p < 0.0001) in the eyes which had undergone stimulation in comparison to the control group.\(^3\) The sham-controlled and prospective study was carried out with 52 patients and a stimulation duration of 12 months.
Observational Study: improved visual acuity

An observation of applications carried out with 97 patients at 11 centers in Europe showed improved visual acuity in the treated eyes. This was statistically significant (p < 0.05) and remained constant throughout the stimulation-free follow-up observation period. No changes were observable in the partner eyes.⁴

How does the TES therapy work?

Further studies have indicated that with Transcorneal Electrical Stimulation it is possible to activate several so-called neuro-protective growth factors, thus generating a cell-preserving effect in the retina. This also means, among other things, a reduction in the rate of apoptosis.⁵,⁶

Safety Confirmed

All studies including the observational study have confirmed the safety of the TES therapy. Further confirmation of this also came from ophthalmological expert commissions and from PRO RETINA e.V., the German patient organisation for people with retinal degeneration.⁷
How is TES therapy with RI OkuStim applied?

The RI OkuStim system stimulates the retina transcorneally with very low electrical impulses. The intensity of the stimulation current is adjusted individually for each patient at RI Competence Centers. The impulses are emitted by RI OkuEl electrodes. These are positioned on the eye by means of the RI OkuSpex frame.

The RI OkuStim system has been designed for home-use. We recommend a phase of initial instruction sessions at a certified RI Competence Centre. On the basis of clinical evaluations, a long-term therapy with weekly stimulation sessions of 30 minutes is recommended.

The disposable RI OkuEl electrodes are positioned below the pupil on the surface of the eye.

The RI OkuSpex frame is used to position the electrodes below the pupil and to conduct the therapeutic current. The frame can be individually adjusted to suit the shape of the patient's face.

Stimulation is controlled with the hand-held unit. The individual treatment parameters are determined and set by the physician.
How can your patient gain access to the therapy?

Your patients can get a prescription for the therapy at certified clinical competence centers. You will find an overview of current competence centers for patient referral under [www.retina-implant.de/en/services/find-a-specialist/](http://www.retina-implant.de/en/services/find-a-specialist/)

We gladly provide support for you and your patients regarding all questions concerning background information and procedures during therapy. Our product specialists are on hand at all times during the therapy to assist your patients. Order our patient brochure by telephone or email. It provides comprehensive, easy-to-understand information for your patients about RI OkuStim as a therapy option.

We will gladly be available for any further questions.

What is the present reimbursement status by health insurance?

The cost of TES therapy must currently be borne by the patient. However, patients can submit an application to their health insurance companies for reimbursement of the costs.

In Germany, the G-BA (“Gemeinsamer Bundesausschuss“, or „Federal Joint Committee“) has formally recognised the therapy’s potential value and has established guidelines for a trial study (in accordance with Section 137 e of the Fifth Code of Social Law).

Sources and Literature

4. TESOLA Observational Study (Results were presented to an expert audience during the Euretina September 2015 and WOC February 2016. A paper is forthcoming.)