Transcorneal Electrical Stimulation for Retinitis Pigmentosa

with the RI OkuStim system

Patient information
Fifteen years of research and development have shown us that although your sight may be deteriorating because of degenerative retinal diseases, you still have options of treatment. Transcorneal electrical stimulation (TES) with RI OkuStim is one of the first treatment options available for retinitis pigmentosa (RP) that can be used at home. The efficacy of TES has been confirmed in clinical trials.¹, ², ³

The RI OkuStim system enables us to slow down the progression of the disease for RP patients with residual vision by using electrical stimulation therapy.

Our aim at Retina Implant is to open a window of hope for people suffering from retinitis pigmentosa. Our objective is to retain vision for longer or to restore a certain degree of vision.

We give you advice and support throughout your treatment.

This brochure contains all important information about TES therapy with the RI OkuStim system: a description of how the disease progresses, insights from a patient’s point of view, technical details about the therapy and its individual components, information about its application and benefits as well as step-by-step instructions for carrying out your TES therapy. We look forward to hearing from you. Our experienced team will assist you with any questions you have about the treatment or implant for retinitis pigmentosa. They will help open a window of hope for you.
Transcorneal electrical stimulation with the RI OkuStim system offers a chance to slow down the progression of retinitis pigmentosa. Studies show that it is possible to activate a number of neuroprotective growth factors, which help to preserve the cells in the retina. After patients have been introduced to the system, they can carry out the therapy independently at home.

In retinitis pigmentosa the sensory cells of the retina die off, whereby rods are initially more severely affected than cones. Typically, the remaining field of vision gradually reduces by half over a 5-year period on average, until the patient becomes completely blind. The sequence of pictures below illustrates the gradual loss of visual field in patients with this disease.

*This is how the development of RP could be perceived by the patient (simulation).*
“Actively working against retinitis pigmentosa”
Verena H. tells us about her experience

How has the disease progressed in your case?
I noticed night blindness when I was 12 years old. My vision in darkness gradually deteriorated. I first noticed reductions in my visual field and increased sensitivity to glare when I was 21. I am pleased that I can still be so active in spite of RP: I spend a lot of time outdoors, I play tennis, I swim and hike, and sometimes I even go canyoning.

How did you hear about the TES therapy?
I heard about the TES therapy for the first time at the PRO RETINA international congress in Hamburg. PRO RETINA is a self-help group for people with eye diseases. I would recommend membership for anyone with RP. Membership has opened many doors for me. I was able to access the TES therapy as part of my medical treatment at the eye clinic in Tübingen.

*This is personal experience that does not apply to all patients. The outcome of the treatment differs for every patient.*
How do you apply the TES therapy?

I use TES therapy independently, generally once a week for half an hour. It is very easy to use and does not restrict me in any way. The Retina Implant team provides excellent support. They are all very approachable and can always help me with my questions.

How does the TES therapy help you?

The TES therapy gives me the feeling that I can do something to slow down the progression of the disease. In addition to the therapy, my family and friends have been a great support. They give me hope and help me stay optimistic.

Would you recommend RI OkuStim?

I would first suggest to all RP patients and their families not to give up hope and not feel bound by any limitations.
I can recommend RI OkuStim because it is easy to learn how to use the device, the therapy is painless and it can be carried out at home.

„The RI OkuStim system is easy for me to use at home.“

After adjusting the individual settings and frame, the therapy can be carried out at home with a little practice.
Easy Start with RI OkuStim

The RI OkuStim system is easy to use. After a training period in the hospital or the eye clinic, you can generally carry out the therapy by yourself at home. The doctor first adjusts the RI OkuSpex frame to the shape of your face and defines the individual treatment parameters with a threshold measurement. Then the first therapy session is carried out. Your specific treatment parameters are saved to the memory card on the RI OkuStim hand-held device.

Just 30 minutes per week

We recommend a stimulation period of 30 minutes a week. This therapy period is based on findings from the clinical studies. The stimulation can be performed easily and conveniently at home. The patients keep their eyes closed during the therapy. During this period the RI OkuStim hand-held device continuously monitors the current and resistance. The therapy can be interrupted at any time by pressing the pause button.

Results that show

The TES therapy has now been applied to around 150 patients in the course of studies, partly over extended periods, and has been confirmed as safe and effective. If you no longer have any residual vision, the RETINA IMPLANT Alpha AMS subretinal implant may help. Under certain circumstances it may be possible to regain a certain degree of vision. Find out more here: www.retina-implant.de/en/implant/ri-alpha-ams/
Verified safety

The clinical trials and observational study conducted to-date confirm the safety of TES therapy. This has also been confirmed by expert ophthalmology groups and the PRO RETINA e.V. patient association.

How does the TES therapy work?

Studies indicate that transcorneal electrical stimulation can activate a number of neuroprotective growth factors, which help to preserve the cells in the retina. Along with other effects, this means that cell-death is slowed down.
The RI OkuSpex frame is designed to position the electrodes directly on the eye. The frame can be adjusted to fit the shape of your face.
One Therapy, Three Components

The TES therapy is a system with three components. The RI OkuStim hand-held device stimulates the eyes using electrodes that deliver a weak electric current.

↑ RI OkuEl electrode

The RI OkuEl electrodes are very fine (100 µm) electrode filaments that are placed below the pupil on the surface of the eye. They are designed for single use only, are barely felt and even with restricted vision the patient can independently insert them into the holders of the RI OkuSpex frame with just a little practice.

← RI OkuStim hand-held device

The eye-specialist saves the specific treatment parameters to the memory card of the RI OkuStim hand-held device. The device not only displays information but also emits sounds so that the system can be used with ease even with limited vision.
Your Path to the TES Therapy with the RI OkuStim System

1. **Personal consultation**
   We are happy to answer all your questions regarding the treatment of retinitis pigmentosa in an individual consultation. Alternatively we can put you in touch with RI Competence Centres. We look forward to hearing from you.

2. **Diagnosis and suitability**
   You can access the therapy at certified RI Competence Centres. At your first appointment the doctor will make a diagnosis and examine you to see whether TES therapy with the RI OkuStim system is right for you and your condition.

3. **Financing**
   Depending on the national health system, you can apply to your health insurance provider for a case-by-case check to determine whether the cost of the requested treatment will be covered.
Therapy sessions
You can conduct the TES therapy with the RI OkuStim system yourself at home once the doctor has adjusted the system to your specific requirements. We recommend having your first therapy sessions assisted at an RI Competence Centre.

Planning and treatment
Your TES therapy will be based on a therapy plan that will be prepared by your doctor. The general rule is one electrical stimulation session each week for 30 minutes. Please get in touch with us or refer to our website for distributor information.

Checkups
A check-up at an RI Competence Centre is recommended at least every six months to assess the therapy progress. Here you will also receive a prescription for your RI OkuEl electrodes.
You can access the therapy at certified clinical RI Competence Centres. For the current list of RI Competence Centres or to obtain a referral, see: www.retina-implant.de/en/services/find-a-specialist/

We look forward to supporting and advising you during your treatment. We are gladly available to answer any further questions you might have.

In Germany the G-BA (Federal Joint Committee) has attributed a potential benefit to the therapy. Clinical testing is in preparation (in accordance with §137e of Book V of the German Social Code).8

The TES therapy is currently a self-pay service.

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