Transcorneal Electrical Stimulation: A Therapy Option for Retinitis Pigmentosa

The progressive reduction of the visual field in retinitis pigmentosa (RP) can so far not be halted or even reversed by any therapy [1]. Transcorneal electrical stimulation (TcES) can help to slow down the progression of RP. The safety of the TcES therapy with the OkuStim System has been demonstrated in extensive clinical trials.

Basis of the therapy

Electrical stimulation with weak currents can activate signalling pathways and the release of substances in the diseased retina that have a protective effect on retinal cells [2]. This neuroprotective effect can maintain physiological functions in the retina for longer and slow down the retinal degeneration.

Application

In TES therapy, retinal stimulation is achieved by transcorneal application of a weak current (< 1mA) to the surface of the eye, which spreads in towards the retina. The current is applied by a thread electrode. The OkuStim application is designed for independent home-use by the patient, after introduction by trained medical staff. The treatment is performed once a week for 30 minutes. Six-monthly follow-ups at the ophthalmologist are expressly recommended.

Clinical investigations

Clinical studies show that TcES triggers physiological processes in the retina of RP patients. The application immediately causes a significant increase in blood flow to the central retina [3] and increased oxygen consumption of retinal cells [4]. Randomized, controlled studies with weekly application also showed a significant improvement in visual acuity [3], visual field [3, 5], and improved b-wave amplitudes in the dark-adapted [5] and light-adapted ERG [6]. The effect of TcES appears to be transient, suggesting long-term application [7].

The safety of the application of the OkuStim system has been clearly proven in all clinical investigations, including a multi-centre post market observational study in 11 European clinics (TESOLA) [8, 9].

All clinical studies conducted with the OkuStim System to date have consistently demonstrated the safety of using TcES therapy in outpatient and home settings. More than 300 patients have participated in the studies and have used the therapy for 130 years, including more than 60 years in home use. In a total of more than 3,600 hours of stimulation, no serious adverse event related to the device or therapy occurred.

Although the clinical data from the various studies do not yet provide a consistent picture of clinically relevant long-term effects, they do indicate significant effects of TcES on photoreceptor function and a positive effect on the visual field and visual acuity. In recognition of this, the German Institute for Quality and Efficiency in Health Care (IQWIG) has confirmed that TcES therapy with the OkuStim System has the potential for patient-relevant benefits [10].

Patient care and support

On the basis of the data obtained so far, the TES therapy is classified as safe by the Arbeitskreis Klinische Fragen (AKF) of PRO RETINA e.V., so that it can also be used outside the context of studies in RP patients. Furthermore, there are no objections to the use of the treatment in other generalised hereditary retinal dystrophies (cone and rod dystrophies, choroideremia, Usher syndrome, etc.) [11]. The OkuStim system is only available on prescription.

Fig.: Home use of the TcES therapy with the OkuStim system

A constantly growing network of eye clinics is available as Competence Centres for patients. The OkuStim system is available at selected Low-Vision-Opticians and through international distributors.

Literature