Transcorneal Electrical Stimulation: A Therapy Option for Retinitis Pigmentosa

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There is no therapy for retinitis pigmentosa (RP) that can halt or even reverse the progressive reduction in visual field [1]. In Germany alone there are about 20,000 patients with the diagnosis RP. Transcorneal electrical stimulation (TES) can help to slow down the progression of RP. The safety of the TES therapy with the OkuStim System has been demonstrated in extensive clinical trials involving more than 200 patients (see chart).

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

A recent study conducted in Basel has shown that TES triggers physiological processes in the retina of RP patients [3]. After stimulation, an increased oxygen consumption in the retina was measured, which proves an increased cell activity. This supports the results of the studies carried out at the University Eye Hospital in Tübingen. In the pilot study EST I it was shown that TES can slow down the reduction in visual field loss [4]. The follow-up study EST II showed significantly increased retinal cell activity [5]. The safety of the application of the OkuStim system was clearly demonstrated in all clinical trials, including a multi-centre observational study in 11 European clinics (TESOLA) [6, 7].

The highest decision-making body in the German health care system, the Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA), has attributed to TES therapy a potential for relevant benefit for patients with RP and issued a guideline for conducting a clinical trial [8].
The investigation is expected to start at the end of 2020.

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.) [9]. The OkuStim system is only available on prescription.
There are currently 13 eye clinics nationwide (in Germany) serving as centres of excellence for people affected by RP. The OkuStim System is available through selected regional low vision opticians. The manufacturer, Okuvision GmbH, is currently expanding its supply network for the therapy in Germany and in Europe (Switzerland, Italy, Turkey, Greece).

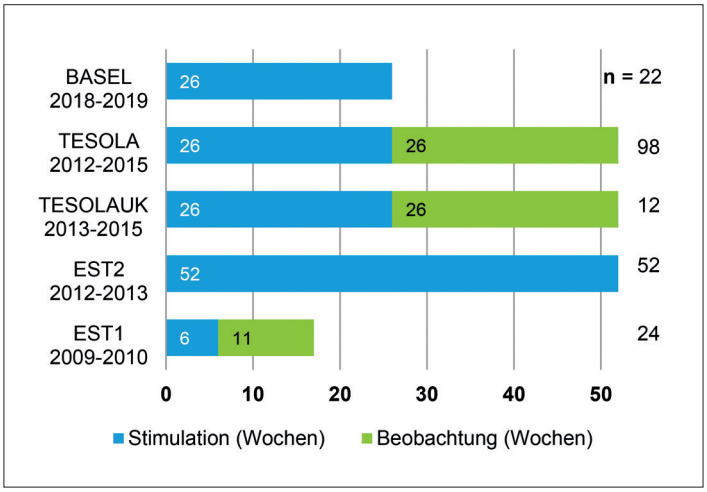

Fig.: Clinical investigations into the use of transcorneal electrical stimulation (TES) with the OkuStim System in retinitis pigmentosa (RP). Left axis: name and duration of the studies, lower axis: duration of the studies (stimulation followed by observation period); right: number of patients participating in the studies.

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