



Ellex 2RT RETINA REGENERATION THERAPY

Retina Regeneration Therapy (Ellex 2RT™)* is a research project aimed at developing a non-damaging laser treatment that stimulates the retinal pigment epithelium (RPE) to preserve vision. As a possible therapy for early age-related macular degeneration (AMD) and other retinal diseases, Ellex 2RT™ aims to treat the cause of the disease, before vision loss occurs.

The effort to develop Ellex 2RT™ has been led by Prof. John Marshall since 2001 when he was appointed chairman of the Ellex Medical Advisory Board. Together with his research colleague, Dr. Ali Hussain, Prof. Marshall has spent many years researching the underlying causes of AMD. Initial laboratory studies successfully demonstrated that Ellex 2RT™ can be used to influence the early cause of AMD by triggering a cell regeneration process to improve the transport properties of Bruch's membrane and thereby partially reverse the degradation that could lead to Wet or Dry AMD. Based on these preliminary results, researchers formulated the Ellex 2RT™ device parameters required to induce the RPE to migrate and release matrix metalloproteinase (MMP), which are the enzymes that clean up Bruch's membrane. Further laboratory studies measuring the hydroconductivity of Bruch's membrane have shown that Ellex 2RT™ rejuvenates the whole transport mechanism of the retina.

At the 2009 annual meeting of the Association for Research in Vision and Ophthalmology (ARVO), Ellex and its key research partners shared the results of ongoing laboratory studies which highlighted the lack of damage or inflammatory response caused by Ellex 2RT™ treatment, as opposed to conventional photocoagulator treatment. These laboratory studies are being undertaken in parallel with Ellex's clinical trials program, with results being used to shape and adjust clinical evaluations. Given the potential of Ellex 2RT™ to change the retinal disease treatment paradigm – and to positively influence the lives of millions of people worldwide – Ellex has employed a systematic approach in its initial clinical evaluations in order to best evaluate the potential of Ellex 2RT™.

The Ellex 2RT™ Research Program has accelerated with the commencement of a series of pilot clinical studies aimed at evaluating the clinical efficacy of Ellex 2RT™ for a number of indications. The studies are making good progress, with prototype Ellex 2RT™ laser systems currently employed throughout Australia and the United Kingdom for use in these studies:

- Studies focused on DME and PDR are being undertaken in collaboration with the Royal Adelaide Hospital across three study sites, led by principal investigator Assoc. Prof. R Casson.
- An additional study focused on early AMD treatment is being undertaken in collaboration with the Royal Victorian Eye and Ear Hospital, a major Australian teaching institution, led by principal investigator Prof. R Guymer.

Ellex is targeting release of the interim results for these pilot studies at the 2010 annual meeting of ARVO.

Notes: Professor Marshall is Frost Professor of Ophthalmology at the Rayne Institute and head of the Academic Department of Ophthalmology at King's College, University of London.

*** Investigational device; not approved by the FDA for sale in the US.**