

Ellex 2RT Clinical Research

ARVO 2011 Abstract

Retinal Functional Improvement with Nano-Laser Treatment in High Risk Early AMD

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Purpose: The aim of this pilot study was to show if a novel nanosecond laser (2RT) treatment could improve visual function and reduce drusen in high risk Early Age-Related Macular Degeneration (AMD), which may then lead to reduced risk of late stage AMD.

Methods: Interim results out to 12 months from a prospective pilot study (ACTRN12609001056280). Early AMD patients selected with high risk Early AMD but without choroidal neovascularization (CNV) or geographic atrophy (GA). Patients examined with visual field perimeter, optical coherence tomography (OCT), autofluorescence (AF) imaging, fundus photography, visual acuity (VA).

Laser treatment consisted of 12 single laser pulses of 3ns duration, placed in "clock face" pattern around the mid-macular (5deg radius) of one eye using an energy range of 0.15mJ to 0.45mJ, spot diameter of 400µm, wavelength of 532nm. The patient's eye with highest risk was treated and main follow-up was performed at 3, 6 and 12mths. Visual field results were used to determine the bilateral regions of greatest dysfunction.

Results: 13 of the 14 patients that have reached 12mth follow-up showed some level of visual function improvement or drusen reduction, in one or both eyes. The regions of greatest dysfunction in visual function improved significantly in 7 of these patients and the majority of improvement occurred in patients with the greatest pretreatment dysfunction. VA significantly improved (>5 letters) in 5 patients and some level of drusen reduction occurred in 13 of the patients in one or both eyes. No association was evident between the location of visual function improvements and the location of the laser treatment or the eye treated. Decreased function or other adverse events did not occur in the region of the laser spots.

Conclusions: Interim results from this pilot study show that the application of 12 extremely low energy, non thermal, 2RT laser pulses to the mid-macula resulted in visual function improvements in the regions of greatest pre-treatment dysfunction. These regions are likely to be at greatest risk of developing late stage AMD, providing circumstantial evidence that the progress of AMD is being slowed or partially reversed by this laser treatment.

SFO 2011 Abstract

An Investigation on the Clinical Efficacy of the Ellex 2RT Laser for Treating Patients with Diabetic Maculopathy and AMD

Author Block: John Marshall. St. Thomas' Hospital, London, United Kingdom.

Introduction: Preliminary laboratory studies have confirmed that the Ellex 2RT Laser can be used to influence the early cause of AMD by triggering a cell regeneration process, thereby partially reversing or slowing the degradation leading to

late Dry or Wet AMD. The present study reports a series of pilot clinical studies currently in progress, designed to evaluate the clinical efficacy of the Ellex 2RT in treating patients with diabetic maculopathy and AMD.

Methods and Equipment: The study assessed patients with either early stage AMD or diabetic maculopathy, recording LogMar visual acuity, dilated funduscopy, optical coherence tomography (OCT), colour-fundus photography and fundus fluorescein angiography (FFA), as part of pre-operative testing. A laser treatment was applied using a 532-nm, Q-switched laser system (2RT, Ellex, Adelaide, Australia). The laser has a pulse duration of 4 nanoseconds, a pulse energy of 1 millijoule max and a spot size of 400 microns. However, the energy is discontinuous and only damages between 15% and 20% of the irradiated cells. A modified macular grid, guided by fluorescein angiography was used to deliver treatment. Patients were evaluated at 3 and 6 weeks and again at 3 and 6 months. A stability or improvement in LogMar visual acuity, central macular thickness measured with OCT, change in exudates and the amount of leakage on FFA and the quantity and distribution of drusen, were the main outcomes measured.

Discussion: An improvement in visual function was seen in the majority of the patients assessed. A 5% reduction in central macular thickness from baseline was measured in 46% of patients, while 39% showed stability, while 15% experienced an increase of more than 5% from baseline. An improvement in retinal function and partial reversal of disease progression were evident due to the decreased number of hard exudates in more than half of the treated eyes. An improvement of central functional vision was seen in 43% of the eyes by 2 or more lines of visual acuity, remained stable in 15% and showed deterioration in 14% of eyes.

Conclusion: Results from the 2008 pilot study and the 2010 Diabetic Retinopathy study show that the Ellex 2RT nanosecond laser treatment produces very similar reductions in macular edema when compared to the conventional retinal photocoagulation, using approximately 500 times less laser energy, and causing no collateral damage. The 2010 AMD studies suggest that the application of the Ellex 2RT to the affected eye reduces drusen and improves visual acuity.

Euretina 2011 Abstract

Evaluation of the Clinical Efficacy of the Ellex 2RT Laser for the Treatment of Diabetic Maculopathy and AMD

Author Block: John Marshall. St. Thomas' Hospital, London, United Kingdom.

Purpose: Initial clinical studies have successfully demonstrated that the Ellex 2RT Laser can be used in treatment of early stage age-related macular degeneration. The present study involves the on-going pilot clinical investigations on the clinical efficacy of the Ellex 2RT in treatment of AMD and diabetic maculopathy patients.

Methods: Patients with either early stage AMD or diabetic maculopathy were included in the study. Pre-operative testing included LogMar visual acuity, dilated funduscopy, optical coherence tomography (OCT), colour-fundus photography and fundus fluorescein angiography (FFA). A laser treatment was performed using a 532-nm, Q-switched laser system (2RT, Ellex, Adelaide, Australia). The laser has a pulse duration of 4 nanoseconds, a pulse energy of 1 milli-joule max and a spot size of 400 microns. However, the energy is discontinuous and only damages between 15% and 20% of the irradiated cells. The treatment was delivered using a modified macular grid, guided by fluorescein angiography. Patients were seen at 3 and 6 weeks and then again at 3 and 6 months at which time the same tests were performed. Main outcome measures were maintenance or improvement in LogMar visual acuity, central macular thickness measured with OCT, change in exudates and the amount of leakage on FFA and the number and distribution of drusen.

Results: The majority of patients enrolled in London and Australia experienced improvement in visual function. A reduction in central macular thickness of 5% from baseline was measured in 46% of patients, while 39% remained stable and 15% had an increase of more than 5% from baseline. The number of hard exudates decreased in more than half of the treated eyes demonstrating an improvement in retinal function and a partial reversal of disease progression. The central functional vision improved in 43% of the eyes by 2 or more lines of visual acuity, while it remained stable in 15% and showed deterioration in 14% of eyes.

Conclusion: The 2008 pilot study and the results from the 2010 Diabetic Retinopathy study show that the Ellex 2RT nanosecond laser treatment produces very similar reductions in macular edema as compared to the conventional retinal photocoagulation, using approx. 500 times less laser energy, and causing no collateral damage. The 2010 AMD studies suggest that the application of the Ellex 2RT to the affected eye reduces drusen and improves visual acuity.

ARVO 2010 Abstracts

Novel Nanosecond Laser Treatment to Prevent Vision Loss From Age-Related Macular Degeneration

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Purpose: To provide proof of concept for a pilot study using a new nanosecond laser based treatment in early Age-related Macular Degeneration (AMD) to reduce progression or even cause regression of disease.

Methods: The study design involved treating one eye with the nanosecond retinal regenerative therapy (2RT) laser in patients with bilateral high risk early AMD, using the contra-lateral eye as a control. Subjects underwent a full clinical evaluation and undertook novel visual function testing: dark adaptation, flicker and colour thresholds, VA or drusen resolution in both eyes at baseline, prior to treatment and then at 1, 3, 6 months and 12 months post laser. The laser was applied in one session with twelve, subthreshold, 400um spots placed in a clock hour distribution, 1400um from the fovea in one eye.

Results: 20 patients have been recruited and treated in one eye. 7 eyes have been tested out to 6 months. Of these 7 recruits, the treated eye improved in at least one parameter in 6 cases; dark adaptation (3), flicker (1) and colour thresholds, (3) VA (1) or drusen resolution (5). The fellow untreated eye improved in at least one parameter in 5 of 7 dark adaptation (3), flicker (1) and colour thresholds, (1) VA (1) or drusen resolution (5).

Conclusions: At 6 months post laser a large number of treated eyes, and untreated eyes were showing some signs of overall retinal function improvement. The dramatic effect seen in some subject's fellow eye was not expected. We aim to treat 50 high risk eyes over the next year to complete the pilot study. It is anticipated that the 2RT laser will address the underlying cause of AMD which appears to be reduced flux across Bruch's membrane. The laser design should enable the positive features of previous laser studies for early AMD to be harnessed without entertaining any of the negative effects such as neovascularization.

Ellex 2RT Clinical Research Abstracts

| ELLEX 2RT™ RETINAL REJUVENATION THERAPY |

A Pilot, Prospective, Randomized Clinical Trial of a New Nanopulse Retinal Laser versus Conventional Photocoagulation for the Treatment of Diabetic Macular Edema

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Purpose: The Retinal Regeneration Therapy (2RT) laser is a new, nanopulse retinal laser that experimentally causes minimal injury to sensory retina at clinically relevant settings. We compared the safety and efficacy of 2RT with photocoagulative (control) laser in a pilot, prospective, randomized, non-inferiority study.

Methods: Patients with previously untreated diabetic macular edema (DME) were randomized to receive either 2RT or control laser. Retinal thickness and logMAR acuity (VA) were recorded at baseline and 3 and 6 months after treatment (3-month data is shown here). The outcomes were the difference in retinal thickness reduction measured by optical coherence tomography (OCT) between the control and 2RT groups (OCT), and the difference in VA change between the control and 2RT groups (VA). Non-inferiority was defined as the one-sided 97.5% confidence intervals (CIs) of OCT.

ARVO 2008 Abstract

Treatment of Diabetic Macular Oedema with a New Laser System 2RT (photoregeneration)

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A pilot study of 2RT laser will be presented. This laser has a wavelength of 532nm is q-switched, has a pulse duration of 3 nanoseconds and a maximum energy of 1mJ per pulse. A total of 18 patients with 29 eyes were treated. The eyes were assessed with visual acuity, fluorescein angiography, OCT and microperimetry. The results showed that this new laser treatment was effective in reducing the retinal thickness in 55% of eyes.



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