

Clinical Research Abstracts

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.

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 > -35 µm (no more than 35 µm more reduction in the control group), and a VA > -.06 (VA change after 2RT no more than 3 letters worse than the control group change). An analysis of covariance (ANCOVA) model was used to determine the CIs for OCT and VA, adjusting for regression to the mean.

The control laser was applied in a conventional focal/grid pattern based on ETDRS protocol. 2RT was applied in a grid pattern so that a barely discernible retinal reaction was visible.

Results: There were 22 eyes in the 2RT group and 18 in the control group, with no significant age and gender differences. The baseline mean retinal thickness was 339 ± 96 µm in the 2RT group and 318 ± 70 µm in the control group; the mean retinal thickness change in the 2RT group was -44 ± 94 µm, and in the control group was -23 ± 52 µm. The adjusted OCT was 2.5 µm (in favour of 2RT) with a one-sided 97.5% CI of -29.6 µm. The baseline mean VA was $.21 \pm .23$ in the 2RT group and $.12 \pm .23$ in the control group; the corresponding 3-month mean VAs were $.18 \pm .27$ and $.12 \pm .24$, respectively. The VA was -0.03 (1.5 letter improvement in favour of 2RT) with a one-sided 97.5% CI such that 2RT was no more than 2 letters worse than the control laser). The safety profile of 2RT was excellent.

Conclusion: In this pilot study, 2RT was safe and at least as clinically effective in the treatment of DME as conventional laser. Given that 2RT causes minimal injury to overlying retina, and can potentially treat edema closer to the fovea, 2RT warrants further evaluation in a larger study.

ARVO 2008 Abstracts

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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