

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

Paper Session 542. Diabetic Retinopathy IV | Thursday, May 6, 2010 11:15 AM - 1:00 PM

Purpose: The Retinal Regeneration Therapy laser (2RT) is a new nanopulse retinal laser that experimentally causes minimal injury to sensory retina at clinically relevant settings. Our aim was to compare the safety and efficacy of 2RT with photocoagulative (control) laser in a prospective, randomized, multicentre, 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 in this Abstract). The primary outcome was the change in retinal thickness in the 2RT group (2RT) compared to the change in retinal thickness in the control group (c). Non-inferiority was defined as the one-sided 95% confidence interval (CI) of (2RT - c = OCT) > -25 µm (reduction in thickness after control laser no more than 25 µm than that after 2RT): an ANCOVA model (adjusting for regression to the mean) was used to determine the CI for OCT. Similar analysis was used to determine the difference in VA change between groups (VA). The control laser was applied in a conventional focal/grid pattern based on ETDRS protocol. 2RT was applied in a grid pattern within 500 µm of the fovea such that a just discernible retinal reaction was visible.

Results: There were 22 patients in the 2RT group and 18 in the control group. Age and gender profiles were not significantly different. The baseline mean retinal thickness was 339 ± 96 µm in the 2RT group and 318 ± 70 µm in the control group; 2RT was -44 ± 94 µm, and c was -23 ± 52 µm. The treatment difference (Δ) by ANCOVA was 2.5 µm (in favour of 2RT) with a one-sided 95% CI of -24.7 µm. The baseline mean VA was .21 ± .23 in the 2RT group and .12 ± .23 in the control group; the corresponding 3-month mean VAs were .18 ± .27 and .12 ± .24, respectively. The ΔVA by ANCOVA was 0.03 (in favour of 2RT) with a one-sided 95% CI of -.03 (at least within 2 letters of the control laser). The safety profile of 2RT was excellent.

Conclusions: In this small, randomized study after 3 months of follow-up, 2RT was safe and at least as clinically effective in the treatment of DME as conventional laser. Given the potentially greater safety profile of 2RT compared to photocoagulation and the ability to treat edema closer to the fovea, this new laser modality warrants further evaluation in a larger study.

Novel Nanosecond Laser Treatment To Prevent Vision Loss From Age-related Macular Degeneration

Poster Session 121. AMD II | Sunday, May 2, 2010 11:15 AM - 1:00 PM

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.