

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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South Australian Institute of Ophthalmology



Background

Retinal Rejuvenation Therapy: 2RT

A novel nanopulse retinal laser similar to SLT with little or no thermolysis of surrounding tissue due to the very short pulse.

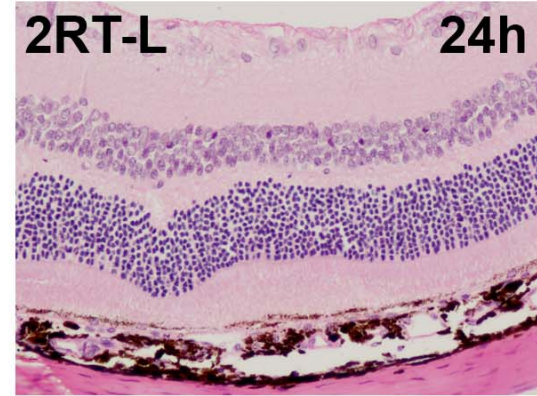
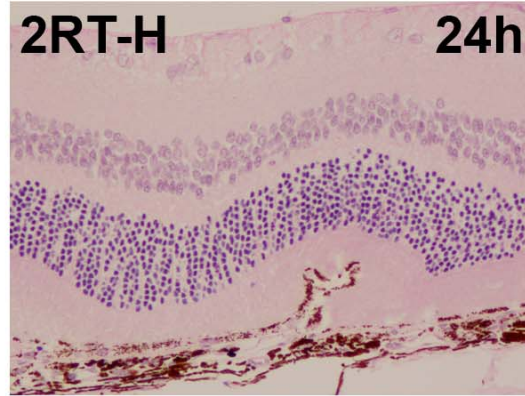
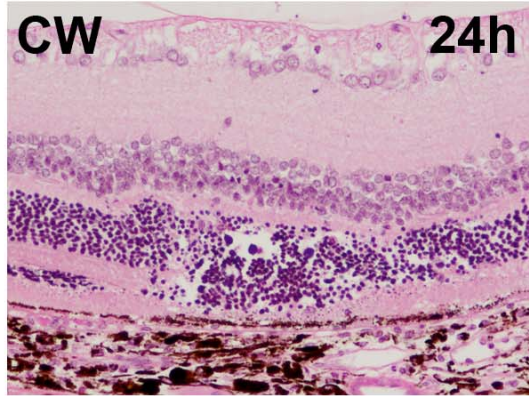
Q-switched YAG lasers that produce very precise 3 nanosecond pulses of 532nm laser energy.

Background

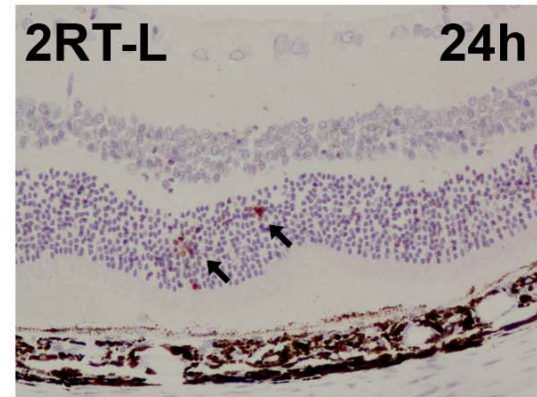
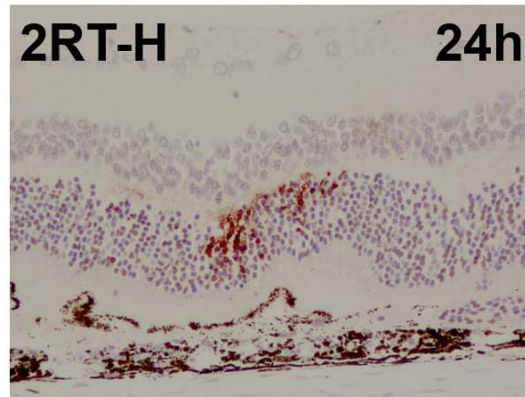
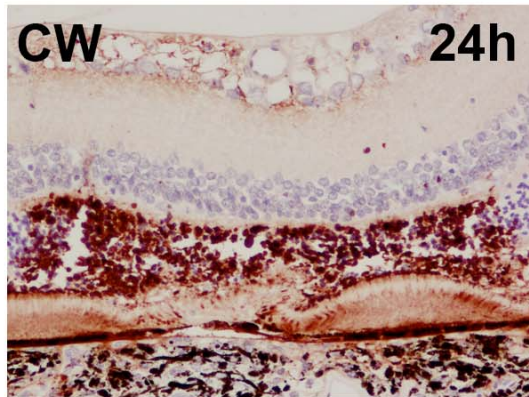
- preliminary case series human data indicated that 2RT was safe and approximated the efficacy of conventional laser.

Photoreceptor cell death - 24h

H&E



TUNEL



Aims

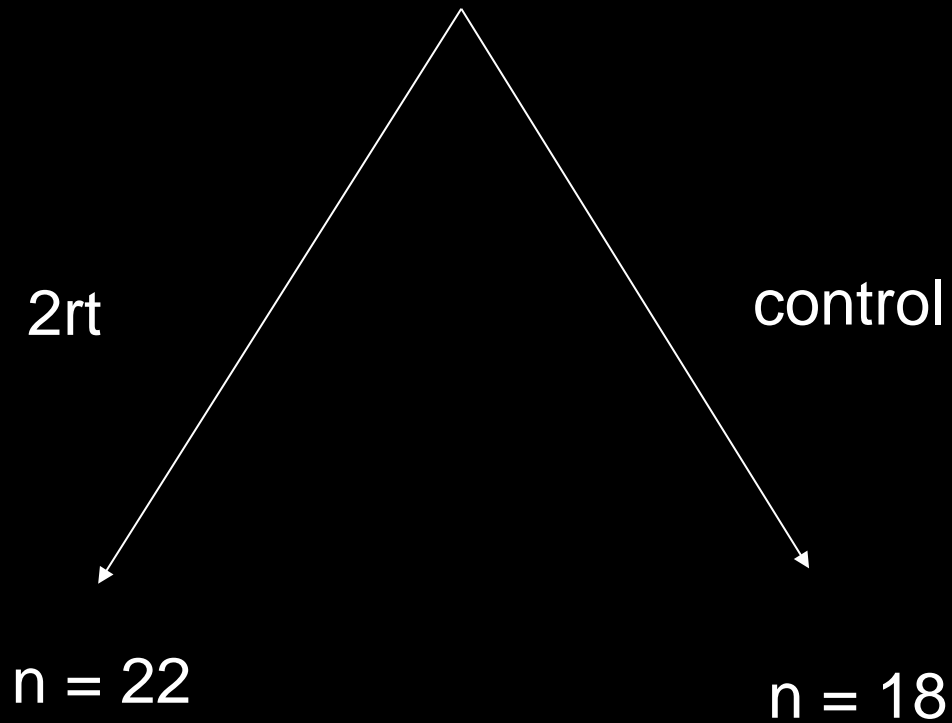
- to conduct a pilot study, assessing the safety and efficacy of 2RT compared to conventional laser in the treatment of diabetic macular edema
- to provide motivation (or not) to proceed to a larger study

Methods

- participants: patients with diabetic macular edema (250-550 μ m)
- design: prospective, randomized non-inferiority study
- outcomes: change in retinal thickness on OCT and change in logMAR acuity at 6 months
- methodology modelled on recent Diabetic Retinopathy Clinical Research Network paper*

*Diabetic Retinopathy Clinical Research Network. Comparison of the Modified Early Treatment Diabetic Retinopathy Study and Mild Macular Grid Laser Photocoagulation Strategies for Diabetic Macular Edema Arch Ophthalmol. 2007;125:469-480

Randomization



Methods

- 2RT was applied in a grid pattern so that the retinal reaction was just visible
- routine focal/grid control laser was applied
- further laser was applied at 3 month visit at clinicians' discretion

Inclusion Criteria

- a best-corrected ETDRS visual acuity score of 19 or more letters (approximately 20/400 or better)
- a retinal thickness measured on optical coherence tomography (OCT) of 250 μm or more in the central subfield or 300 μm or more in at least 1 of the 4 inner subfields
- had no prior laser or other treatment for DME.

Non-inferiority Design

95% one-sided CI of:

$$\text{control} \Delta_{\text{thickness}} - 2RT \Delta_{\text{thickness}} = \Delta_{\text{OCT}}$$

We require $\Delta_{\text{OCT}} < 35 \mu\text{m}$

95% one-sided CI of:

$$\text{control} \Delta_{\text{va}} - 2RT \Delta_{\text{vA}} = \Delta_{\text{logmar}}$$

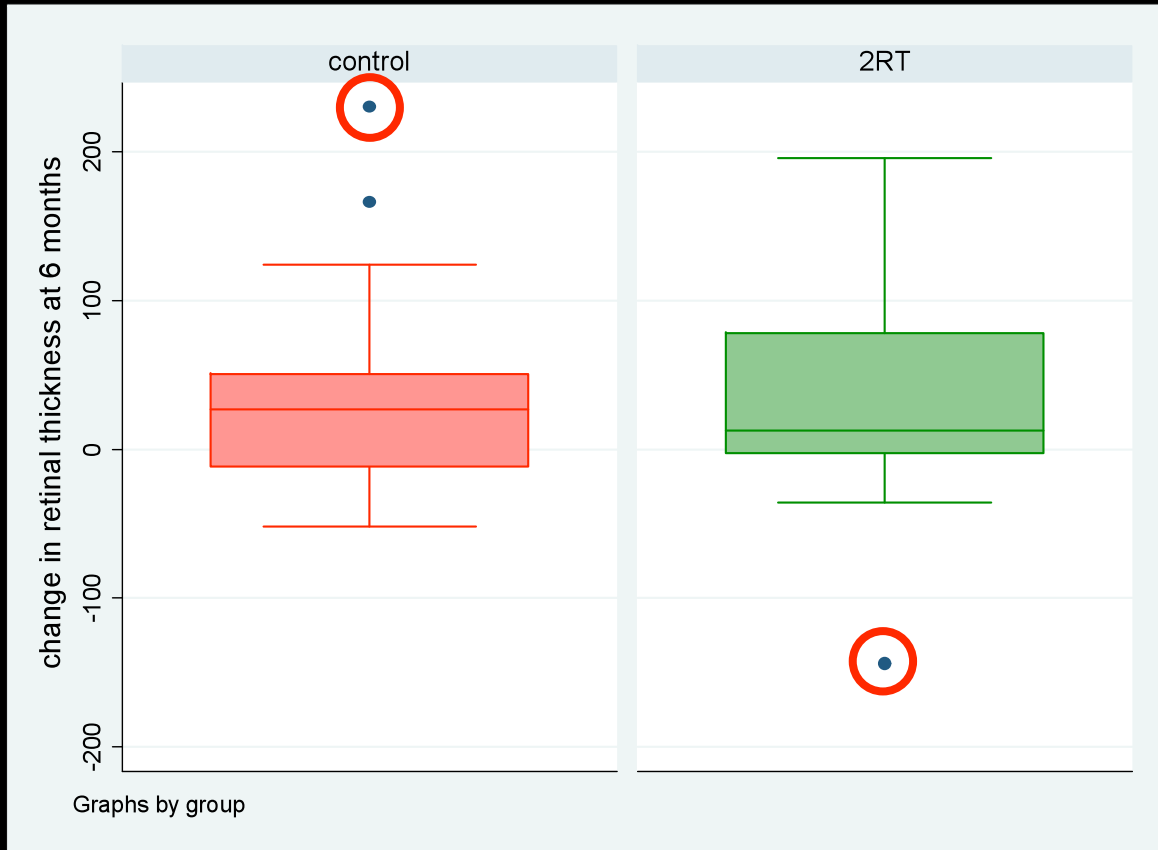
We require $\Delta_{\text{logmar}} < .06$ (3 letters)

Results

- 2RT was well-tolerated
- No adverse events related to the laser
- main technical difficulty reported by investigators was difficulty in assessing the treatment area.

Results

Reduction in Retinal Thickness at 6 months



Mean Reduction in Retinal Thickness at 6 months

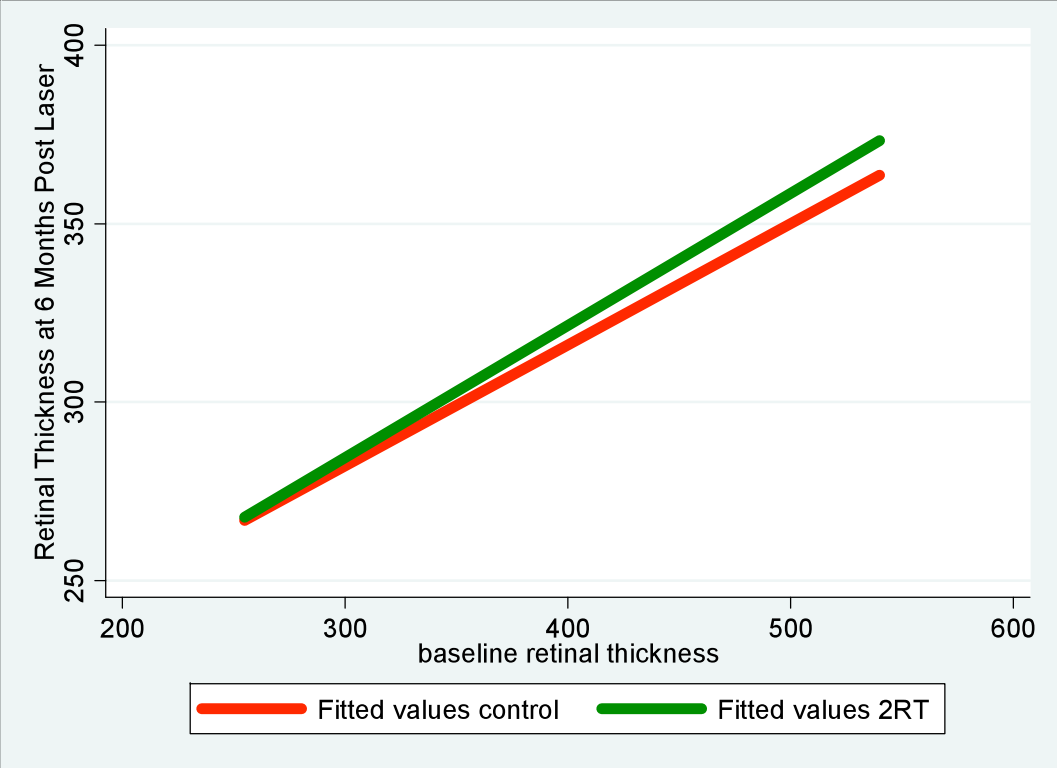
2RT

$35 \pm 76 \mu\text{m}$

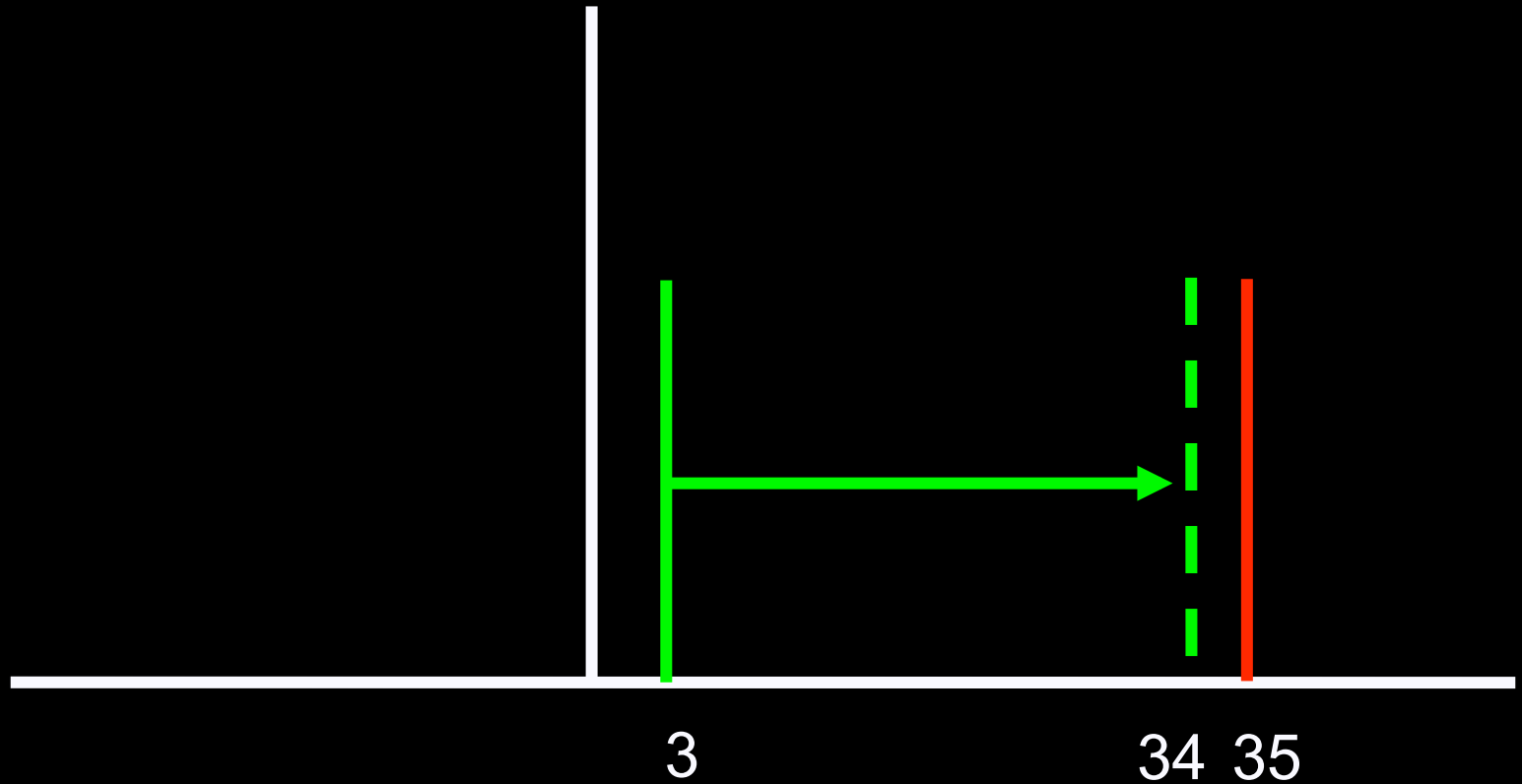
control

$28 \pm 57 \mu\text{m}$

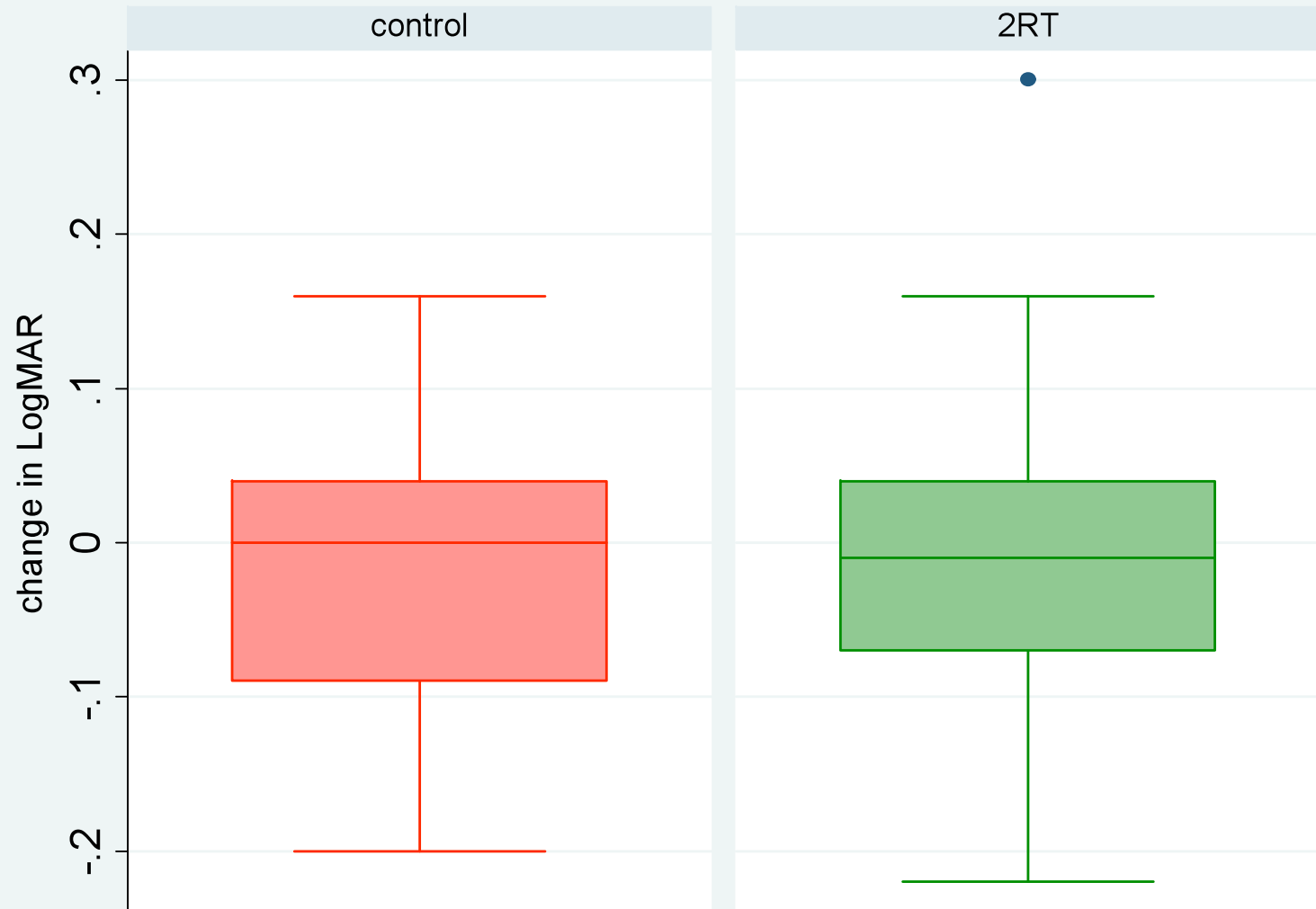
mean difference in retinal thickness reduction = 2.9 μm



$$\Delta OCT = 30\mu m$$



Change in VA at 6 months



Mean Change in VA at 6 months

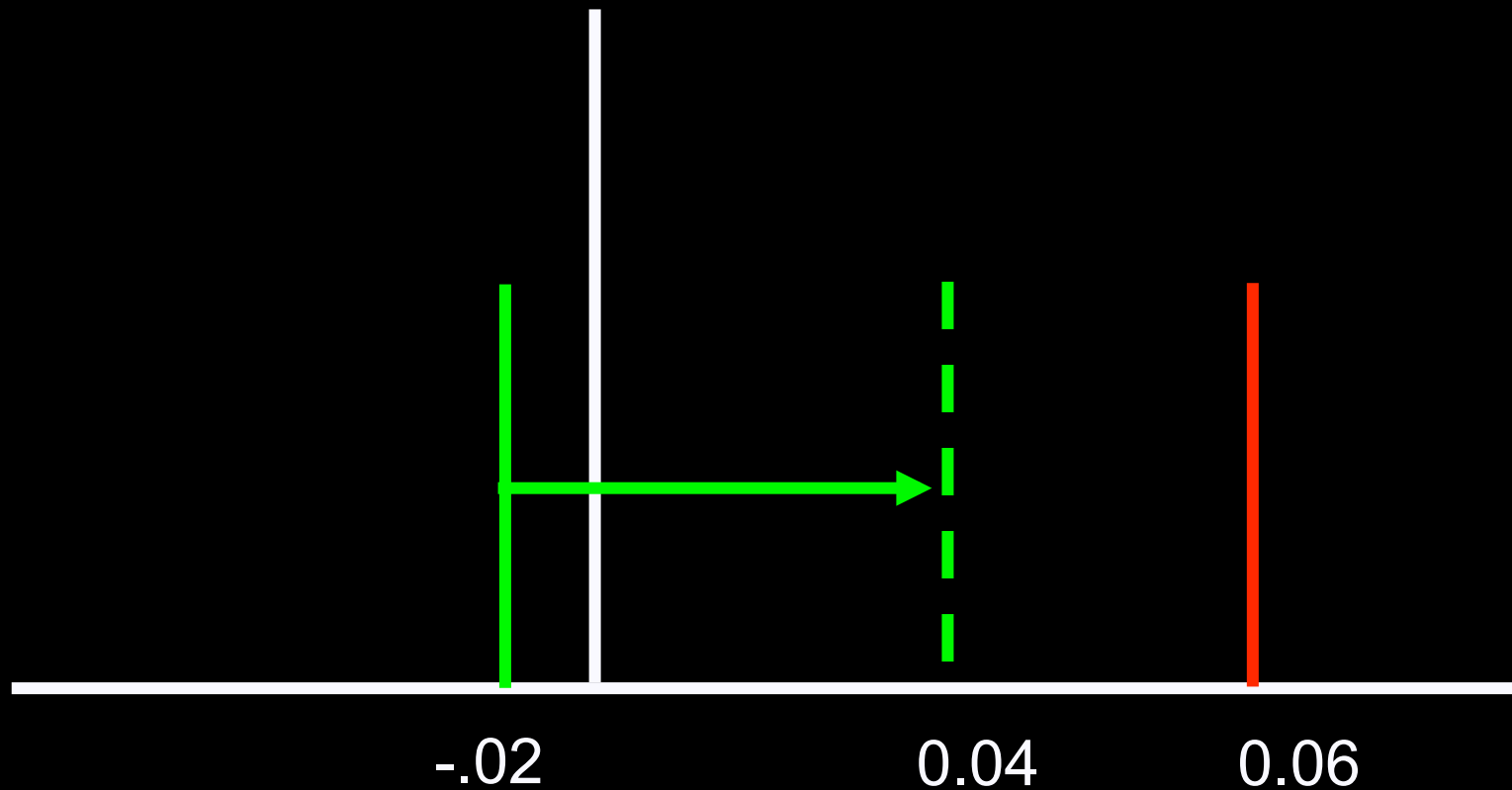
2RT

$0.012 \pm .11 \mu\text{m}$

control

$0.028 \pm .10 \mu\text{m}$

$$\Delta \log m_{\text{ar}} = 0.04 \mu\text{m}$$



Limitations

Non-inferiority Study

No placebo control

? Underperforming Active Control

How did we chose the Δ ?

Conclusions

- 2RT was non-inferior to conventional laser in this pilot study in terms of OCT and VA criteria
- This pilot study provides promising data and sufficient motivation to proceed with further clinical trials.

Acknowledgements

Clinical Investigators

Henry Newland
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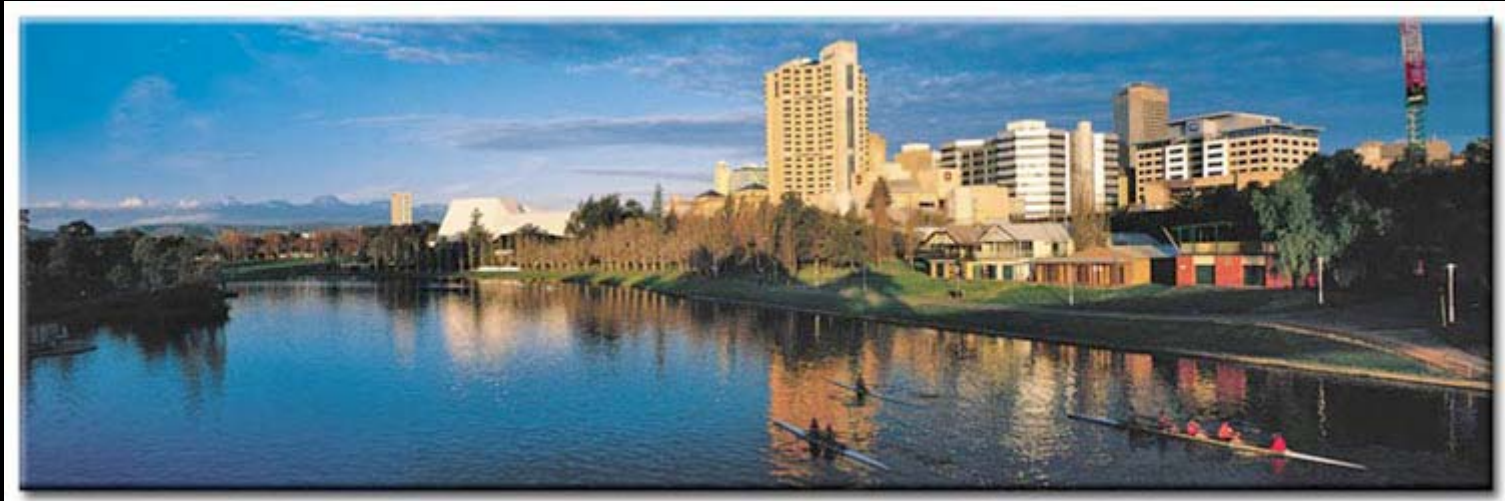
Industry

Malcolm Plunkett



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Thank you



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