2RT, RETINAL REJUVENATION

NANOSECOND LASER THERAPY REVERSES PATHOLOGICAL CHANGES IN AGE-RELATED MACULAR DEGENERATION WITHOUT RETINAL DAMAGE


The publication incorporates two sets of research:

1. 24-month clinical data, which is a follow-up to the 12-month pilot study “2RT for Early AMD” (ACTRN 1260900E1056280) conducted at the Centre for Eye Research Australia (CERA) by Professor Robyn Guymer, MB, BS PhD, FRANZCO
2. Scientific data addressing the impact of 2RT™ in two exenterated human eyes and a series of mouse eye models, conducted at the University of Melbourne, Australia, by Erica L. Fletcher, MScOptom, PhD.

1. Clinical Research Demonstrates Sustained Reduction in Drusen Over 24-Month Period
   - Fifty (50) AMD patients were treated with a single application of 2RT. Subsequent changes in drusen area were compared against a natural history cohort at 12 months and 24 months post-treatment.
   - At 12 months and 24 months drusen reduction was 40% and 35% respectively, compared to 11% in the natural history cohort. There was no evidence of disease progression as would be indicated with RPE change.
   - No patient was observed to progress to "wet" advanced form of AMD: 75% of patients showed no alteration in FAF indicating no progression to AMD. At 24 months post-treatment no patients had developed CNV.

2. Scientific Research Validates Mechanism of Action
   - Two enucleated eyes were examined following application of 2RT at clinical and supra-threshold energy levels. A series of mouse eye models were also examined post-treatment with 2RT.
   - In both the mouse eye models and human eyes a process of PRE proliferation and migration with no increase in glial activity (Gliosis) was observed. Retinal structure was preserved over treated area on comparison with the untreated area.
   - **Human Eyes:** imaging conducted prior to and post collection of the enucleated eyes exhibited enlarged RPE cells on lesion boundary, with some cells extending into the lesion site. At one month post-treatment, the lesion site was completely occupied by enlarged RPE cells. The application of 2RT did not alter retinal structure. Endogenous retinal microglial processes extending through ONL towards lesion site demonstrated normal microglial responses in the retina following 2RT.
   - **Mouse Eye Models:** ApoE knock-out mice (genes altered to exhibit thickened Bruch’s membrane) exhibited a dramatic thinning of Bruch’s membrane following treatment with 2RT; this occurred over the entire retina and was not confined to the lesion area. Increased expression of ECM proteins was observed in the treated eye. This expression change was also noted in the fellow eye, with 72% of altered genes affected.