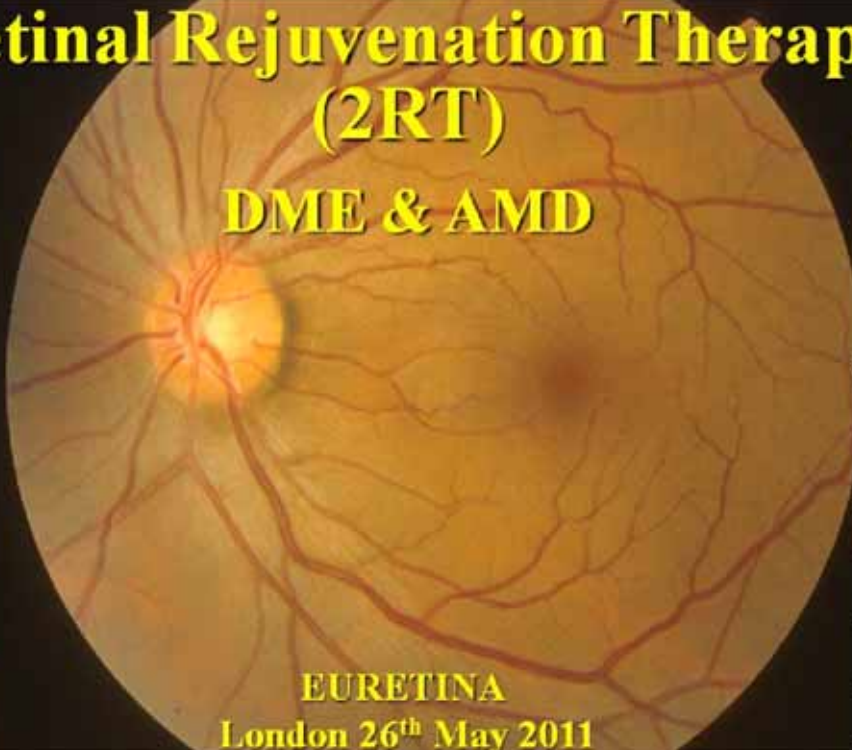


Retinal Rejuvenation Therapy (2RT)

DME & AMD



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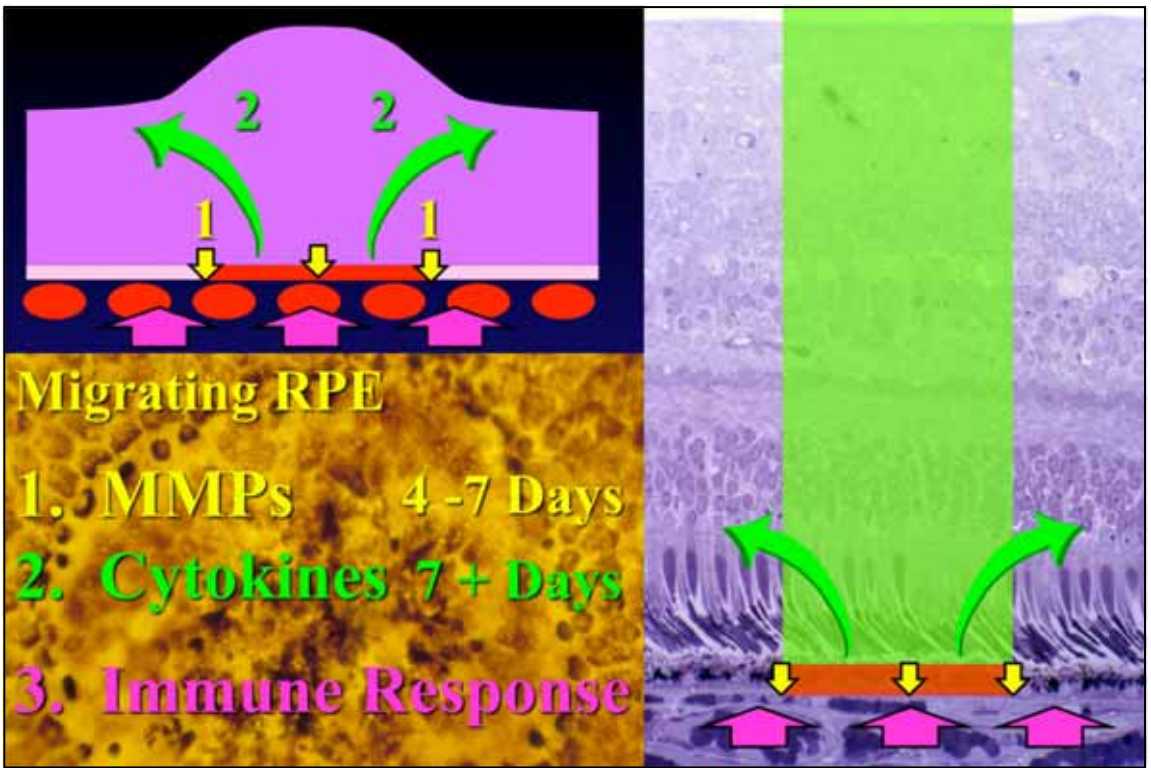
London 26th May 2011

Milliseconds

**Photoreceptor Cell Damage
Primary**



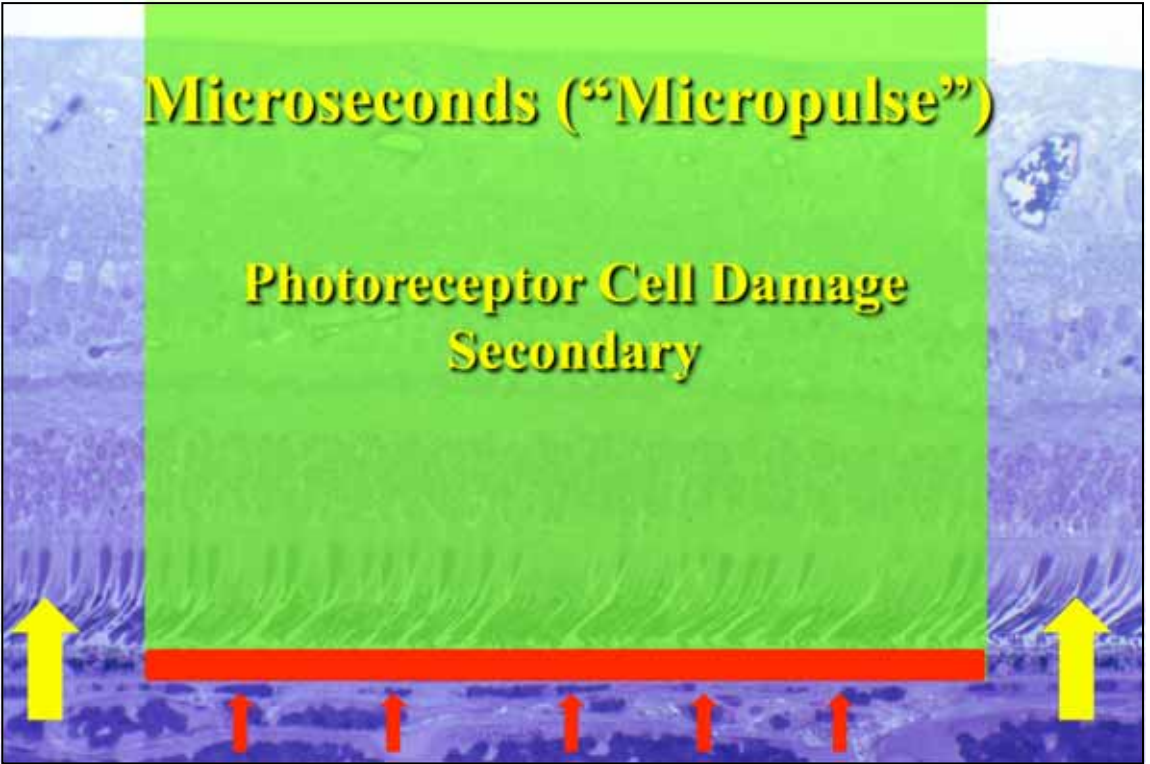
The millisecond laser pulses of traditional retinal photocoagulation are associated with primary damage to the RPE and photoreceptors.



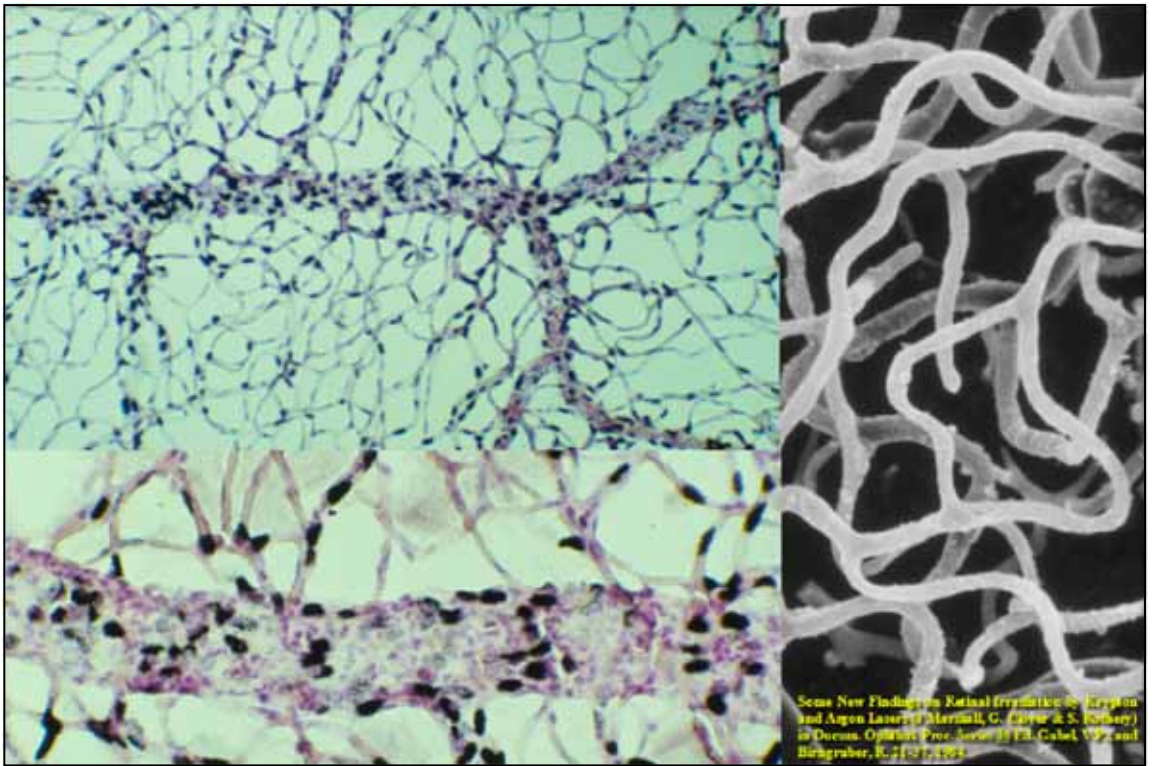
Despite the resultant damage to the RPE and photoreceptors, risk-benefit evaluation has shown an overall benefit of laser photocoagulation – it is known that the treatment mechanism of photocoagulation involves a complex triad of MMP release, cytokines and an immune response.

Microseconds (“Micropulse”)


Photoreceptor Cell Damage Secondary



The shorter microsecond pulses of micropulse laser technology (MLT) result in less primary damage as compared to traditional retinal photocoagulation, given that most of the energy is confined to the RPE layer. However, MLT takes out a whole plaque of the RPE, thereby resulting in secondary damage to the photoreceptors.



Enzyme and cytokine release following laser treatment of retina.



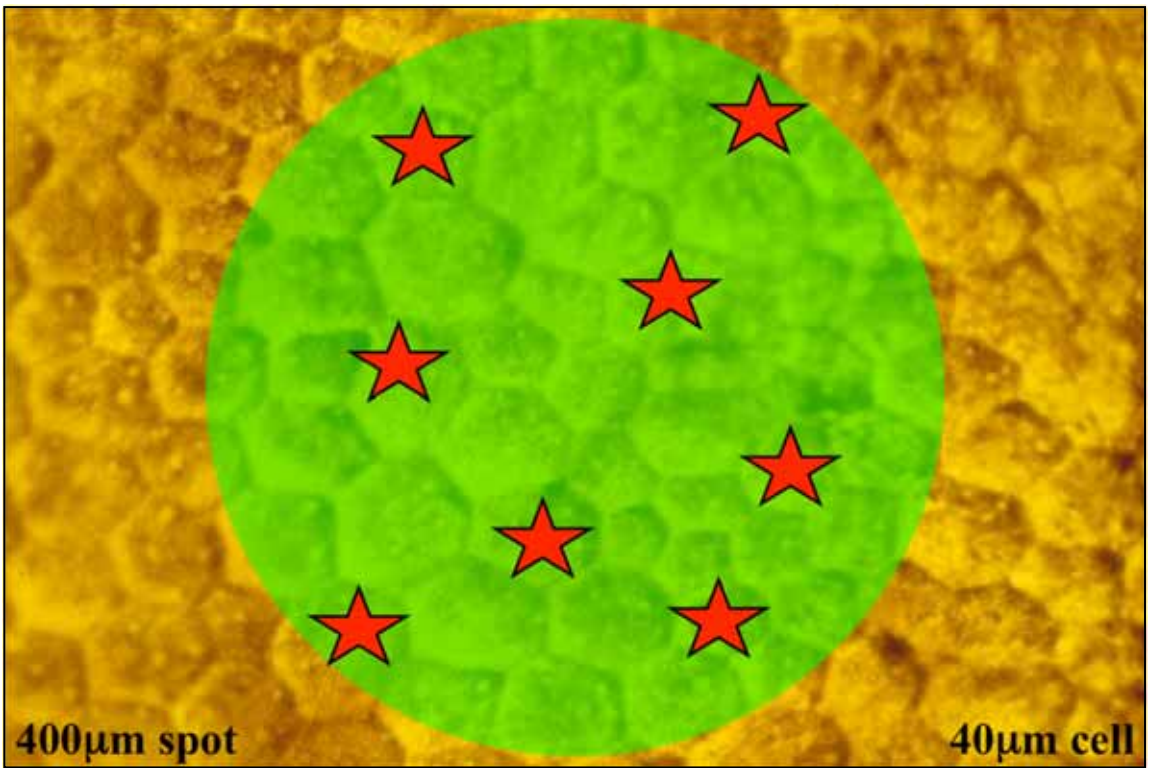
2RT
Wavelength
532nm
Pulse duration
3 nanoseconds
Discontinuous
Beam
Distribution
Max energy
1mJ/pulse
Spot size
400 microns
Not
SLT Laser

“Photorejuvenation”

Courtesy of N. Cuenca 2007

Ellex 2RT is a nanosecond, non-thermal laser therapy. It is important to make the distinction that Ellex 2RT is not the same as SLT. Whilst both treatments utilize nanosecond laser technology, the major advancement of Ellex 2RT is that it features an enhanced beam profile instead of the typical top-hat energy distribution.

Ellex 2RT is designed to treat a range of retinal diseases caused by a compromised retinal pigment epithelium (RPE) and Bruch’s membrane, the structures responsible for transporting the energy supply to, and removing the waste from, the retinal photoreceptors. Ellex 2RT stimulates a biological healing process that results in cellular rejuvenation, reversing these impaired transport mechanisms. This process of rejuvenation preserves or improves functional vision and reduces disease progression – without causing collateral damage to the overlying photoreceptor rods and cones of the retina.



Ellex 2RT induces a therapeutic effect without the permanent collateral damage caused by conventional thermal retinal laser treatment. Ellex 2RT allows the precise and specific delivery of laser energy to nano-sized targets within the cellular structure of the ageing RPE cells – without causing thermal destruction of the retina. As illustrated above, 15% of the RPE cells within the 2RT laser treatment spot (represented by the red stars) are damaged as a result of treatment.

2RT

No Damage to Neural Retina



Ellex 2RT does not cause any damage to the neural retina.

Outcome Measures

Exudates and leakage on FA

Macular thickness OCT

logMAR BCVA

SLO microperimetr

Ellex 2RT Clinical Research: the first clinical trial investigating the efficacy of Ellex 2RT for the treatment of DME, undertaken by Prof. John Marshall in collaboration with Dr. Peter Hamilton, London, UK, involved the placement of 100 spots in the treatment eye.

(Treatment of Diabetic Macular Oedema with a New Laser System 2RT (photoregeneration). Author Block: A. Hamilton¹, L. Pelosin², R. Hamilton², M. Mohamed², J. Marshall². ¹London, United Kingdom; Ophthalmology, ²St Thomas' Hospital, London, United Kingdom. ARVO 2008.)

Treatment

29 eyes, 18 patients

Mean age 64.6, 10.4SD, range 47-83

Gender 8f (44.4%), 10m (55.6%)

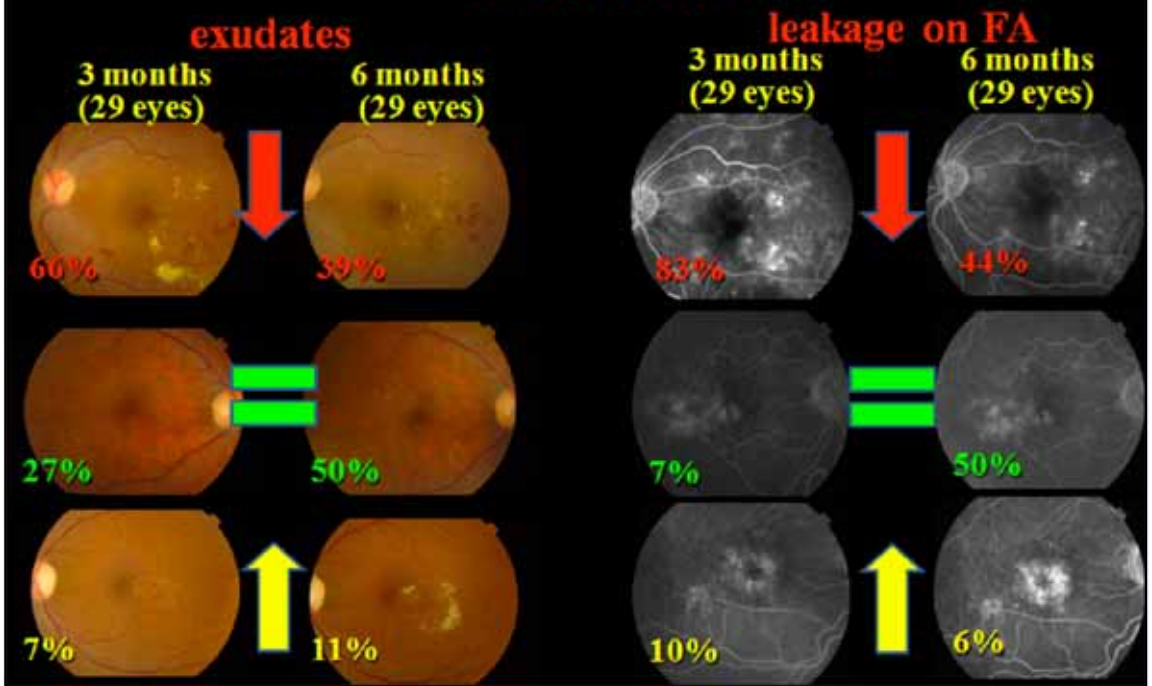
ENERGY/ PULSE	#EYES	#PULSES (Mean)	TOTAL ENERGY
0.3mJ (78µJ)	22 eyes (75.8%)	94.5 (7-232)	7.371mJ (0.085-18.09 mJ)
0.5 mJ (109µJ)	4 eyes (13.8%)	75.75(31-85)	8.17mJ (3.38-9.26 mJ)
0.6 mJ (131µJ)	3 eyes (10.3%)	72 (14-124)	9.4 mJ (1.8-16.2 mJ)

A 0.3 neutral density filter was used for all treatments

Ellex 2RT Clinical Research: protocol of first London DME trial

(Treatment of Diabetic Macular Oedema with a New Laser System 2RT (photoregeneration). Author Block: A. Hamilton¹, L. Pelosin², R. Hamilton², M. Mohamed², J. Marshall². ¹London, United Kingdom; Ophthalmology, ²St Thomas' Hospital, London, United Kingdom. ARVO 2008.)

Results

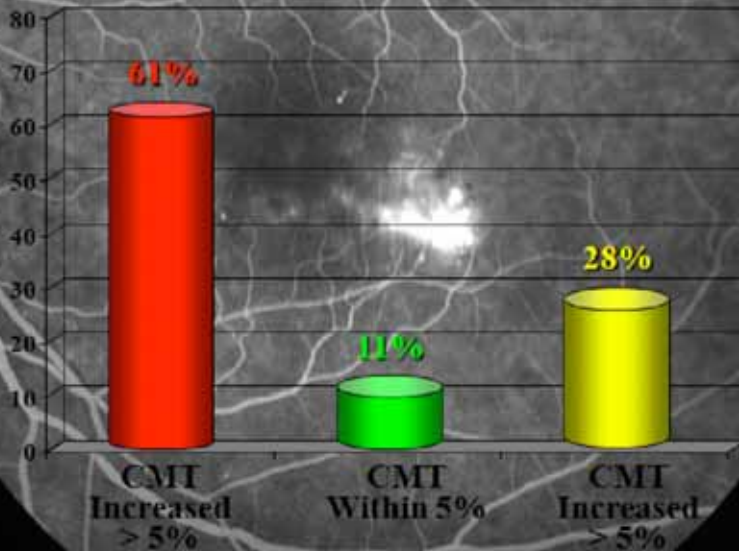


Ellex 2RT Clinical Research: trial results of first London DME trial

(Treatment of Diabetic Macular Oedema with a New Laser System 2RT (photoregeneration). Author Block: A. Hamilton¹, L. Pelosin², R. Hamilton², M. Mohamed², J. Marshall². ¹London, United Kingdom; Ophthalmology, ²St Thomas' Hospital, London, United Kingdom. ARVO 2008.)

Results

CMT at 6 months (29)

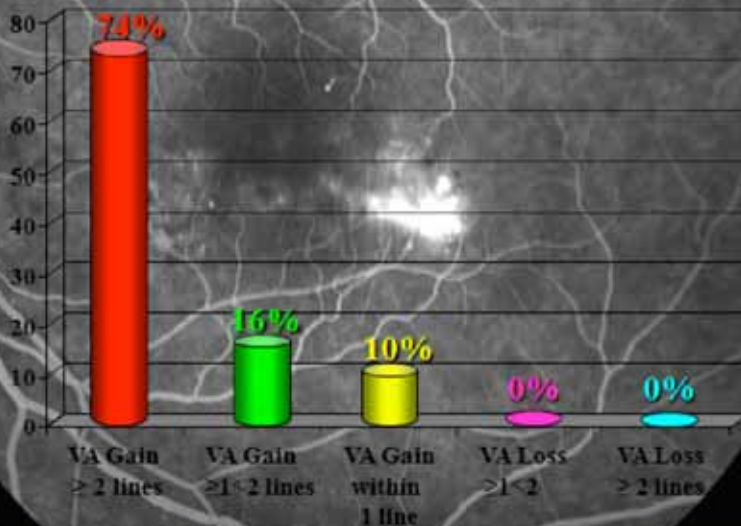


Ellex 2RT Clinical Research: **central macular thickness** results of first London DME trial

(Treatment of Diabetic Macular Oedema with a New Laser System 2RT (photoregeneration). Author Block: A. Hamilton¹, L. Pelosin², R. Hamilton², M. Mohamed², J. Marshall². ¹London, United Kingdom; Ophthalmology, ²St Thomas' Hospital, London, United Kingdom. ARVO 2008.)

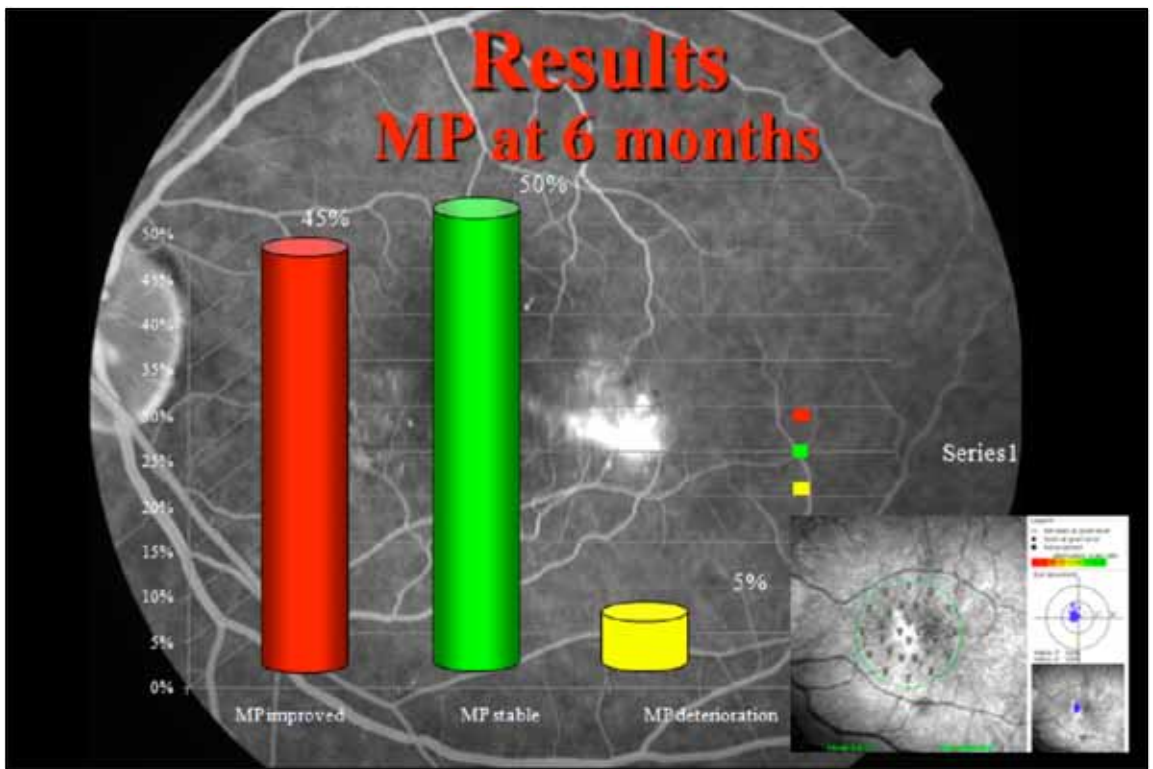
Results

logMAR VA 6 months (29)



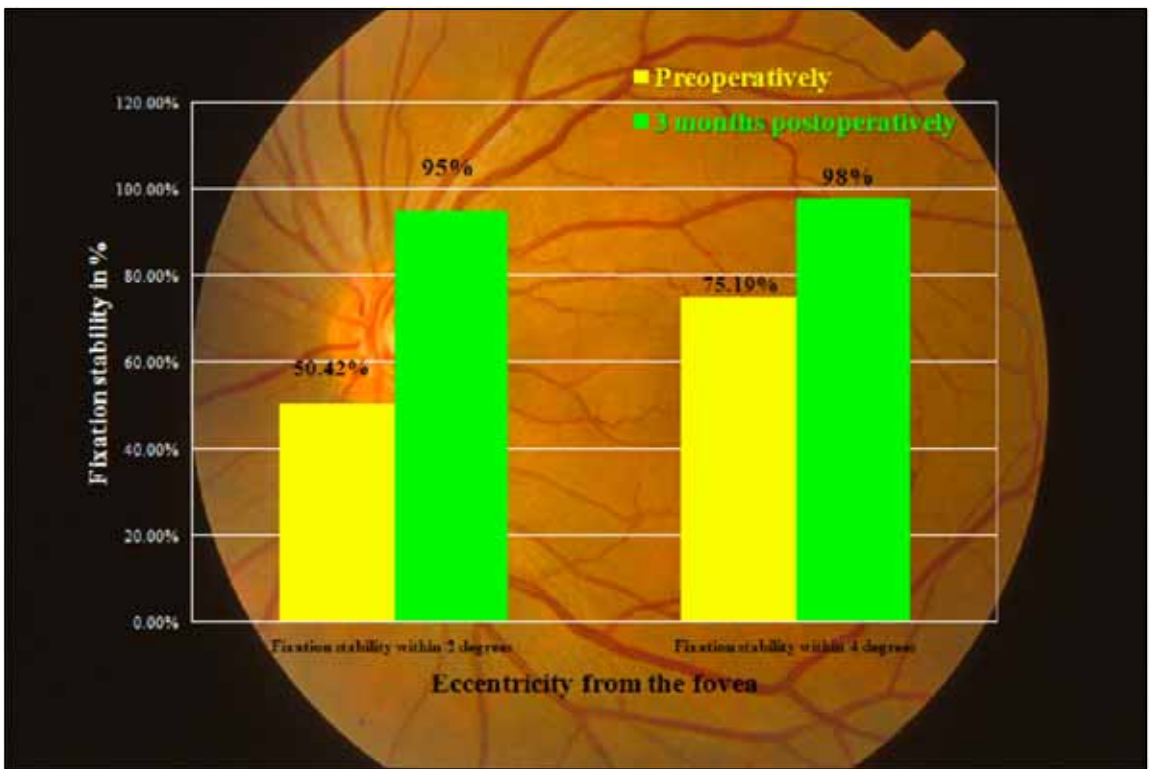
Ellex 2RT Clinical Research: **visual acuity** results of first London DME trial

(Treatment of Diabetic Macular Oedema with a New Laser System 2RT (photoregeneration). Author Block: A. Hamilton¹, L. Pelosin², R. Hamilton², M. Mohamed², J. Marshall². ¹London, United Kingdom; Ophthalmology, ²St Thomas' Hospital, London, United Kingdom. ARVO 2008.)



Ellex 2RT Clinical Research: first London DME trial – microperimetry shows excellent results; not only have the photoreceptors been spared but there are also signs of improvement.

(Treatment of Diabetic Macular Oedema with a New Laser System 2RT (photoregeneration). Author Block: A. Hamilton¹, L. Pelosin², R. Hamilton², M. Mohamed², J. Marshall². ¹London, United Kingdom; Ophthalmology, ²St Thomas' Hospital, London, United Kingdom. ARVO 2008.)



Ellex 2RT Clinical Research: **improvement in fixation stability** results of first London DME trial

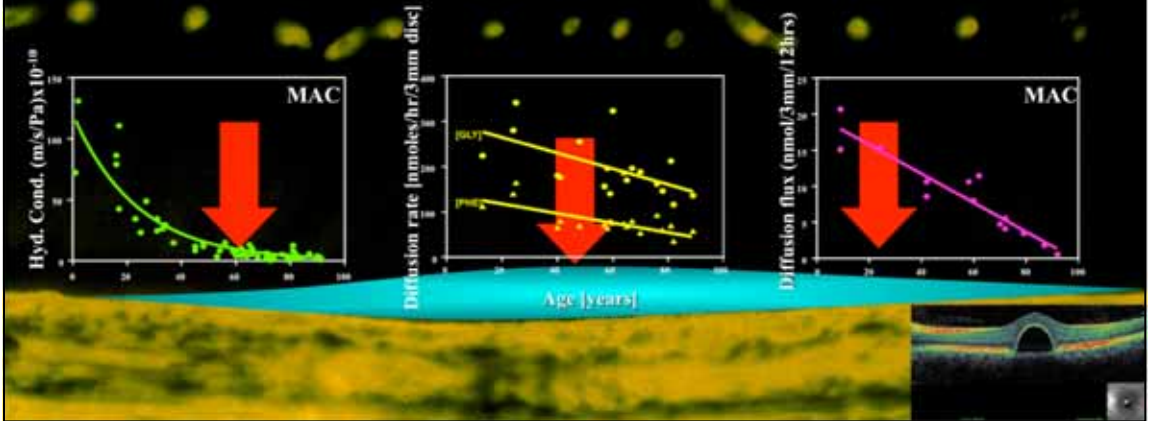
(Treatment of Diabetic Macular Oedema with a New Laser System 2RT (photoregeneration). Author Block: A. Hamilton¹, L. Pelosin², R. Hamilton², M. Mohamed², J. Marshall². ¹London, United Kingdom; Ophthalmology, ²St Thomas' Hospital, London, United Kingdom. ARVO 2008.)

Age Related Macular Degeneration

Fluid transport

A. Acid transport

Carrier transport



Age-Related Macular Degeneration (AMD): the transport mechanism fails as a function of age, causing a build-up of debris in Bruch's membrane.

AMD is the leading cause of blindness in the developed world. Unlike other treatments for AMD (i.e. anti-VEGF medications for the treatment of Wet AMD) Ellex 2RT offers the potential to intervene much earlier and to slow or partially reverse the degenerative processes of the disease, thereby eliminating or delaying the risk of late vision threatening complications associated with AMD.

Treatment

Outcomes

(48) patients, 24 at 1 year

2RT

532nm, 3 ns, 400µm diameter

Twelve laser pulses clock hours

Energy 0.15mJ to 0.45mJ

Flicker Perimetry

Optical Coherence Tomography (OCT)

Auto-Fluorescence (AF) imaging

Fundus Photography

Visual Acuity at Pre Op, 3, 6 and 12

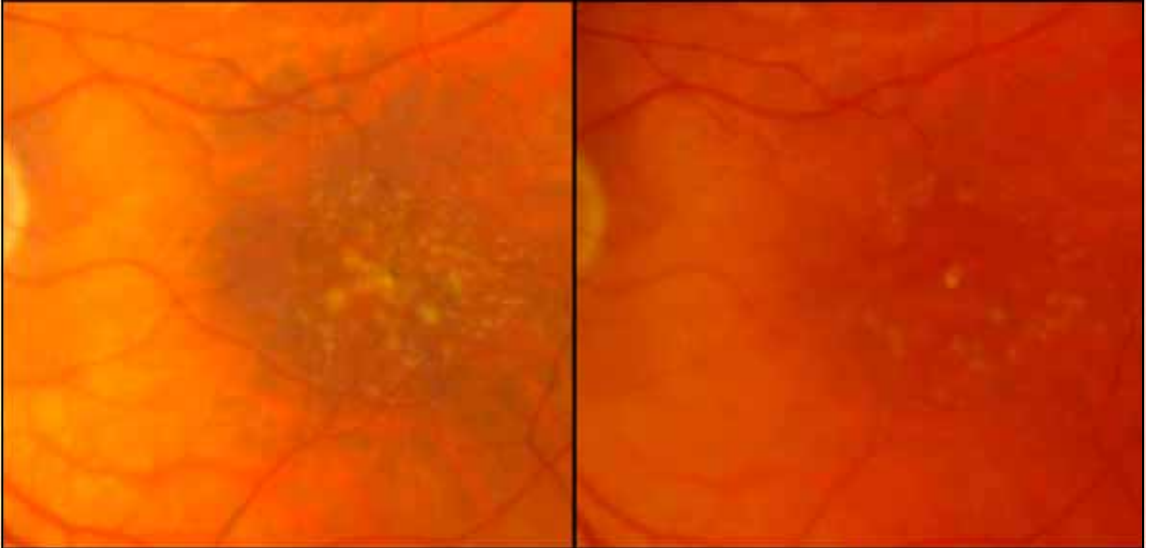
Courtesy of Mark Metzler and C. P. Wilkinson, MD
©1978 Greater Baltimore Medical Center

Clinical Research: Ellex 2RT for Early AMD Trial, Royal Victorian Eye and Ear Hospital (RVEEH) and the Centre for Eye Research Australia (CERA)

(Retinal Functional Improvement with Nano-Laser Treatment in High Risk Early AMD. Author Block: Robyn H. Guymer¹, Kate Brassington¹, Peter N. Dimitrov¹, Mary Varsamidis¹, Galina Makeyeva¹, Khin Zaw Aung¹, Devinder Chauhan², Algis Vingrys³, Chi Luu¹. ¹Ctr for Eye Rsch - AU, University of Melbourne, East Melbourne, Australia; ²Vision Retinal Institute, Box Hill Vic. 3128, Box Hill Vic. 3128, Australia; ³University of Melbourne, Optometry & Vision Sciences, Carlton, Australia., Australia. ARVO 2011.)

(Novel Nanosecond Laser Treatment to Prevent Vision Loss From Age-Related Macular Degeneration. Author Block: R.H. Guymer¹, K. Bassington¹, P.N.D. Dimitrov¹, A.J. Vingrys², M.J. Plunkett³. ¹Ctr for Eye Rsch - AU, University of Melbourne, East Melbourne, Australia; ²Optometry & Vision Sciences, University of Melbourne, Carlton, Australia; ³Ellex R&D, Adelaide, Australia. ARVO 2010.)

Drusen Reduction



R. H. Guymer¹ et al. ARVO 2010, 523/A169

71 yr Pre

71 yr 12 month

Clinical Research: Ellex 2RT for Early AMD Trial: **drusen resolution**

(Retinal Functional Improvement with Nano-Laser Treatment in High Risk Early AMD. Author Block: Robyn H. Guymer¹, Kate Brassington¹, Peter N. Dimitrov¹, Mary Varsamidis¹, Galina Makeyeva¹, Khin Zaw Aung¹, Devinder Chauhan², Algis Vingrys³, Chi Luu¹. ¹Ctr for Eye Rsch - AU, University of Melbourne, East Melbourne, Australia; ²Vision Retinal Institute, Box Hill Vic. 3128, Box Hill Vic. 3128, Australia; ³University of Melbourne, Optometry & Vision Sciences, Carlton, Australia., Australia. ARVO 2011.)

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Outcomes



Drusen Reduced
Flicker Improved <9dB
VA Improved < 5 Letters in 5 Eyes
Effects in Lasered and Non-Lasered Eyes

Courtesy of Mark Metzler and C. P. Wilkinson, MD
©1978 Greater Baltimore Medical Center

Clinical Research: Ellex 2RT for Early AMD Trial: **improvement in flicker visual and visual acuity improved; bilateral effect noted (known in SLT, but not in retinal treatments).**

(Retinal Functional Improvement with Nano-Laser Treatment in High Risk Early AMD. Author Block: Robyn H. Guymer¹, Kate Brassington¹, Peter N. Dimitrov¹, Mary Varsamidis¹, Galina Makeyeva¹, Khin Zaw Aung¹, Devinder Chauhan², Algis Vingrys³, Chi Luu¹. ¹Ctr for Eye Rsch - AU, University of Melbourne, East Melbourne, Australia; ²Vision Retinal Institute, Box Hill Vic. 3128, Box Hill Vic. 3128, Australia; ³University of Melbourne, Optometry & Vision Sciences, Carlton, Australia., Australia. ARVO 2011.)

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