

## ASX RELEASE

**Ellex Medical Lasers Limited (ASX:ELX)**

**Adelaide, Australia**

**Date: 14 September 2015**

**Release: Immediate**

**Topic: Ellex releases first case study results for 2RT™ at major tradeshow**

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**Adelaide, Australia, 14 September 2015** – Ellex Medical Lasers Limited (ASX:ELX), a global leader in medical devices for the diagnosis and treatment of eye disease, today announced that it released its first case study results from commercial users of its 2RT™ retinal rejuvenation laser.

In conjunction with Ellex's commercial release of 2RT™ at the European Society of Cataract and Refractive Surgeons (ESCRS) meeting in Barcelona, Spain, 5-9 September 2015, Dr Christopher Kiss PhD (Austria) and Dr David Worsley MB, ChB, Dip Obs, FRANZCO (New Zealand) also released results of their clinical experience with 2RT™.

Dr Worsley stated with respect to a particular case (attached) "2RT™ Nano second laser has demonstrated an effective intervention for degeneration and improvement in macular function".

Dr Kiss similarly concluded "For me this case [attached] represents 2RT™ providing a benefit in macular function and appearance in patients with drusen and functional defects. I will continue to consider 2RT™ for further intermediate AMD patients".

Doctor's Kiss and Worsley are part of a growing cohort of doctors who have purchased a 2RT™ laser for use in their clinics. Along with the other early adopters Ellex calculates that, as of mid-August 2015, commercial 2RT™ procedures have been carried out on approximately 1,000 patients. The positive case studies generated through these pioneering procedures will be an important marketing tool for Ellex to demonstrate the potential of the 2RT™ device to other clinicians.

Ellex CEO, Tom Spurling, stated "The long term LEAD clinical trial on 2RT™ being conducted in Australia is expected to ultimately provide quantitative data on the efficacy of 2RT™. In the meantime our early adopters are providing important information about 2RT™'s clinical usage and potential."

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### **About Ellex**

Ellex designs, develops, manufactures and sells innovative products that help eye surgeons around the world to effectively and efficiently treat eye disease. Ellex is a world leader in this field. Headquartered in Adelaide, Australia, Ellex has ophthalmic lasers and devices that treat glaucoma, retinal disease primarily caused by diabetes, secondary cataract and vitreous opacities, as well as age-related macular degeneration. Manufacturing is carried out in Adelaide, Australia and Fremont, California. Sales and service directly to eye surgeons is conducted via subsidiary offices in Minneapolis, Lyon, Berlin and Tokyo. A network of more than 50 distribution partners around the world services other markets.

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**For further information on Ellex, please contact:**

Tom Spurling, CEO  
Ellex Medical Lasers Limited  
82 Gilbert Street, Adelaide, SA, 5000  
W +61 8 8104 5293 | M +61 417 818 658  
tspurling@ellex.com

Victor Previn, Chairman  
Ellex Medical Lasers Limited  
82 Gilbert Street, Adelaide, SA, 5000  
W +61 8 8104 5200 | M +61 414 661 994  
vprevin@ellex.com

Maria Maieli, Company Secretary  
Ellex Medical Lasers Limited  
82 Gilbert Street, Adelaide, SA, 5000  
W +61 8 8104 5200  
mmaieli@ellex.com

# 2RT<sup>®</sup>

## Retinal Rejuvenation

### **2RT FOR EARLY AMD: CASE STUDY 1** **Christopher Kiss, PhD (Austria)**

84-year old female patient with large confluent soft drusen with few hyper-pigmented areas. Some drusen calcified. Drusen located directly foveal. Advanced AMD noted in fellow eye. Significant functional defect at majority of sensitivity points, as per MAIA macular function assessment . Treatment with 2RT<sup>®</sup> resulted in increased BCVA and contrast sensitivity and marked reduction in drusen.

## PRE-TREATMENT STEPS: MAIA

MAIA microperimetry was applied in customized expert mode over the 1-6° field.

Test conducted prior to 2RT and follow up 4/12 post 2RT (refer to Table 1).

## TREATMENT STEPS: 2RT

Average treatment power was 0.29 mJ (refer to Table 2.)

To determine treatment power, titration shots were applied outside the arcades at an initial dose of 0.20 mJ. At the visual effect threshold i.e. “blanching”, treatment power was set at 0.29 mJ (refer to Table 2).

24 laser spots were delivered, applied in a semi-circle arc above the macula. The laser spots were not observable on color fundus.

## TREATMENT OUTCOME

A marked improvement in drusen resolution under the fovea was noted (refer to Figure 1, 2). BCVA improved from 6/9.5 to 6/7.5. MAIA macular function assessment indicated an improvement in macula integrity average threshold from 18.9 to 22.2, with sensitivity map illustrating an overall improvement (refer to Figure 3).

*“For me this case clearly represents 2RT producing a benefit in macular function and appearance in patients with drusen and functional defects. I will continue to consider 2RT for further early intermediate AMD patients.”*

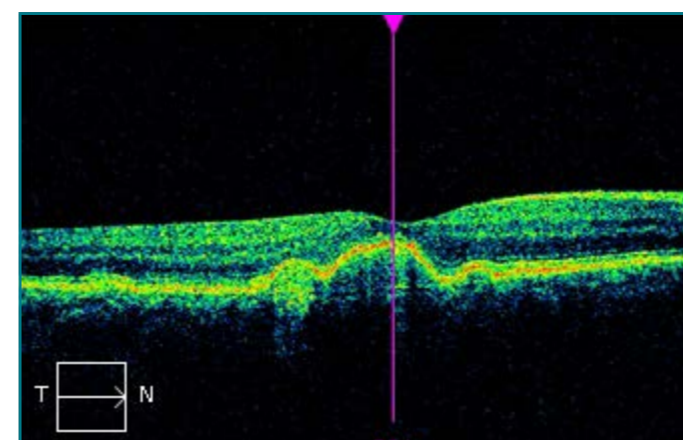
Christopher Kiss, PhD

**TABLE 1: MAIA PARAMETERS AND OUTCOMES**

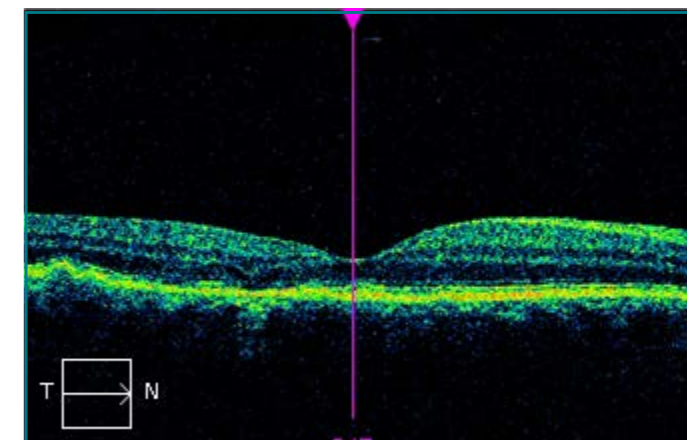
- **Examination Mode; Customized Expert Test with 36 stimuli surrounding the central (degree)**
- **Projection strategy: 4-2**
- **Average Sensitivity:**  
18.9 Pre-Rx  
22.2 post-Rx
- **Macular Integrity:**  
100 Pre-Rx  
99.4 Post-Rx
- **Fixation stability:**  
Stable (P1=86%,P2=99%) Pre-Rx  
Stable (P1=89%,P2=97%) Post-Rx
- **BCVA:**  
63% = 1.7<sup>02</sup>  
95% = 5.1<sup>02</sup> Pre-Rx  
63% = 0.0<sup>02</sup>  
95% = 0.0<sup>02</sup> Post-Rx
- **Fixation Location (PRL): Central**
- **Test Duration:**  
4' 57" Pre-Rx  
7' 55" Post-Rx

**TABLE 2: 2RT PARAMETERS**

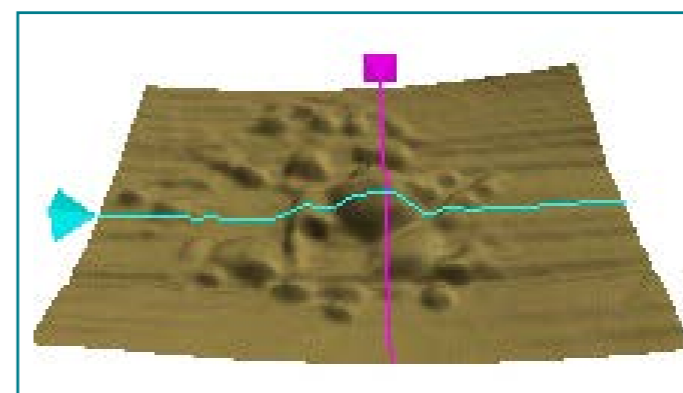
- **Wavelength: 532 nm**
- **Spot size on slit lamp adapter: 400 µm**
- **Contact lens: Mainster Grid**
- **Power (Ave): 0.29 mJ**
- **Exposure duration: 3 ns**
- **Application of semi-circle arc above and below macula of 24 laser spots**



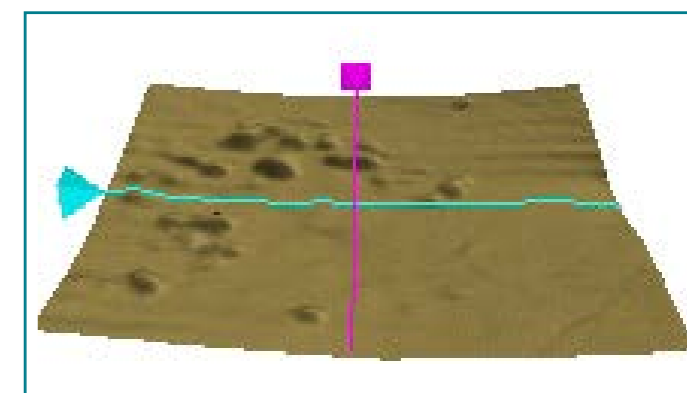
**FIGURE 1: Pre-2RT**



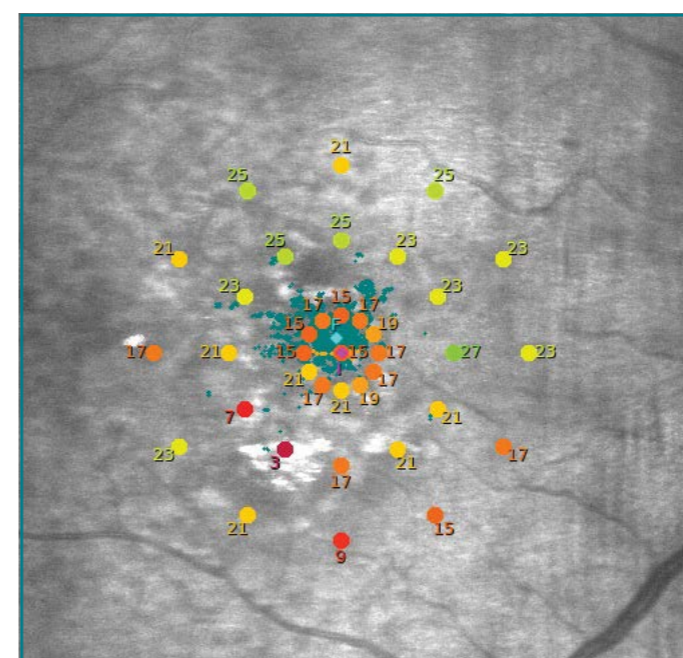
**FIGURE 1: 4/12 Post-2RT**



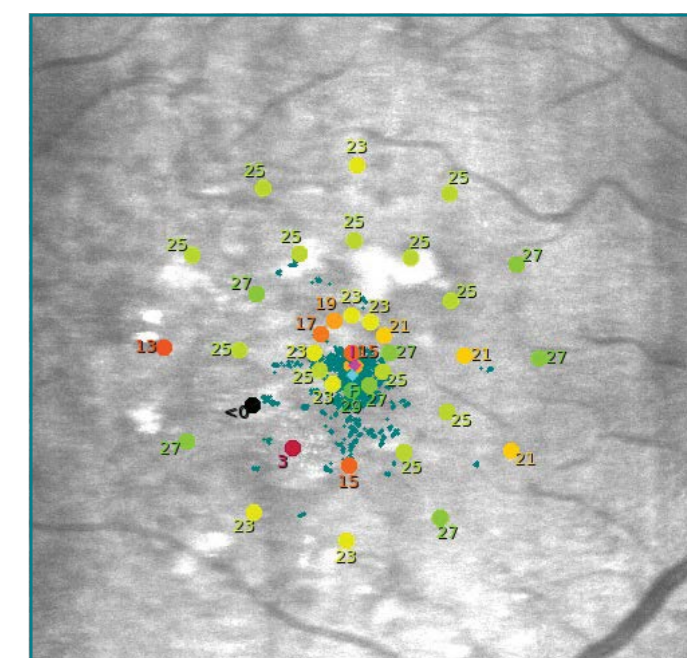
**FIGURE 2: Pre-2RT**



**FIGURE 2: 4/12 Post-2RT**



**FIGURE 3: Pre-2RT**



**FIGURE 3: 4/12 Post-2RT**

## ABOUT 2RT

### Retinal Rejuvenation Therapy

A non-thermal laser therapy, Retinal Rejuvenation Therapy (2RT®) stimulates a natural, biological healing response in patients with early Age-Related Macular Degeneration (AMD). Clinical and scientific studies have demonstrated the ability of 2RT® to improve retinal function and to halt or delay the degenerative processes that cause retinal disease. Specifically, 2RT® has been shown to reduce drusen and can produce bilateral improvements in macular appearance and function in high-risk early AMD patients.(1)

2RT® utilizes solid-state, nanosecond laser technology delivered through a patented beam profile. This breakthrough treatment approach selectively targets individual organelles (specialized cells) within the retinal pigment epithelium (RPE) in order to induce a therapeutic effect without causing thermal damage to the underlying Bruch's membrane and overlying photoreceptors.(2)

1. Guymer, R.H., et al., Nanosecond-laser application in intermediate AMD - 12-month results of fundus appearance and macular function. Clin Experiment Ophthalmol. 2013 Oct 3. doi: 10.1111/ceo.12247)
2. I. Jobling et al., "Nanosecond Laser Therapy Reverses Pathologic and Molecular Changes in Age-Related Macular Degeneration without Retinal Damage," The FASEB Journal 29, no. 2 (February 1, 2015): 696–710, doi:10.1096/fj.14-262444.

## ABOUT THE PHYSICIAN

### Christopher Kiss, PhD (Austria)

Associate Professor Christopher Kiss is in private practice at "Eye & Laser". He commenced his ophthalmic career at the Vienna University Clinic of Ophthalmology and Optometry and also worked as a senior physician at the University Eye Hospital in Vienna (2010 - 2014). Additionally, he was the former director of the Study Center of the Department of Ophthalmology, Vienna University Clinic.



Opinions and treatment technique presented in this case report are those of the contributing author.

2RT® has a CE Mark (Conformité Européenne) and is included on the Australian Register of Therapeutic Goods (ARTG) for the indication of early AMD, where it can produce bilateral improvements in macular appearance and function. It also has a CE Mark (Conformité Européenne) and US Food and Drug Administration (FDA) (510k) market release for the treatment of Clinically Significant Macula Edema (CSME).

PB2RTCASE-AMD2. E&OE.



ellex.com

#### Headquarters

82 Gilbert Street  
Adelaide, SA, 5000 AUSTRALIA  
+61 8 8104 5200

#### Japan

3F, 3-2-22 Harumi Chuo-ku  
Tokyo 104-0053 JAPAN  
+81 3 5859 0470

#### USA

7138 Shady Oak Road  
Minneapolis, MN, 55344 USA  
800 824 7444

#### Germany

ZPO floor 1, Carl-Scheele-Str.16  
12489 Berlin GERMANY  
+49 30 6392896 00

#### Australia

82 Gilbert Street  
Adelaide, SA, 5000 AUSTRALIA  
+61 8 8104 5264

#### France

La Chaufferie - 555 chemin du bois  
69140 Rillieux la Pape FRANCE  
+33 4 8291 0460

# 2RT<sup>®</sup>

## Retinal Rejuvenation

### **2RT FOR EARLY AMD: CASE STUDY 2**

**David Worsley MB ChB, Dip. Obs, FRANZCO (New Zealand)**

81-year old female patient with bilateral confluent soft drusen and pigmentary change. Past history of bilateral cataract surgery. MAIA macular function assessment indicated significant functional defect at majority of sensitivity points. Treatment with 2RT<sup>®</sup> resulted in drusen resolution and concurrent improvement in BCVA and contrast sensitivity.

## PRE-TREATMENT STEPS: MAIA

MAIA microperimetry was applied in customized expert mode over the 1-6° field.

Test conducted prior to 2RT and follow-up 4/12 post 2RT (refer to Table 1).

## TREATMENT STEPS: 2RT

Average treatment power was 0.30 mJ (refer to Table 2.)

12 laser spots were delivered in a circle outside the macula, with laser spots not observable on color fundus.

## TREATMENT OUTCOME

At 9/12 post 2RT, clear resolution of drusen was observable on the OCT scan with concurrent improvement in MAIA sensitivity (refer to Figure 1-3). At 14/12 post 2RT MAIA threshold improvement was also noted (refer to Figure 2).

*“2RT nanosecond pulse laser has demonstrated an effective intervention for drusen regression and improvement in macular function.”*

David Worsley MB ChB, Dip. Obs, FRANZCO

### TABLE 1: MAIA PARAMETERS AND OUTCOMES

- **Examination Mode; Customized Expert Test with 36 stimuli surrounding the central (degree)**
- **Projection strategy: 4-2**
- **Average Sensitivity:**  
21.9 Pre-Rx  
24.6 post-Rx
- **Macular Integrity:**  
99.8 Pre-Rx  
88.9 Post-Rx
- **Fixation stability:**  
Stable (P1=98%, P2=100%) Pre-Rx, Stable Stable (P1=90%, P2=98%) Post-Rx
- **BCVA:**  
63% = 0.3<sup>02</sup>  
95% = 3.0<sup>02</sup> Pre-Rx  
63% = 0.7<sup>02</sup>  
95% = 05.9<sup>02</sup> Post-Rx
- **Fixation Location (PRL): Central**
- **Test Duration:**  
6' 4" Pre-Rx  
5' 21" Post-Rx

### TABLE 2: 2RT PARAMETERS

- **Wavelength: 532 nm**
- **Spot size on slit lamp adapter: 400 µm**
- **Contact lens: Volk Area Centralis**
- **Power (Ave): 0.30 mJ**
- **Exposure duration: 3 ns**
- **Application of circle outside the macula of 12 laser spots**

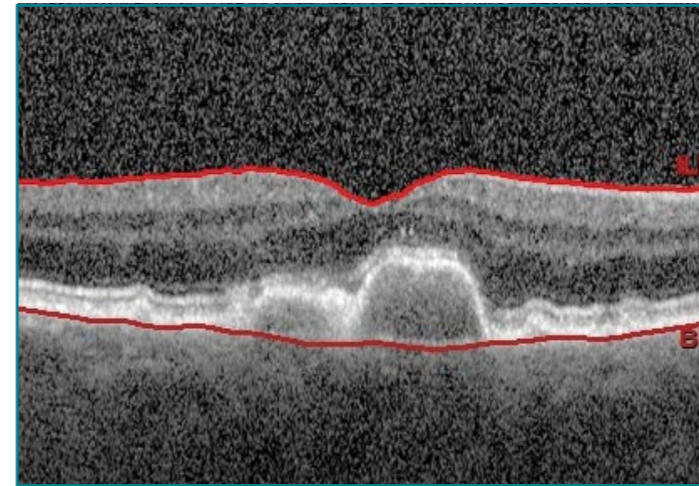


FIGURE 1: Pre-2RT

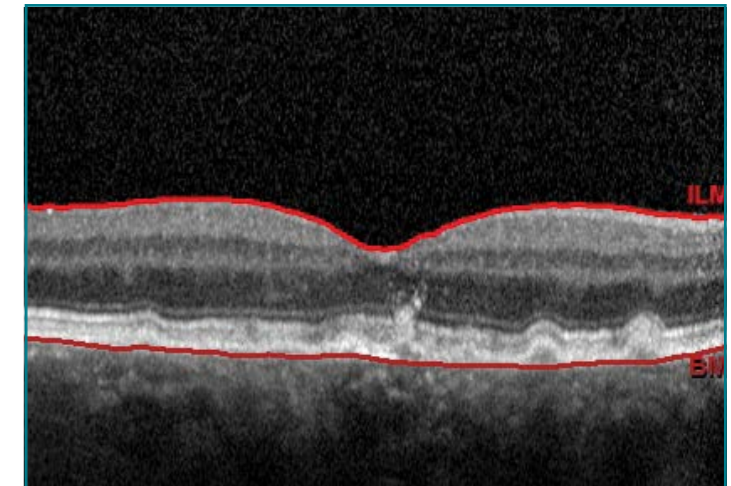


FIGURE 1: 9/12 Post -2RT

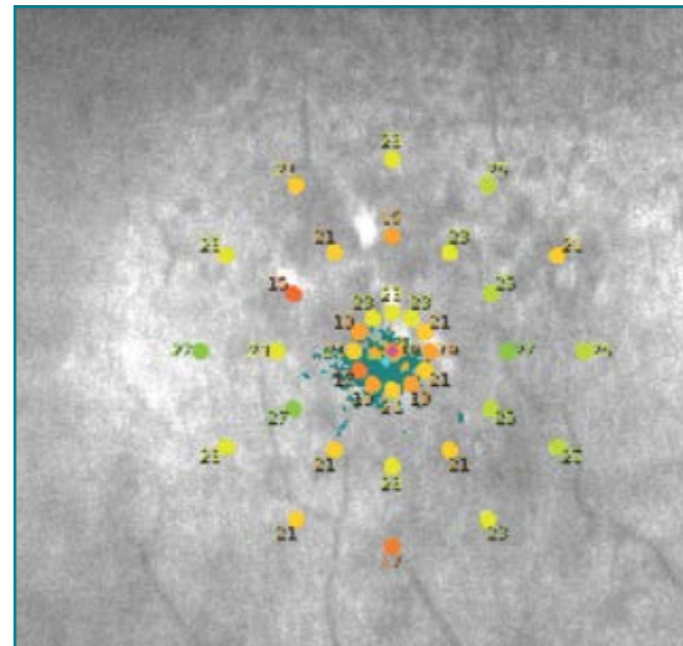


FIGURE 2: Pre-2RT

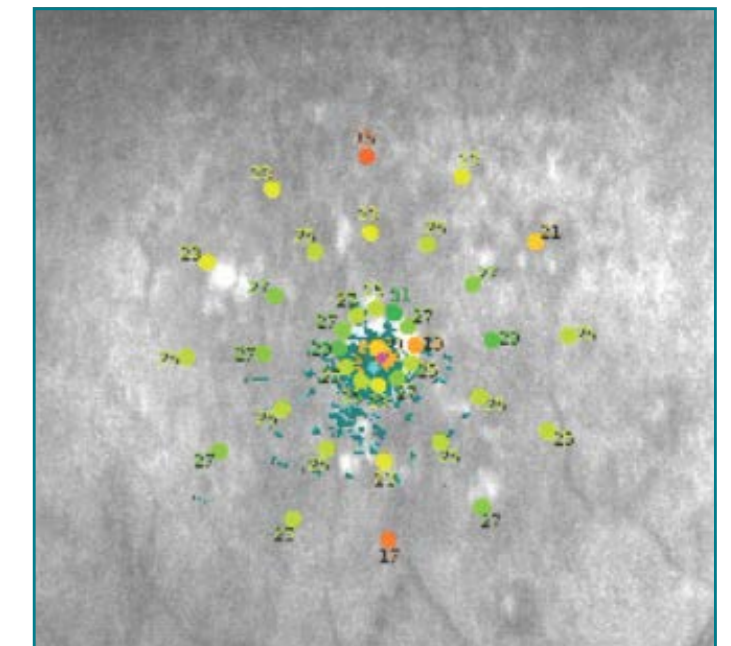


FIGURE 2: 14/12 Post-2RT

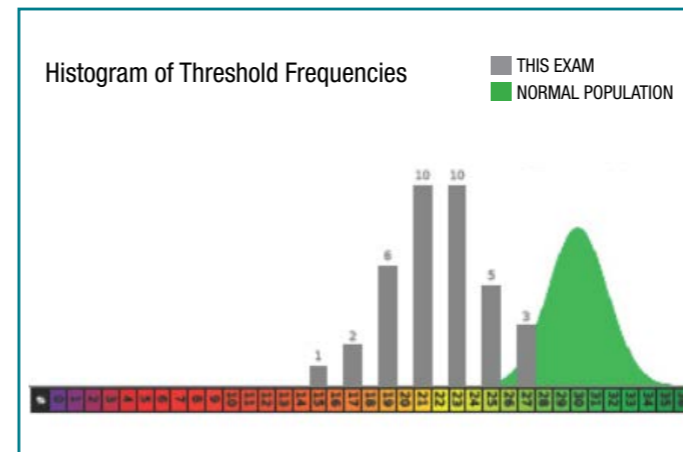


FIGURE 3: Pre-2RT

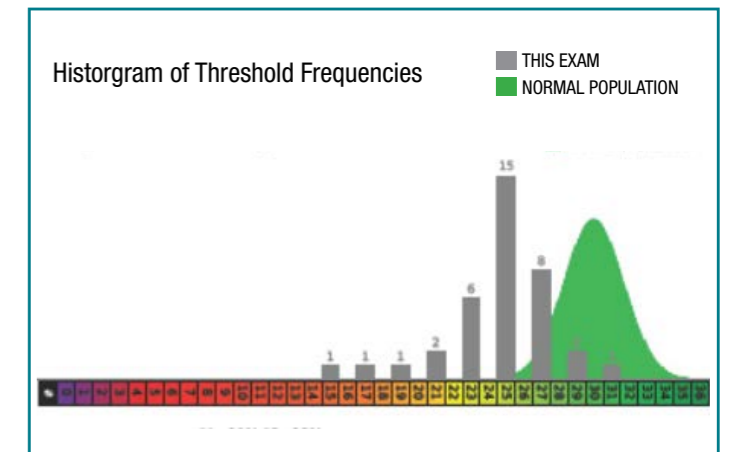


FIGURE 3: 14/12 Post-2RT

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## ABOUT THE PHYSICIAN

### David Worsley (MB. ChB. Dip. Obst. FRANZCO)

Dr. Worsley specializes in medical and surgical retina and was responsible for introducing vitreoretinal surgery to the Waikato Public Hospital in 1991. In private practice at Hamilton Eye Clinic, Dr. Worsley is also a visiting specialist at Waikato Public Hospital. He holds Clinics in both Thames and Whangamata in order to provide much-needed support to patients in the greater Waikato region. Dr. Worsley is a medical advisory board member for the Macular Degeneration New Zealand and Retina New Zealand.



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#### Headquarters

82 Gilbert Street  
Adelaide, SA, 5000 AUSTRALIA  
+61 8 8104 5200

#### Japan

3F, 3-2-22 Harumi Chuo-ku  
Tokyo 104-0053 JAPAN  
+81 3 5859 0470

#### USA

7138 Shady Oak Road  
Minneapolis, MN, 55344 USA  
800 824 7444

#### Germany

ZPO floor 1, Carl-Scheele-Str.16  
12489 Berlin GERMANY  
+49 30 6392896 00

#### Australia

82 Gilbert Street  
Adelaide, SA, 5000 AUSTRALIA  
+61 8 8104 5264

#### France

La Chaufferie - 555 chemin du bois  
69140 Rillieux la Pape FRANCE  
+33 4 8291 0460