2RT® EARLY AMD PROCEDURE GUIDE

IMPORTANT: The following treatment guidelines are based on the procedures reported in the evidence-based literature[1] and are provided for information purposes only.

1. PATIENT SELECTION

2RT® (Retinal Rejuvenation Therapy) is indicated in patients with early Aged-Related Macular Degeneration (AMD)[2] where it can produce bilateral improvements in macula appearance and function.

For the purpose of these guidelines a patient is considered to have early AMD if they have bilateral large drusen > 125 µm with/or without any AMD pigmentary abnormalities* within an inner macular zone (a circle with a radius of 3000 microns centered on the fovea).[3]

(*) Note: AMD pigmentary abnormalities are defined as any definite hyper- or hypopigmentary abnormalities associated with large drusen but not associated with other known disease entities.[3]

Based on recent clinical data[4], caution should be exercised when considering treatment in patients with coexistent reticular pseudodrusen.

2RT® is contraindicated under the following conditions:

1. Any situation where the view of the target tissue (retinal pigment epithelium, RPE) is compromised or limited.
2. The presence of any other significant vision threatening ocular pathology (for example, uveitis, glaucoma or large subfoveal drusenoid pigment epithelial detachment [PED] > 1000 µm).
3. The presence of advanced stage AMD, such as geographic atrophy or choroidal neovascularization

2. PRE-TREATMENT

- Apply a topical mydriatic and local anesthetic drops into the conjunctival sac of the eye to be treated.
- It is recommended that patients should be able to achieve a 5 mm pupil dilation.

3. TREATMENT

A. Set-Up:

- Position the patient's head on the chinrest of the 2RT® laser system.
- Position and focus the slit lamp microscope including the eyepiece dioptre settings to observe the eye to be treated.

B. Contact Lens:

- Use of a contact lens that approximates a 1:1 conversion ratio, such as Area Centralis, for viewing and laser application.

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C. Power Setting:

- Apply test applications of single laser pulses spaced approximately one laser spot diameter (400 µm) apart outside the arcades while increasing the power level until a faintly visible blanching of the lasered spot is observed. The starting power level should be set to the minimum 0.1 mJ and increased by 2 steps to 0.3 mJ, and then by 1 step at a time until the blanching point is reached. It is recommended to not increase the energy level beyond 0.4 mJ.
- Reduce the energy by one step of this setting and then apply in the outer macula as described below.

D. Spot Placement:

- Apply the laser spots superiorly and inferiorly, inside the temporal retinal vascular arcades with at least one laser spot diameter between them. An example of a laser application is illustrated in Figure 1.
- Do not place laser applications closer than one disc diameter from the edge of the optic disc. It is suggested that laser spots should not be placed closer than one disc diameter to the fovea.

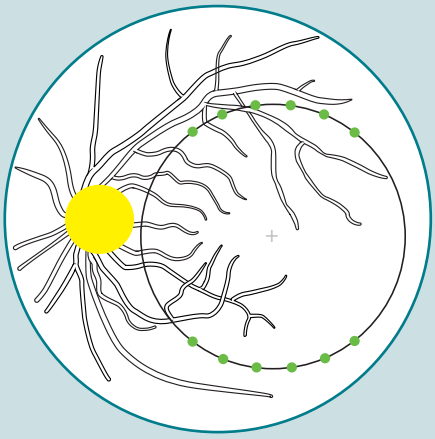

Figure 1. Sample Laser Application

4. POST-TREATMENT

Periodic re-check of treated eye to be determined by treating ophthalmologist.

5. OBSERVABLE SIDE EFFECTS

Adverse events reported in the literature[4,5] included retinal hemorrhage and after images. These resolved with no sequellae.[4,5]

REFERENCES

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2. Ellex 2RT Operator Manual.
3. Ferris FL 3rd, et al. Clinical Classification of Age-related Macular Degeneration. Ophthalmology. 2013;120:844-51. doi: 10.1016/j.ophtha.2012.10.036. Epub 2013 Jan 16.
4. Guymer RH, et al (in press). Sub-Threshold Nanosecond Laser Intervention in Age-Related Macular Degeneration: The LEAD Randomized Controlled Clinical Trial. Ophthalmology. doi: https://doi.org/10.1016/j.ophtha.2018.09.015.
5. Data on file. Available upon request