



Courtesy of Jesse Jung MD

(A) Colour fundus photo of the right eye of a study patient with DME before treatment; (B) represents fluorescein angiogram (FA) of the right eye prior to NAVILAS treatment; (C) colour fundus photo of the right eye after treatment showing reduction in exudates and microaneurysms; (D) represents FA of the right eye after treatment showing reduced macular oedema; (E) an image overlay composed and displayed over the pre-treatment FA showing a single no-treatment zone over the fovea; (F) an image overlay over the pre-treatment FA showing the planned elements of microaneurysm treatments

DME TREATMENT

Novel laser system improves treatment accuracy, efficiency, efficacy and safety

by Cheryl Guttman Krader in Fort Lauderdale

A novel navigated retinal laser system (Navilas, OD-OS) provides a safe and effective treatment option for patients with diabetic macular oedema (DME) reported independent groups of investigators at the annual meeting of the Association for Research in Vision and Ophthalmology.

The platform is a scanning slit-based instrument that integrates navigated retinal laser therapy by a 532-nm laser photocoagulator with digital imaging capabilities (live colour fundus, red-free, infrared, and fluorescein angiography). It allows digital pre-planning of the treatment, while real-time registration between the diagnostic images, treatment plan and the live retinal image assures the laser spots are delivered to their intended target. The system generates digital documentation of the applied treatment.

In a poster presentation, Marcus Kernt MD, and colleagues reported findings from a comparative study that showed benefits of using the navigated laser system versus a conventional laser for treating clinically

significant DME. They analysed data from 46 eyes treated with the navigated laser and 28 control eyes treated by conventional laser. The controls were selected through propensity score matching based on age, gender, baseline visual acuity (VA), number of laser spots and follow-up time from a contemporarily treated group of 119 eyes.

“This is an important study because it is the first comparison between the navigated laser and conventional laser treatment for DME in terms of clinical outcomes, and while it is not a prospective randomised trial, it used a sophisticated technique to create well-matched study groups,” Dr Kernt told *EuroTimes*.

Baseline mean logMAR VA was similar in the navigated laser and matched control group (0.48 and 0.49). Mean number of laser spots planned was greater for the navigated laser group compared with the control eyes (105 vs. 74), although the difference between groups was not statistically significant.

VA remained within three lines of baseline in all eyes at three and six months, and there were no significant differences

between groups in mean VA at any follow-up. Data from follow-up at one, three and six months showed VA gradually increased after the navigated laser treatment whereas it deteriorated slightly during the first three months after conventional laser treatment. Analyses of re-treatments by Kaplan-Meier analysis showed a statistically significant difference favouring the navigated laser group for needing fewer re-treatment procedures during the first six months, and a separation between groups was noticeable as early as two months, reported Dr Kernt, Department of Ophthalmology, Ludwig-Maximilians-University.

He proposed that the differences between groups in number of spots placed and the post-treatment outcomes may be explained by the ability to provide more complete and more accurate treatment using the navigated laser. A study published in *Ophthalmology*, for example, demonstrated that navigated laser allows more precise execution of the pre-planned laser spots to close microaneurysms, he said. Pre-planning of the laser treatment based on diagnostic images seems to lead to a more complete treatment, which is reflected by a higher amount of laser spots applied compared to conventional slit-lamp based lasers. “Surgeons may under-treat when using a conventional laser due to concern about damaging critical structures. This tendency is minimised using the navigated laser that allows careful pre-planning and precise delivery,” he said.

Dr Kernt noted that even if not investigated in this study, the data may support the idea that there may be a benefit

combining the navigated laser treatment with intravitreal pharmacotherapy as faster stabilisation of DME through more complete treatment, which might result in patients needing fewer repeat injections as well as fewer laser re-treatments. Data presented by investigators from Bellevue Hospital, New York, at this meeting are consistent with this idea, although the researchers noted that their study was not designed to investigate this specific issue. Several investigators in the US and Europe are validating a combination therapy of Anti-VEGF and navigated laser therapy to prove this concept.

Irene Barbazetto MD, Jesse Jung MD and Jonathan Huz MD, reviewed their experience using the navigated retinal laser for focal treatment of DME in nine eyes of patients with poorly controlled diabetes (mean HbA1c = 9.2), including six that had received prior intravitreal bevacizumab (Avastin, Genentech). They reported the laser treatment (mean shots=30, mean energy=94.8 mW) was well tolerated.

Data from pre-treatment to 12 months’ follow-up showed that the treatment was safe and resulted in statistically significant improvements from baseline in mean logMAR VA (0.62 to 0.47) as well as in OCT-measured anatomic endpoints, including largest subfield of macular thickness (358 to 320 microns). Among the patients who had prior anti-VEGF treatment, only three (50 per cent) received additional bevacizumab injections, and only one needed monthly injections.

“This is a small pilot study, but it is important to keep in mind that the good outcomes were achieved in a cohort of poorly controlled diabetics who are usually excluded from clinical trials,” said Dr Barbazetto, a vitreoretinal specialist and attending physician at New York University School of Medicine (NYU) and Bellevue Hospital. “I believe the technology definitely increases the safety of focal photocoagulation, and our findings support undertaking further studies to investigate a possible benefit for using this laser system in a combination approach that might reduce anti-VEGF injection burden.”

Dr Barbazetto added that thanks to its documentation feature, the system might also allow researchers to design improved treatment strategies for DME. She also noted the novel laser system has been an excellent teaching tool. Her co-author, Dr Jung, an ophthalmology resident at NYU, concurred.

“The need to manually locate each microaneurysm and select the correct energy for closure makes conventional focal laser treatment of DME challenging for residents and requires close supervision. Using the navigated retinal laser system, microaneurysms closer to the fovea can be accurately targeted, and the non-contact technique makes it easily tolerated by patients,” Dr Jung said.