

Determining Clinical Performance and Treatment Accuracy of Navigated Retinal Photocoagulation

Study evaluates safety and efficacy with the Navilas retinal photocoagulator.

BY IGOR KOZAK, MD

Laser photocoagulation of the retina using standard slit-lamp delivery systems has been used as a treatment for numerous retinovascular diseases for more than 40 years. Although more recent pattern laser delivery systems have gained popularity due to the fact that they reduce time of treatment, they do not compensate for eye movements or increase treatment accuracy. To improve accuracy and reproducibility of retinal laser treatments, a computer-guided targeting system should allow surgeons to plan each laser pulse with precision and to accurately position and stabilize the laser onto the planned retinal target.

As part of the team of retina specialists and researchers at the University of California at San Diego's Jacobs Retina Center directed by William R. Freeman, MD, I took part in the first clinical evaluation of the performance and treatment accuracy of such a navigated retinal photocoagulator, the Navilas from OD-OS (Teltow, Germany). This novel laser photocoagulator integrates retinal imaging, image registration, and laser photocoagulation technology.

The study, which was recently published in *Ophthalmology*,¹ involved 86 eyes of 61 patients with diabetic retinopathy from the University of California, San Diego, California, and the Instituto de Sub-Especialidades Oftalmologicas in Tijuana, Mexico. The study evaluated the safety and accuracy of the Navilas system by compar-



Figure 1. Color fundus photograph with Navilas instrument demonstrating vascular abnormality and exudation in an eye with branch retinal vein occlusion.

ing an intended treatment plan with achieved laser spot placement.

ABOUT NAVILAS

More than 25 years ago, the Early Treatment Diabetic Retinopathy Study (ETDRS) showed that laser photocoagulation reduced the 3-year risk of losing three lines or more of visual acuity: from 24% in the control group as opposed

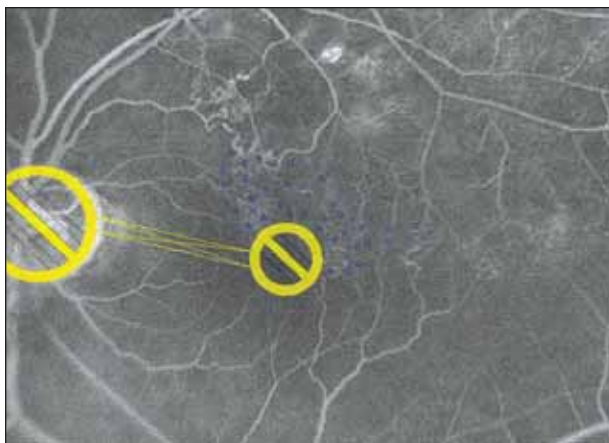


Figure 2. Treatment grid plan (blue dots) overlaid on fluorescein angiogram by Navilas in perifoveal areas with diffuse leakage. Yellow circles over the fovea and optic nerve mark no-treatment zone.

to 12% in the laser group.² Today, ophthalmologists continue to follow modified ETDRS guidelines using slit-lamp delivery of relatively long-pulse duration laser light.

The Navilas photocoagulation system has been designed to improve treatment accuracy by integrating imaging and laser delivery into one system. This allows registration of the fluorescein angiogram and surgical plan onto the live retinal image (Figure 1). The system then prepositions and stabilizes the laser beam onto the targeted locations, allowing the surgeon to efficiently complete the treatment plan. The Navilas also allows infrared illumination and does not require a contact lens, making the patient's experience more comfortable than standard laser treatment. The surgeon also benefits with improved visualization from the large-field, reflex-free real-time image.

THE IMPORTANCE OF ACCURACY

Accuracy is particularly important for focal laser photocoagulation, a common laser technique for the treatment of diabetic macular edema (DME). Accuracy was assessed in our study by visualizing post-treatment burns on fundus photographs and matching them with microaneurysm targets identified on pre-treatment fluorescein angiography images. The location of the post-treatment burn was judged as a central hit of the microaneurysm, a marginal hit, or a complete miss. Each image set was assessed by two independent retina specialists, which demonstrated high intra- and inter-observer reproducibility. The Fisher exact test was used to compare accuracy outcomes between navigated laser treatment and standard manual treatment.

An analysis of 400 random laser spots using Navilas

By compensating for the eye's movements during treatment, retinal navigation also minimizes the possibility of inadvertent burn placement.

and 100 single focal spots using standard slit-lamp laser in 20 and 4 eyes, respectively, found a significantly higher rate of accuracy in the Navilas group averaging 92% compared with 72% in the standard laser group ($P < .01$). Taken together, the accuracy of laser placement with the Navilas was significantly higher than that of standard manual treatments.

ADVANCED TECHNOLOGY

The Navilas is the first retinal system that uses registration technology to allow highly accurate and reproducible planning and execution of retinal laser treatments, something that cannot be accomplished with conventional lasers or pattern laser systems. By compensating for the eye's movements during treatment, retinal navigation also minimizes the possibility of inadvertent burn placement, which is crucial when treating close to the fovea (Figure 2). Treatments are comfortable for both the patient and the physician, who views the retina on a standard computer monitor rather than through oculars to apply the treatments. Additional clinical studies are now under way, with several focused on taking advantage of the unique attributes of the Navilas system in combination with anti-vascular endothelial growth factor drug therapies. ■

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1. Kozak, I., Oster, S.F., Cortes, M., et al. Clinical evaluation and treatment accuracy in diabetic macular edema using navigated laser photocoagulator NAVILAS. *Ophthalmology*. 2011;118:1119-1124.

2. Early Treatment Diabetic Retinopathy Study Research Group. Photocoagulation for diabetic macular edema: Early Treatment Diabetic Retinopathy Study report number 1. *Arch Ophthalmol*. 1985; 103: 1796-806.

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