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Road Testing the Navilas 577s Navigated Laser

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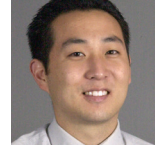
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Road Testing the Navilas 577s Navigated Laser

Since the introduction of the first laser-based photocoagulation machine—Theodore Maiman's ruby crystal red laser in 1960—the principles of laser treatment have remained relatively constant. Laser therapy requires a cooperative patient, a contact or condensing lens with a glaring-light source, and manual targeting with a steady hand.

The Navilas 577s (OD-OS, GmbH, Teltow, Germany) aims to change that paradigm. Utilizing image registration for automated targeting, a non-contact-lens option for focal laser, and an infrared light source to reduce glare, the Navilas 577s has the potential to be a game changer. But is it? Road Test invited 3 ASRS members to objectively review the Navilas 577s and inform our readers.



Raymond Iezzi, MD, MS
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The Navilas 577s is a computer-controlled, 577-nanometer laser that allows surgeons to perform image-guided treatments using an augmented-reality, live-image display. As the name implies, the system employs a single 577-nm yellow laser source. The unit is entirely self-contained and includes a touch screen for surgical planning and display, a computer for image capture and navigation control, as well as the treatment laser.

The internal scanning laser ophthalmoscope allows the surgeon to alternate between infrared or white-light digital fundus visualization during treatment. Angiographic images may be imported into the system through a network connection to an imaging server or via a USB storage device.

The key feature of the 577s is the navigation system that overlays fluorescein, indocyanine green, or OCT angiograms onto the real-time digital display to permit augmented-reality-guided treatment. This operating environment is created using 3 steps.

First, an angiographic image is imported into the system. Second, the 577s lens system captures a fundus photograph to be used during laser treatment. Third, the surgeon aligns the angiogram with the 577s fundus image by selecting several retinal vascular

bifurcations common to the 2 images. After some image scaling, rotation, and registration, the system is ready to accept a surgical plan.

At this point, the surgeon uses the angiogram, now displayed with the 577s software, to manually select each point of laser treatment. Initially, the software allows the surgeon to select “no-fly” zones over the disc and foveola to prevent the laser from treating those areas.

For focal treatment, the surgeon identifies all of the microaneurysms to be treated from the angiogram by clicking with a mouse or by pointing on the touchscreen. During the review, it was evident that the mouse was more precise than the touchscreen for this

purpose. For panretinal photocoagulation (PRP) or grid laser, the surgeon can use tools to “paint” laser spots onto the fundus image.

Working with the laser

Sitting down at the Navilas laser system, I was immediately impressed by the technology and struck by the concept of planning a treatment on the computer and basically having a robot assist me in executing the procedure. All of this technology brings the expectation that the level of precision will exceed what can be achieved without navigated augmented reality. It takes some experience with the system to realize that the surgeon is not relinquishing too much control to the computer-controller, though. Ultimately, the laser is actively controlled by the foot pedal and does not automatically fire without surgeon control—it knows who's master.

During 2 one-week trial periods, I did feel like I had taken a crash course in ophthalmic photography because everything the 577s does depend on fundus photography. Three types of images are used to treat each patient, and the surgeon is responsible for capturing at least 2 of these during the laser treatment session. I used the non-contact-lens system as well as several classic fundus contact lenses and found that it was much easier to perform non-contact fundus photography than to use the contact lens.

I also found that non-contact laser treatment using the 577s was significantly less complex than procedures that employed a contact lens.

‘The key feature of the 577s is the navigation system that overlays fluorescein, indocyanine green, or OCT angiograms onto the real-time digital display to permit augmented-reality-guided treatment.’

—Raymond Iezzi, MD, MS



Figure 1. The touchscreen of the all-digital Navilas Laser System allows surgeons to pre-program laser treatments. Image courtesy OD-OS, GmbH.

It was evident during my initial dozen cases that by using one hand to hold the contact lens and the other hand to position and focus the laser, I could not use the mouse or touchscreen to control the system. I found it takes experience to become familiar with the system's highly sophisticated joystick. The company did state that the joystick can control most, if not all, functions that would require mouse or touchscreen control. To get around this during the trial, I employed an assistant during procedures.

To define an appropriate power level for each spot size used during treatment, a series of laser test spots may be placed onto the retina over a range of power levels and spot sizes. The surgeon must then take another color fundus photograph using the 577s to establish the laser power that corresponds to the desired treatment endpoint for each spot size used.

The software does not permit the surgeon to titrate the laser power for each spot

while a treatment plan is in progress. Consequently, if the surgeon notices that a specific treatment site has not been treated to the desired endpoint while a plan is being executed, it is not possible to remain on that spot to adjust the power to a higher (or lower) level.

Either the current treatment plan must be aborted and a new plan started, or the current treatment plan must be completed and a new one subsequently defined at a different laser power. Because of this, it is more efficient to create a treatment plan for each spot size/power level used. Then, if adjustments are required, it is easier to abort that treatment plan as a whole, assign a new power level to the plan, and re-execute it.

Patient experience

Interestingly, some patients commented on how the technology differed from other laser treatments they had experienced.

They were impressed by the concept of a computer-controlled laser. The most notable comment made by patients treated over the 2-week trial period was how they preferred non-contact treatment. They commented that this was more comfortable than having the contact lens on their eye. Further, panretinal laser photocoagulation was reported to be more comfortable using the non-contact-lens system. From a surgeon-perspective, it was evident that PRP laser delivery was very efficient and well tolerated by the patient.

Overall impression

Based on a 2-week trial, it was my impression that the Navilas 577s augmented-reality, navigated-laser system allowed me to more precisely use angiographic testing to guide laser treatment sessions. Even OCT angiography can be used to guide treatment to areas of retinal thickening or to target retinal microaneurysms. This capacity comes only to surgeons motivated to take the time to employ these features.

'The most notable comment made by patients treated over the 2-week trial period was how they preferred non-contact treatment.'

—Raymond Iezzi, MD, MS

Focal laser treatment procedures did take longer with the 577s than did procedures done using conventional laser methods; however, panretinal laser photocoagulation procedures were more efficient using the non-contact 577s than non-guided contact lens-based treatment. The balance between efficiency and precision largely depends on how the surgeon employs the 577s.



David T. Goldenberg, MD
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The Navilas 577s laser is the first all-digital system for navigated focal and peripheral laser treatments. It is essentially a "smart" laser,

and its advances are to conventional lasers what the iPhone advances are to flip phones. The major advance is its ability to precisely target treatment locations directly from its own fundus photo or an uploaded fluorescein angiogram (FA).

The Navilas laser is designed to be used for focal treatments in the macula as well as peripheral treatment. I was able to demo the laser on several patients who needed focal laser treatment for diabetic macular edema, and others who needed PRP for proliferative diabetic retinopathy.

At first glance, the laser system appears unusual, as there is no slit lamp and no oculars. Instead, it consists of a digital camera and laser housing mounted on a table with an adjacent large digital screen. The camera/laser is adjustable with a joystick similar to that of many slit lamps and utilizes a foot-pedal delivery system. The laser head is small and allows you to see and interact with the patient. Overall, the design is quite sleek and the system is easy to operate.

The Navilas laser system's digital fundus camera (true color and infrared) takes quality pictures of eyes with a moderately dilated pupil, and the images are instantly displayed on the adjacent large screen. The image can be magnified by "pinching" 2 fingers (similar to smartphone screens), and the resolution remains excellent. Then you can set your treatment plan by marking the screen with specific locations to target (ie, grid pattern, individual microaneurysms, or other pathologic lesion).

However, the system's most significant upgrade is its ability to integrate with FA and OCT images, which can be easily uploaded

'The [Navilas 577s laser system's] major advance is its ability to precisely target treatment locations directly from its own fundus photo or an uploaded fluorescein angiogram.'

—David T. Goldenberg, MD

to the Navilas computer via a USB port. The Navilas software has excellent registry to match its own color photo with the uploaded FA image. This system makes it simple and more accurate to pinpoint any extrafoveal lesion for treatment.

Small microaneurysms that were difficult to detect on traditional color photos are now much easier to identify and treat with an uploaded FA image. Once you're ready and press the foot pedal, treatment starts automatically and continuously based on your planned, targeted locations.

Several safety features further enhance the Navilas laser. During the treatment planning phase, you can select areas on the fundus photo or FA image where laser treatment is to be avoided. For example, you can place a "no-treatment zone" over the optic nerve and the fovea and easily adjust the size of the zone.

The system also utilizes advanced eye tracking, which further reduces the risk of inadvertent error. If the patient moves her eye or blinks, the laser won't fire. I suspect both of these features would be helpful when treating pathology close to the foveal avascular zone or optic nerve, although I did not have the opportunity to try it in such cases. These safety mechanisms would be especially beneficial for teaching institutions with inexperienced residents and fellows.

When performing treatment in the macula, laser can be applied with or without a contact lens. I admit I was quite skeptical about the non-contact-lens option. However, I was happily surprised by how easy it was—and it makes the entire procedure quicker and more comfortable for the patient. Focusing the laser without a contact lens is straightforward and, more importantly, there's no need for messy viscoelastic!

Prior to performing the laser and while focusing the camera, you can use a standard light to illuminate the fundus, which projects a color image on the adjacent screen, or you can use the infrared mode, which shows up as a nice black-and-white image. I found that using the infrared mode was a significant advancement. It creates a high-resolution image and is much more comfortable for the patient because it avoids the bright light. Using the infrared mode along with the eye tracking eliminates the need for a contact lens.

Unfortunately, peripheral laser treatment (ie, PRP repairing retinal tears) still requires a contact lens with the Navilas 577s. Similar to the PASCAL laser (Topcon, Inc, Livermore, CA), the Navilas 577s is fully customizable

as you can adjust spot size, patterns, and spacing. Again, the main difference is that you pre-place your treatment location on the adjacent screen. Planning your treatment is very similar to macular laser. On the screen you can essentially "paint" where to apply laser in the periphery. Then just step on the pedal and fire away.

After each laser session, the module prints a digital report that summarizes the treatment parameters (total shots, duration, power, and spot size) and an image of the fundus showing where the laser spots were placed. This feature would certainly be helpful in patients who require multiple macular treatments.

'Small microaneurysms that were difficult to detect on traditional color photos are now much easier to identify and treat with an uploaded FA image.'

—David T. Goldenberg, MD

My clinical staff thought the laser was quick to set up, and uploading FA images was easy. My patients commented on their lack of discomfort during the procedure, especially while in infrared mode. Laser uptake was good and similar to other traditional lasers; low power is needed for darkly pigmented eyes and increased power is needed for eyes with lighter pigment. There is a short learning curve when using a contact lens, as it must stay perfectly straight as opposed to being able to manipulate it a bit with a conventional laser. However, this is quickly mastered after only a few cases. Overall, I thought the laser was simply cool and a notable step forward.



Christine R. Gonzales, MD
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The Navilas 577s laser system by OD-OS is an all-digital navigated laser system for focal macular laser, microsecond pulse laser pattern grids, and PRP. FA and OCT overlays can be imported to plan for precise delivery of laser spots.

The real-time infrared images for eye-tracking and planned exclusion zones provide precise spot placement and possibly increased safety. I had the opportunity to test the Navilas laser on a few patients with macular edema and proliferative disease from diabetic retinopathy.

Overall, I found the Navilas laser easy to use and comfortable for the patient and physician. Planning and treatment occur with heads-up viewing after taking a registration photograph of the retina (ie, you look at the monitor, not through a slit lamp). The screen is on an arm off to the side and can be adjusted to a comfortable ergonomic position to prevent neck strain during the procedure.

There is a learning curve to focus the digital fundus image for registration and to maintain the view during treatment, but I found this relatively easy. The registration photos are quick, and it is possible to train a technician to take these photos and to import the FA and/or OCT images for the overlay before the doctor enters the room.

The focal macular laser does not require a contact lens; however, if the patient is unable to fixate or has excessive eye movement during the procedure, a contact lens can be used for the focal treatment. As an additional safety feature, if the patient moves suddenly during the procedure, the laser will not fire. The contact lens is necessary for PRP.

I found that in a patient with media opacity from cataract, the registration of the fundus image to the FA or OCT overlay was more difficult. The software allows for rapid automated overlay of these diagnostic tests on the fundus registration photo; however, if it fails to align properly, as occurred in the patient with cataract, manual overlay is possible by using vascular landmarks.

‘There is a learning curve to focus the digital fundus image for registration and to maintain the view during treatment, but I found this relatively easy.’

—Christine R. Gonzales, MD



Figure 2. The Navilas Laser System enables surgeons to perform focal treatments without a contact lens. *Image courtesy OD-OS, GmbH.*

‘Overall, I found the Navilas laser easy to use and comfortable for the patient and physician.’

—Christine R. Gonzales, MD

A treatment plan is generated using the digital registration image with or without the overlays, using the touch screen or the mouse. Microaneurysms can be targeted with continuous-wave laser, areas of avascular peripheral laser can be selected for PRP, and areas for zero-spacing microsecond pulse laser can be selected on the screen before beginning laser treatment. This plan is then executed using the eye-tracking with the physician-controlled foot pedal. You can pause during the treatment plan at any time.

To titrate the power of the laser, you can see the uptake of the laser spots in the color view, but the spots are less visible when using the infrared viewing. For this reason, I found it more comfortable from a safety standpoint to treat while in the color viewing mode. There is the option to take a color image during the laser treatment, which displays below the real-time viewing. On this screen, the program toggles between pre- and post-laser images—a useful feature.

I found it important to turn off the overlay during treatment so I could continually monitor my spot uptake; otherwise the small circle with an “x” blocked the view of the laser spot. If you turn off the overlay, the small

circle is replaced with a larger circle that allows you to see uptake.

During microsecond pulse treatment, the microsecond pulse grid plan overlay does obstruct your view of the retina, which does not allow you to confirm that you are not seeing a treatment effect from the microsecond pulse (which might occur if you were doing a combined focal and microsecond pulse grid and forgot to switch from continuous wave to 5% duty cycle).

Although the small, planned aiming spots are replaced by an open, larger blue circle, the pattern is such that the spots are not placed contiguously, so you cannot see the underlying retina for the first pass through the planned grid. It would be better if you could toggle off the aiming spots for the grid during treatment.

If planning to do any focal spots within a zone of planned microsecond pulse, I would recommend doing the spots within the microsecond pulse planned area manually after the treatment plan is executed or doing 2 separate treatment plans. When planning both conventional and microsecond pulsing laser treatments in the same treatment plan, the surgeon must currently change the power settings and the laser mode manually between such treatments. This can be avoided by performing microsecond pulsing and conventional treatments in different treatment plans.

Also, if you are doing a focal laser plan to treat microaneurysms together with microsecond pulse in one treatment plan, it is important to note the treatment parameters must be manually changed when moving from the focal to the microsecond pulse grid. It is therefore very important to pay attention

to the aiming beam. When the last microaneurysm is hit, the next spot will be at the first spot laid out on the grid, and the grid will change from green to white. This is the only warning that you are now moving to the grid.

While treating the microaneurysms with continuous wave does require you to push the foot pedal for each spot, the grid does not and will rapidly begin treatment as soon as it locks on to the grid. I was told by the OD-OS representative that a software update will make this transition point much more obvious to the treating physician, and that the settings for the continuous-wave focal and microsecond pulse grid will be tagged to a specific color spot in the plan in the new release.

I was very impressed with the PRP and the speed with which a section of peripheral laser could be filled. I was able to treat one quadrant at a time in each plan. The spots were very uniform with good uptake in the entire region treated. I did not have to adjust the power settings at all. I was less impressed when using the pattern grid without a treatment plan (which can be set between 2 x 2 and 5 x 5) for peripheral PRP, as I had less uniform treatment, and the grid did not complete on most times due to problems with patient movement and cataract.


The procedure reports are very comprehensive with pre- and post-treatment images and parameters. Furthermore, the precise areas of treatment are mapped and can be used for future laser planning. These reports can be imported into some electronic medical records.

A disadvantage: There is no laser indirect ophthalmoscope (LIO), so this laser may not be a good stand-alone laser, as it would not be helpful for peripheral tears that require LIO.

Overall, I was very impressed with the planning and safety features, optics, ease of use, and speed and uniformity with which PRP laser could be performed. Although this is a fully automated and computerized laser, the operator must always be aware of the aiming beam location and settings before applying the laser spots. This is still a machine and mechanical errors can occur, so physician oversight and attention remain vitally important.

Editor's note: OD-OS, GmbH had the opportunity to see the reviews just prior to publication. Stefanie Gehrke, director of marketing, says:

OD-OS would like to thank the Road Test reviewers and editors for the opportunity to present Navilas, which allows surgeons to precisely plan and deliver the widest variety of laser treatments based on almost any diagnostic image. The advantages noted in the reviews include highly accurate and efficient macular and peripheral laser application, the ability to perform treatments without a contact lens for enhanced patient comfort, and complete procedure documentation.

OD-OS is committed to continued development and optimization of its novel digital technology, including suggestions by the reviewers for remote treatment planning and advanced combined subthreshold and threshold treatment plans, which are already included in planned software releases. 

Financial Disclosures

Dr. Goldenberg – None.

Dr. Gonzales – ALCON LABORATORIES, INC: Investigator, Grants; ALLERGAN, INC: Advisory Board, Investigator, Grants; GENENTECH, INC: Investigator, Grants; ICONIC THERAPEUTICS: Advisory Board, Investigator, Speaker, Grants, Honoraria.

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Dr. Iezzi – None.

Dr. Rhee – ALLERGAN, INC: Advisory Board, Honoraria; CONNECTONCALL.COM, LLC: Founder, Stock; COVALENT MEDICAL, LLC: Stockholder, Stock; LUMENIS LTD: Consultant, Equipment (Department or Practice), Honoraria.

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