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Special Section: Refractive

Innovation

LASIK tool helps manage ocular surface

Device allows surgeons to perform multiple tasks in the surgical field

New Product Focus

By Lynda Charters

Reviewed by Leon C. LaHaye II, MD

Lafayette, LA—The LaFaci Surgical System (Vision Pro, LLC, Opelousas, LA) allows the LASIK surgeon to perform a number of specialized functions in the surgical field through the use of one handpiece. This capability, according to the developer of the system, Leon C. LaHaye II, MD, facilitates the entire second stage, i.e., following lifting of the flap, of the LASIK procedure.

"The LaFaci handpiece," he explained, "is placed on the patient's eye before lifting the flap, remains positioned until flap fixation is assured, and provides 11 specialized functions."

The introduction of this system is a departure from conventionally performed LASIK in that it standardizes the procedure, according to Dr. LaHaye, who has used this system on 119 eyes.

Take-Home Message

The LaFaci Surgical System (Vision Pro) allows LASIK surgeons to perform a number of specialized functions in the surgical field through the use of one handpiece. This capability facilitates the entire second stage of the LASIK procedure, i.e., following lifting of the flap, making LASIK less demanding on the surgeon, increasing efficiency, and standardizing the LASIK technique.

"The data confirm that the majority of complications from LASIK will arise from stage II of LASIK, which is technique related, and not as a direct result of keratome or laser technologies," he said.

"Stage II begins the moment the corneal flap is reflected (incision exposure) and is completed with the corneal flap returned and sealed in its original position (incision closure)," he said.

"As an industry, LASIK surgeons have become very skilled in the management of diffuse lamellar keratitis, infectious keratitis, epithelial ingrowth, undercorrection, overcorrection, de-centered ablations, islands, flap striae, interface debris, plume dispersal, and other complications. Now we need to become more aggressive in prevention," Dr. LaHaye explained.

"In conventional LASIK, numerous techniques, methods, and instruments are used by LASIK surgeons to perform all aspects of

Figure 1 The LaFaci Surgical System (Vision Pro, LLC, Opelousas, LA) is a useful device for flap repositioning. The corneal flap is anatomically supported on the platform (left). Corneal flap repositioning is facilitated with the platform function (middle, right). (Photos courtesy of Leon C. LaHaye II, MD)

the multitasked stage II. There is considerable variability and inconsistency in the performance of the numerous steps of stage II of conventional LASIK," Dr. LaHaye emphasized.

'The device is compatible with most laser tracker systems by minimizing large saccadic movements.'

Leon C. LaHaye II, MD

Standardization of LASIK

"LaFaci, which is short for LASIK Facilitator, was designed so that functionality and standardization of the LASIK procedure are achieved using this new surgical ocular surface management system. The system comprehensively combines surgical field downsizing, surgical field containment, ocular fixation, ciliary vessel tamponade, temporary flap placement, proactive fluid removal from the surgical field, plume evacuation, stromal bed hydration management, irrigation, aspiration, and flap repositioning and adherence," said Dr. LaHaye, who is in private practice in Lafayette, LA.

To use this system, the handpiece is positioned on the patient's eye before the newly cut flap is lifted. The positioning of the instrument, which is composed of a lower ring, a cylinder wall, a platform, and a preemptive aspiration function, establishes the limits of the surgical field and prevents the cornea, the flap, and the stromal bed from coming into contact with the adjacent ocular structures, lid margins, instrumentation, and fluids present in the surgical field.

The system also allows the surgeon to control eye movements during LASIK via eight smooth fixation teeth and lower ring design that provide globe fixation relative to the handpiece.

"The device is compatible with and complements most laser tracker systems by minimizing large saccadic movements and provides for cyclotorsion management," he said.

The handpiece also provides 360° of atraumatic tamponade of the ciliary vessels, which facilitates rapid hemostasis, according to Dr. LaHaye. This minimizes direct manipulation of the bleeding vessels and the margins of the flap and the stromal bed.

A flap platform, which is a component of the instrument, anatomically supports and elevates the flap over the adjacent tissues, which eliminates much of the possible direct contact of the flap to these tissues and surgical field fluids that may occur.

Continuous aspiration "preemptively removes fluids from the lowest point (lower than the stromal bed and the flap lying on the platform) within the cylinder of the handpiece, which minimizes backwash or 'creep' of fluids onto these exposed stromal tissues," Dr. LaHaye said.

The system, which generates laminar vacuum flow, also facilitates plume evacuation through seven ports. The vacuum flow is designed to minimize the vertical flow of the plume, which minimizes exposure to laser pulses that travel vertically downward.

"This function allows a range of flow settings to balance plume removal effectiveness with stromal dehydration control, thereby creating a microclimate above the target tissue," he said.

LaFaci also provides delivery of symmetrical, laminar (non-turbulent) flow, sterile air to the stromal bed to remove any excessive beam masking fluid through evaporation.

"The air delivery function of LaFaci allows the surgeon to measure the desired effect visibly and facilitate a 'no touch' technique for removing visible stromal surface fluid from patient to patient. Effective and efficient management of plume and target tissue hydration are both essential in order to achieve standardization of pulse-to-pulse laser etching," he explained.

After treating the stromal bed with the laser, the laminar flow irrigation and aspiration functions are used to clean and re-hydrate the corneal bed and flap before the flap is repositioned. The LaFaci ring design in combination with the irrigation and fluid aspiration functions provides a "water vacuum" means of cleansing and re-hydrating the corneal flap and stromal bed while simultaneously eliminating backwash.

Flap repositioning, fixation

Finally, the system facilitates flap repositioning and fixation. With the flap on the supporting platform, the platform then is rotated and the flap slides off and is repositioned on the stromal bed. Dr. LaHaye pointed out that the design of the LaFaci System reduces excessive manipulation and eliminates the introduction of instruments and irrigation into the flap/bed interface in order to "re-float" the flap and remove backwash debris.

"Proper use of the platform function returns the corneal flap to the bed in perfect alignment," he said. Flap adhesion is then enhanced by the delivery of 0.2-µm microfiltered laminar flow air through the handpiece. Dr. LaHaye explained that the handpiece provides the surgeon a method of accelerated flap adhesion through evaporation.

"Flap fixation with LaFaci takes only 10 to 15 seconds," he said.

After this stage is completed, the handpiece is then removed.

Considering the functions that the handpiece provides, Dr. LaHaye believes that LASIK is less demanding on the surgeon and the surgical assistant and, importantly, the surgical time is reduced. He also believes that improved standardization of LASIK technique will ultimately result in an overall reduction of complications, thereby improving outcomes.

He also said that there is a learning curve associated with this surgical system.

"The surgeon must re-think his or her surgical approach to performing LASIK when initially using the LaFaci Surgical System. This is not a drawback but a learning curve associated with the integration of a new technology. Performing LASIK with LaFaci can be easily mastered. LaFaci has provided a means for me to be more efficient as well as standardize the procedure and has injected a new level of surgical enthusiasm, making LASIK more enjoyable," he said.

Dr. LaHaye emphasized that the focus of this system is on patient safety.

"Instead of safety, supervision, and cost, I believe that patients are more interested in safety, safety, and safety. Patients are continuously exposed to radio, TV, and Website ads that promote the benefits of the newest technology, but few prospective patients are reaching for the phones to call and make appointments (less than 3% of the potential refractive market has had vision correction surgery). It becomes apparent why patients are not standing in line for LASIK when one analyzes the data," he said.

"The bottom line is that every potential refractive patient knows someone who has had a less than desirable outcome. Nothing is more frustrating to the patient and surgeon than to have planned on a perfect custom or wavefront procedure and instead experience an outcome that requires additional medical and surgical management," Dr. LaHaye noted.

"Our patients are receiving mixed messages of technological advances with promises of supervision, nonetheless, a significant percentage of technique-related complications occur. One unhappy patient tells 13 others of his or her dissatisfaction. Until we prioritize and refocus our energies and resources on prevention of the more frequently occurring and more serious complications, we will continue to create patient dissatisfaction that can affect the entire industry," he said. OT

FYI

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Dr. LaHaye has a proprietary interest in this technology. The LaFaci Surgical System is approved for use in Europe and has received FDA 510(k) clearance.

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As a traditional, yet innovative manufacturing company, Vision Pro, LLC restricts its services to its core competencies and concentrates on developing state-of-the-art ophthalmic surgical instruments and medical devices that are designed to "help the doctor help the patient". This is achieved by establishing and maintaining genuinely close relationships with its physician clients that have preserved the traditional and reliable conviction …***because patients come FIRST***.

In fact, in past years we have deliberately avoided being caught up in the superficial hustle and bustle that, in some circumstances, has taken over the practice of medicine. We prefer instead to cultivate and further strengthen our core competencies, designed to manufacture equipment, allowing the physician to standardize and maximize his or her overall skills and talents.

At the same time we are aware, of course, that preserving tradition and reliability must under no circumstances obstruct our efforts to further improve both our physician clients and their patients with the tools and educational materials to meet exacting needs and maximize outcomes.

We are confident that in doing so we are best able to honor the great trust that our client physicians and their patients place in us.

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