

Aiming for fewer retreatments

Introducing the LAHayeSIK surgical system

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One surgeon's quest to reduce intraoperative LASIK complications has led to the development of a new multifunctional instrument, which is hoped will help standardize surgical manoeuvres and reduce the need for retreatment. The LAHayeSIK Surgical System has been designed to perform cleaner LASIK for more consistent outcomes and fewer complications, according to inventor/developer Leon LaHaye, MD of Lafayette, Louisiana, USA.

The LAHayeSIK instrument (Vision Pro, LLC; USA) comes in either a compact table-top console or a surgical cart consisting of a multifunctional handpiece, a pivoting surgical tray, a foot pedal controlled irrigation/aspiration and sterile filtered air delivery system, disposable tubing sets, and smoke and fluid collection receptacles. The system is approximately the size of a phacoemulsification instrument.

"As we know, keratotomy complications are almost nil today thanks to the advanced, automated technology of modern microkeratomes and the femtosecond laser. Hence, the early difficulties associated with creating the corneal flap have largely become a thing of the past. Most of the LASIK complications we still see occur in what I refer to as the second stage of the procedure, or in other words, during the manoeuvres and the laser treatment that follow the keratotomy," says Dr LaHaye. "There remain less than optimal issues associated with traditional LASIK such as: direct exposure of the open stroma and flap to contamination from lids, secretions, conjunctiva; non-uniform hydration of the target stroma and associated etch variability; extraneous instrumentation; excessive manipulations; sub-optimal intraoperative flap management; ineffective means of cleansing and rinsing post ablation; backwash contamination; involuntary eye movements; non-uniform and poor flap adherence. All of these sub-optimal issues are, in my opinion, synergistically addressed by the LAHayeSIK device," insists Dr LaHaye.

The LAHayeSIK instrument was developed over a period of several years and received US FDA clearance and European

regulatory approvals in 2004. It is designed and engineered to reduce LASIK complications associated with flap/stroma interface debris, attenuation of the excimer laser beam caused by surgical smoke, inaccurate ablation, inconsistent tissue hydration, extraneous manipulations and contamination by irrigation backwash and other sources. The surgical field is reduced to include only the ablation area and is protected by virtue of the handpiece, which allows the surgeon to perform nine different functions with a single instrument.

"In addition to reducing complications, I wanted to create a system by which I could standardize and automate the procedure for more consistent outcomes," says Dr LaHaye. "By reducing the number of instruments normally used, I have found certain ergonomic economies are achieved and the procedure is substantially shortened and made more reproducible."

Performing the procedure

After the flap has been created but prior to exposure of the stroma, the LAHayeSIK handpiece is placed on the eye. It remains in position throughout the remainder of the procedure, held in place by the surgeon or assistant. The stainless steel conical wall of the instrument forms a fluid tight barrier at the margins of the cornea to reduce the area of the surgical field and prevent contact contamination by lashes, lid secretions, conjunctiva and surgical debris.

Within the handpiece cone, a hinged, non-metallic platform provides a resting place for the reflected corneal cap to anatomically support and protect it from pooling irrigation fluids and other sources of infectious and non-infectious contamination (Figure 1). At the conclusion of the procedure, a simple flip of the hinged platform re-positions the flap into the exact position on the cornea with minimal manipulation, eliminating "refloating" manoeuvres.

The multifunctional handpiece also provides 360° haemostasis against potential bleeding that can sometimes occur with today's large keratotomies. Throughout the procedure, sterile, pulsed irrigation at the rate of



Figure 1: The amber-coloured hinged platform isolates and protects the corneal flap.



Figure 2a: Smoke generation demonstrating random vortices of plume propelled towards last optic in a turbulent distal evacuator.

Figure 2b: Distal smoke removal systems allow extensive vertical ascension of the plume which can interfere with ablation.

Table 1: LAHayeSIK results in 431 eyes.

LAHayeSIK complications (n=431 eyes)	
	% occurrence
Under corrections	0.7% (3 eyes)
Over corrections	0
DLK	0
Epithelial ingrowth	0
Flap striae	0.2% (1 eye*)
Decentred ablations	0
Microbial keratitis	0
Retreatment rate totals	0.93% (4 eyes)

*This eye sustained a 40% epithelial slide to the flap from the keratotomy.

Total incidence of epithelial defects from keratotomy: 2.3%

1.8 cc/second and simultaneous aspiration of the surgical field is available on demand to flush away surgical debris via a foot control. Antibiotics may be added to the irrigating solution at the surgeon's discretion.

Laminar flow sterile filtered air is delivered in the same manner at the rate of 30 ml/minute, evaporating excess moisture as needed. The instrument's aspiration ports are strategically located at the lowest possible point in the handpiece preventing pooling and backwash of irrigation fluids, or occlusion by the conjunctiva, delivering a cleaner interface.

What impact does it have on ablation?

According to Dr LaHaye, the LAHayeSIK instrument provides for an effective excimer laser ablation in a number of ways:

- Seven smoke evacuation ports are positioned just millimetres above the stroma to quickly remove ablation smoke plume from the surgical field and minimize interference and blocking of subsequent laser pulses.
- The proximity of the evacuation ports to the corneal surface greatly increases efficiency in comparison to systems located several inches from the eye. Engineering studies demonstrate that having the ports close to the smoke source eliminates air turbulence and subsequent scattering of smoke particles resulting in less random beam masking and a cleaner operating room environment. Other smoke abatement systems positioned inches from the eye have been found to be only marginally effective by some researchers. These systems also generate a high volume of room airflow into the surgical field — up to ten times the rate of the LAHayeSIK system, according to Dr LaHaye — to remove the smoke plume. (Figure 2 & 3).
- The handpiece affords the surgeon manual control of eye movement to reduce off-axis ablation.
- The lower ring design of the handpiece provides secure, atraumatic fixation of the globe to prevent untrackable fast saccades and compensate for fixation difficulties, relieving total dependence on eye trackers and patient compliance.
- The sterile oxygen delivery function allows the surgeon to enhance laser effectiveness by providing an evaporative method of uniformly removing only the surface beam masking fluid from the target stroma throughout ablation

without causing dehydration.

Faster surgery, fewer complications

"Having the various functions of LAHayeSIK at my fingertips reduces the number of instruments normally used in conventional LASIK and shortens operating time," says Dr LaHaye. "Typically, all of the manoeuvres involved in stage two of the procedure are usually accomplished in under two minutes. The final LASIK procedural steps, including post-ablation rinsing, cleansing, flap repositioning, alignment and adhesion is routinely accomplished in 15 to 20 seconds. The traditional three to five minutes for these steps is not necessary and the issues concerning backwash and extraneous manipulations are eliminated."

As with any new technology, there is a learning curve associated with the LAHayeSIK system. "After a few dozen procedures, its use becomes second nature and the benefits of case-to-case consistency begin to become apparent," insists Dr LaHaye.

What do the stats say?

In a retrospective study of LASIK cases performed with LAHayeSIK, Dr LaHaye reports a low incidence of complications and retreatments. Presentations at the XXIV ESCRS Congress in London, last September, reported results obtained by Dr LaHaye in 431 eyes treated with the Nidek EC-5000 excimer laser and the LAHayeSIK surgical system (Table 1). This data was collected on myopic corrections up to -15 D and cylinder up to 4 D. At six months postoperatively, 87% and 98% of eyes achieved refractions within ± 0.25 D and ± 0.5 D of emmetropia, respectively.

"In my opinion, one of the best indicators of the accuracy, effectiveness and overall success of a LASIK procedure is the retreatment rate," says Dr LaHaye. "In my study of more than 400 eyes treated with metal blade microkeratomers, an excimer laser without eye tracking using 'off the shelf' standard nomograms, and the LAHayeSIK surgical system, the need to retreat fell to less than 1%. In addition, my procedural time improved allowing me to perform eight to nine LASIK procedures per hour," Dr LaHaye concludes.

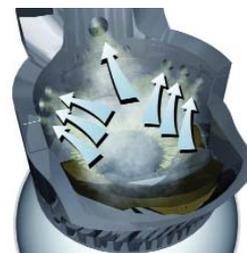


Figure 3: Proximal LAHayeSIK plume evacuation ports immediately and efficiently remove surgical smoke.

In short...

Leon LaHaye, MD informs us of his invention, the LAHayeSIK surgical system, which he designed to reduce the incidence of intraoperative LASIK complications and, ultimately, the number of LASIK retreatments. As well as detailing the main features of the system and the surgical technique, he provides data from a study in 431 eyes undergoing refractive correction, where he achieved a retreatment rate of less than 1%.



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