CATARACT

Potential Electrosurgery Advance: The Pulsed Electron Avalanche Knife

BY ANNIE STUART, CONTRIBUTING WRITER

When William T. Bovie developed his innovative electrosurgical unit—the Bovie continuous radiofrequency (RF) generator—more than 80 years ago, he pioneered a technique that produced high-frequency currents for both cutting and coagulating tissue. Since then, electrosurgery has remained a fundamental tool in the practice of surgery, growing into a $1 billion market by 2006.[1]

Using Joule heating by electric current, the Bovie generator causes vaporization and ionization of water in tissue adjacent to the electrode, leading to tissue fragmentation. In the process, however, it produces collateral thermal damage—in the range of 100 to 400 µm[2]—making it a less-than-ideal option for delicate tissues in the eye.

Laser got a later start in the 1960s but, unlike electrosurgery, it continued to rapidly evolve through optimization of its wavelength, pulse duration, beam shape and repetition rate—all of which helped produce higher precision and less collateral damage.[2] However, the relatively high cost, large size and somewhat cumbersome hand piece delivery system limited its widespread use.

A cutting tool now in development is achieving results similar to laser but with pulsed energy. Called the pulsed electron avalanche knife (PEAK), it applies some of the same principles used with laser to radiofrequency cautery—producing greater precision, faster healing and less scarring than that achieved with conventional RF electrosurgery.[1]

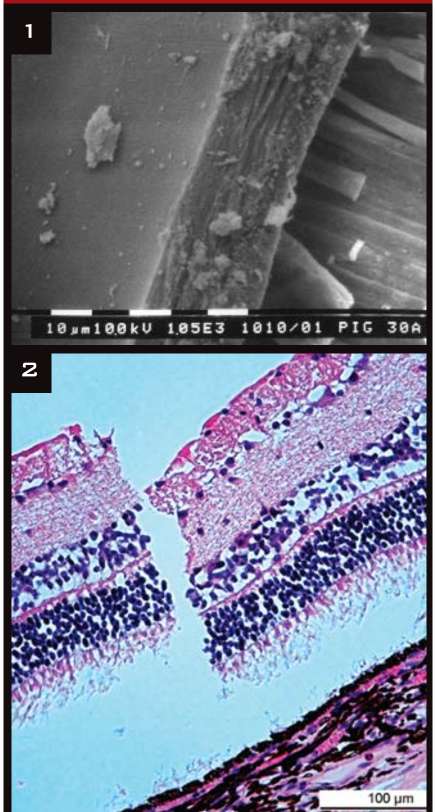
PEAK Principles

PEAK was invented in 2001 by physicist Daniel Palanker, PhD, an associate professor of ophthalmology and in the Hansen Experimental Physics Laboratory at Stanford University, and by Alexander Vankov, PhD, who was a postdoctoral colleague of Dr. Palanker at the time. Largely drawing on observations about laser, Drs. Palanker and Vankov optimized microelectrodes and microsecond electrical waveforms with PEAK to produce traction-free, cellular precision in tissue dissection.

"Laser produces plasma, which is the driving force of transparent tissue ablation," said Dr. Palanker. "Ophthalmic examples of this include posterior capsulotomy with nanosecond lasers and corneal cutting with femtosecond laser." The physics involve an electrical field sufficient for ionization of water to create plasma that can absorb the light—and lead to the energy deposition necessary—to ablate tissue. "Our goal was to replicate this process in electrosurgery by using very small electrodes and applying short pulses of high voltage," explained Dr. Palanker. "But we also needed to optimize pulse duration to minimize both mechanical and thermal damage. Mechanical damage is caused by rapidly forming and collapsing vapor bubbles, a process we know as cavitation."

Possible applications. Beginning with a prototype for ophthalmic applications, Dr. Palanker and codevelopers worked to fine-tune its features, and then scaled it for other applications, including general surgery, plastic surgery, obstetrics and cardiovascular surgery. "The physics of ionization, formation of plasma and ablation of tissue are not linear," said Dr. Palanker, "so we couldn't just scale it up and hope that precision would be preserved. The size of electrodes matters. We had to design a

Clear Cut



(1) Scanning electron micrograph of a pig lens capsulotomy performed with the pulsed electron avalanche knife. (2) Pig retina dissected by PEAK.

PEAK SURGICAL

unique blade shape and unique waveform features that allowed us to maintain precision in a scalpel-sized tool."

Now in its third iteration, PEAK combines a generator, that produces a higher burst frequency than previous prototypes, with a plasma blade that has a flat, scalpel-like shape with insulated sides and an exposed-edge electrode. This allowed for a uniform and concentrated electric field that might be used for surgery on all types of soft tissues.[1] Insulation of the electrode also creates the possibility of operating in both dry and wet fields, eliminating the need to change instruments. This third iteration includes coagulation and cutting modalities that can be mixed for applications where both are desired, said Dr. Palanker, and it minimizes a problem with gas bubbles similar to those seen during conventional diathermy. Gas bubbles had been found to slightly obscure the surgeons' view.[3]

PEAK's Potential

PEAK cuts as precisely as a scalpel but with little of the tissue damage associated with traditional electrosurgery, said Mark S. Blumenkranz, MD, a cofounder of PEAK Surgical, which is developing the technology, and professor and chairman of ophthalmology at Stanford University. Dr. Palanker agreed. "The pulse structure of PEAK has been shown to provide precision of up to 2 to 4 µm."

Enhanced damage control. Although instruments such as sharpened stainless steel or diamond knives do offer precision with no thermal damage, said Dr. Palanker, they have other inherent deficits that can lead to unpredictable incision depth and bleeding. "You have to apply pressure to any organ you cut," said Dr. Palanker. "It's almost impossible to cut membranes such as the lens capsule with a scalpel just because the tissues are flimsy." A "jumping scalpel" isn't a problem with PEAK, nor is bleeding, which is reduced by up to 70 percent when compared with standard scalpels, he said. Confinement of heat by short plasma-mediated discharges is what distinguishes PEAK from conventional radiofrequency devices, such as the Fugo Blade, said Dr. Blumenkranz.

Ophthalmic Applications

"I think it may have broad applications across many subspecialities, with some more promising than others," said Dr. Blumenkranz. Initial multicenter studies conducted in Germany successfully evaluated its multifunctional use for both vitreoretinal surgery and anterior capsulotomy.[3,4,5]

Cataract surgeries. David F. Chang, MD, is a clinical professor of ophthalmology at the University of California, San Francisco, and is a consultant for PEAK Surgical. He suggested that one advantage of PEAK for cataract surgeons is a precise and reproducible capsulorhexis.

"Anterior segment surgeons would like to have a precise way to cut or trace a capsulorhexis—the single most important step in the cataract operation," said Dr. Chang.

"If the capsulorhexis tears radially, you'll have a complicated case. But it's one step that we still do entirely freehand, sizing according to visual clues." Cataract surgeons still struggle with the capsulorhexis in a significant number of complicated eyes, such as those with small pupils, weak zonules, poor visibility, very shallow chambers or pediatric cases, Dr. Chang said. In cases where the capsulorhexis is made too small, he would like to be able to enlarge it with a cutting probe.

Another benefit of a precise, reproducible capsulorhexis would be with presbyopia-correcting IOLs, for which centration and effective lens position are critical.

"Now the stakes have been raised for getting a perfect anatomic result," said Dr. Chang, who used the example of the Synchrony lens, a dual-optic accommodating IOL that is currently in phase 3 trials. "With this lens, the anterior optic is moving. If the capsulorhexis is too large, the optic will pop through. The Synchrony cannot be implanted unless you have a well-centered capsulorhexis that is smaller in diameter than the front optic."

Vitreoretinal surgeries. PEAK's multifunctionality also might serve retina surgeons well, said Dr. Blumenkranz, offering illumination and aspiration capabilities in addition to cutting and coagulation. "I think PEAK has promise, especially for complex retinal dissections required for diabetic retinopathy," he said, adding that it looks promising for treating complex cases of proliferative vitreoretinopathy or traumatic retinal detachments.

Corneal, glaucoma and oculoplastic surgeries. Because PEAK can cauterize as it cuts, it might be useful for cutting iridocorneal adhesions, as well as for peripheral iridotomies during a secondary implant, said Dr. Chang. Dr. Blumenkranz added that PEAK might also enhance surgery involving the lacrimal drainage system, orbital dissection or other procedures with a premium on precision, hemostasis and the need to work in both wet and dry fields. "It might be helpful for glaucoma filtration surgery, where you can combine precision and dissecting capabilities."

In the meantime, PEAK prototypes continue to be tested. John R. Tighe, president and CEO of PEAK Surgical, expects FDA approval for its general surgery application sometime in the first half of 2008. "Then we will submit applications for specific surgical specialties, such as ophthalmology, cardiology and gynecology," Mr.Tighe said.

Dr. Blumenkranz is a cofounder of PEAK Surgical. Dr. Palanker is a consultant to PEAK Surgical. Dr. Chang is a consultant to PEAK Surgical and to Visiogen.

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3 Priglinger, S. G. et al. *Br J Ophthalmol* 2007;91:949–954.
4 Priglinger, S. G. et al. *Retina* 2005;25(7): 889–896.
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As is often the case with emerging technology, the only experts that *EyeNet* was able to interview about the pulsed electron avalanche knife have interests in it. Readers are encouraged to scrutinize peer-reviewed studies or take note of broader reports as they appear.