Anterior capsulotomy with a pulsed-electron avalanche knife

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PURPOSE: To evaluate a new pulsed-electron avalanche knife design for creating a continuous curvilinear capsulotomy (CCC) and compare the CCC with a mechanical capsulorhexis.

SETTING: Department of Ophthalmology, Stanford University, Stanford, California, USA.

METHODS: In this study, CCCs were created in freshly enucleated bovine eyes and in rabbit eyes in vivo. The cutting velocity was adjusted by controlling the burst repetition rate, voltage amplitude, and burst duration. Tissue samples were fixed and processed for histology and scanning electron microscopy (SEM) immediately after surgery.

RESULTS: The study included 50 bovine eyes and 10 rabbit eyes. By adjusting the electrosurgical waveforms, gas-bubble formation was minimized to permit good surgical visualization. The optimum voltage level was determined to be $\pm$410 V with a burst duration of 20 μs. Burst repetition rate, continuously adjustable from 20 to 200 Hz with footpedal control, allowed the surgeon to vary linear cutting velocity up to 2.0 mm/s. Histology and SEM showed that the pulsed-electron avalanche knife produced sharp-edged capsule cutting without radial nicks or tears.

CONCLUSIONS: The probe of the pulsed-electron avalanche knife duplicated the surgical feel of a 25-gauge cystotome and created a histologically smooth capsule cut. It may improve precision and reproducibility of creating a CCC, as well as improve its proper sizing and centration, especially in the face of surgical risk factors, such as weak zonules or poor visibility.

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The capsulorhexis, or continuous curvilinear capsulotomy (CCC) is one of the most important steps in cataract surgery. A properly sized capsulorhexis enhances surgical safety, hydrodissection, cortical cleanup, and intraocular lens (IOL) centration and inhibits posterior capsule opacification.[1–10] The introduction of newer refractive IOLs has increased the importance of consistently achieving a symmetrically round and properly sized capsulorhexis.

Beginning resident surgeons usually rate the capsulorhexis as the most difficult step in cataract surgery.[11] However, even for experienced surgeons, achieving a properly sized capsulorhexis is more difficult in the presence of common surgical risk factors, including a small pupil, a shallow anterior chamber, weak zonules, pediatric eyes, and poor visibility or a poor red reflex. It is ironic, therefore, that the capsulorhexis is the rare step in cataract surgery that has not been enhanced by technology. The maneuvers are still performed free hand, and the surgeon must rely on visual clues, such as the diameter of the pupil and the cornea. A precise way to cut or trace a capsulorhexis or to safely enlarge a small diameter capsulorhexis after IOL implantation would be beneficial.

A pulsed-electron avalanche knife (PEAK-fc, Carl Zeiss Meditec) was initially designed for vitreoretinal surgery and has been successful in clinical testing.[12,13] The system was developed for "cold" and traction-free dissection of soft tissue.[14,15] We describe a modified system and probe configuration that is optimized for creating CCCs and report the test results and histologic findings in porcine and rabbit eyes.

MATERIALS AND METHODS

This study evaluated the pulsed-electron avalanche knife electrosurgical system (PEAK Surgical, Inc.) for creating

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CCCs and compared them with CCCs created mechanically. As opposed to conventional radiofrequency electrosurgery, in which continuous waveforms are applied for tissue cutting, the pulsed-electron avalanche knife system produces plasma-mediated discharges driven by radiofrequency bursts lasting several tenths of microseconds, and are applied at a repetition rate of 10 to 1000 Hz.[15,16] Because of the short duration of the radiofrequency bursts, heat diffusion into the surrounding tissue is limited to a distance of approximately 10 μm. This restricts thermal damage at the edge of the cut tissue to the cellular scale, in contrast to a much larger damage zone (typically hundreds of micrometers) produced by conventional electrosurgical devices. The duty cycle of the system's waveform, defined as the ratio of the "power on" duration to the total application time, typically does not exceed 1%. These low average power settings significantly reduce heat generation over that generated by conventional continuous radiofrequency instruments; this technology is referred to as cold cutting.

The cutting tip of the system's capsulotomy probe is a protruding tungsten wire with a diameter of 75 μm (Figure 1). The shaft of the probe is identical to that of a 25-gauge needle (0.51 mm in diameter) and curved into a slight arc to accommodate the convexity of the lens capsule. The insulating material at the tip of the probe is transparent to allow visualization of the cutting wire, which extends 250 to 300 μm from the insulator.

The cutting probe was used to create anterior CCCs in freshly enucleated bovine eyes, and after initial optimization, in rabbit eyes in vivo. The corneal incisions were created using a 15-degree keratome (Alcon, Inc.), and the anterior chamber was kept inflated with sodium hyaluronate 1.0% (Provisc).

Regarding the cutting parameters, the pulse repetition rate was adjusted continuously (range 20 to 200 Hz) by the surgeon using a footpedal, the voltage amplitude was adjusted in the range of $\pm$350 to $\pm$450 V, and burst duration was 20 μs, or 40 cycles at a radiofrequency of 2 MHz. The cutting probe was slowly moved along the capsule in a circular manner with a velocity of approximately 1.0 mm/s to avoid tractional forces and minimize pressure on the lens capsule. The cutting velocity was adjusted by controlling the pulse repetition rate with the footpedal.

For light microscopy, specimens were fixed in 10% formaldehyde dehydrated with a graded series of ethanol and embedded in paraffin. Semithin sections (8 μm) were stained with hematoxylin–eosin. For scanning electron microscopy, treated eyes were fixed in 2.5% glutaraldehyde in sodium cacodylate buffer (pH 7.4), postfixed in 1% osmium tetroxide, dehydrated in a series of methanols, and critical point dried. The samples were plasma coated with gold–palladium and evaluated with a scanning electron microscope.

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RESULTS

The study included 50 bovine eyes and 10 rabbit eyes. During initial experimentation with porcine eyes, 2 parameters of the electrosurgical waveforms (voltage and burst repetition rate) were optimized for capsule cutting. After multiple experiments, an optimum voltage level of $\pm$410 V was determined. The optimum range of burst repetition rate was 20 to 200 Hz, with a maximum linear cutting velocity of approximately 2.0 mm/s. To allow surgeon control of the cutting speed, the burst repetition rate was kept adjustable under footpedal control.

Figure 2, *A*, is a video frame showing a CCC nearing completion. Although the gas bubbles seen could not be eliminated, they were minimized by adjusting the electrosurgical waveforms until they no longer impaired the surgeon's visualization. Depending on the cutting rate, capsulotomy completion took approximately 12 to 20 seconds in porcine eyes and up to 25 seconds in rabbit eyes.

Figure 2, *B*, shows the typical histology of a porcine lens after pulsed-electron avalanche knife capsulotomy. The reduced osmolarity of the anterior chamber was likely responsible for the bulging of lens tissue through the capsulotomy. Figure 3 shows a higher magnification histological comparison of anterior porcine capsulotomy edges created by a forceps tear and by a pulsed-electron avalanche knife cut. Both techniques resulted in a sharply cut edge to the capsule. After mechanical capsulorhexis, the capsule was detached from the lens near the edge while after PEAK cutting, it was fully attached to the lens cortex all the way to the edge.

Figure 4 shows scanning electron microscopy (SEM) of the edge of a capsulorhexis that was mechanically torn with a forceps. Figure 5 shows SEM of a pulsed-electron avalanche knife capsulotomy. Both methods produced a sharp edge without radial nicks or tears. The cut face of the mechanically torn capsule edge was smoother on SEM than the edge created by the pulsed-electron avalanche knife because the cutting probe left behind residual microstructures.

DISCUSSION

Creating a proper anterior CCC has many intraoperative and postoperative advantages in cataract surgery.[1–10] A symmetric, properly sized capsulorhexis

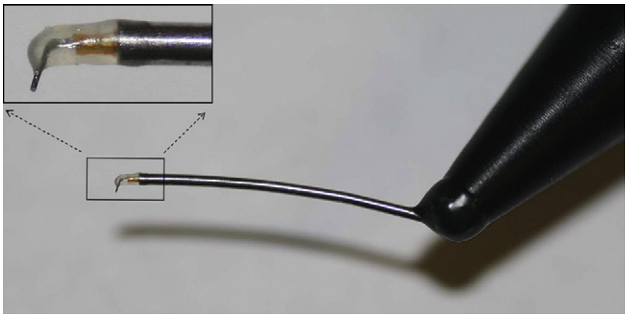

Figure 1. The capsulotomy probe. *Inset*: The cutting wire.

is even more important for implantation of refractive IOLs, such as multifocal and accommodating models, for which excellent optic centration is critical. The effective axial lens position may also vary depending on whether the capsulorhexis completely or incompletely overlaps the optic, thereby affecting accuracy of the IOL power calculation. Due to their different designs, most accommodating IOLs should not be implanted if the capsulorhexis is torn. For example, the Synchrony dual-optic accommodating IOL is a bag-filling lens designed to produce forward movement of the anterior optic during accommodative effort.[17,18] This requires a completely overlapping capsulorhexis to prevent partial prolapse of the anterior optic out of the bag.

Successfully creating a CCC is more difficult under challenging circumstances, such as poor capsule visibility, a small pupil, a shallow anterior chamber, weak zonules, a thickened and fibrotic capsule, or an elastic pediatric anterior capsule. Particularly when it is difficult to control the path of the flap, the ability

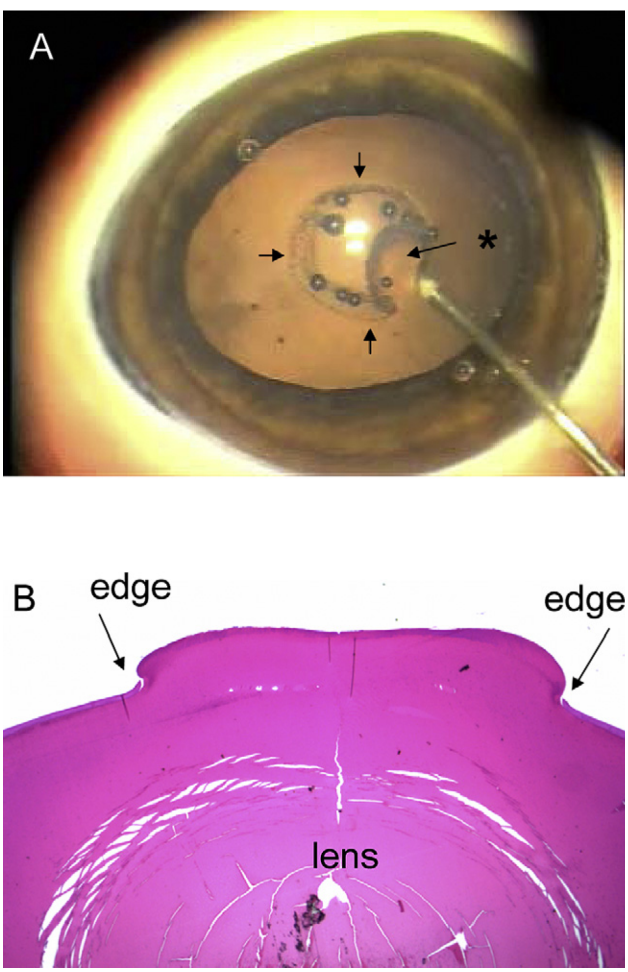

Figure 2. *A*: Video frame showing a nearly completed CCC. The remaining uncut capsule is shown by the asterisk. Tiny residual gas bubbles are seen along the cutting path (*arrows*). This video frame was taken at 15 seconds, and the capsulotomy was completed in 18 seconds. *B*: Typical histology of a porcine lens after a CCC created with the cutting probe.

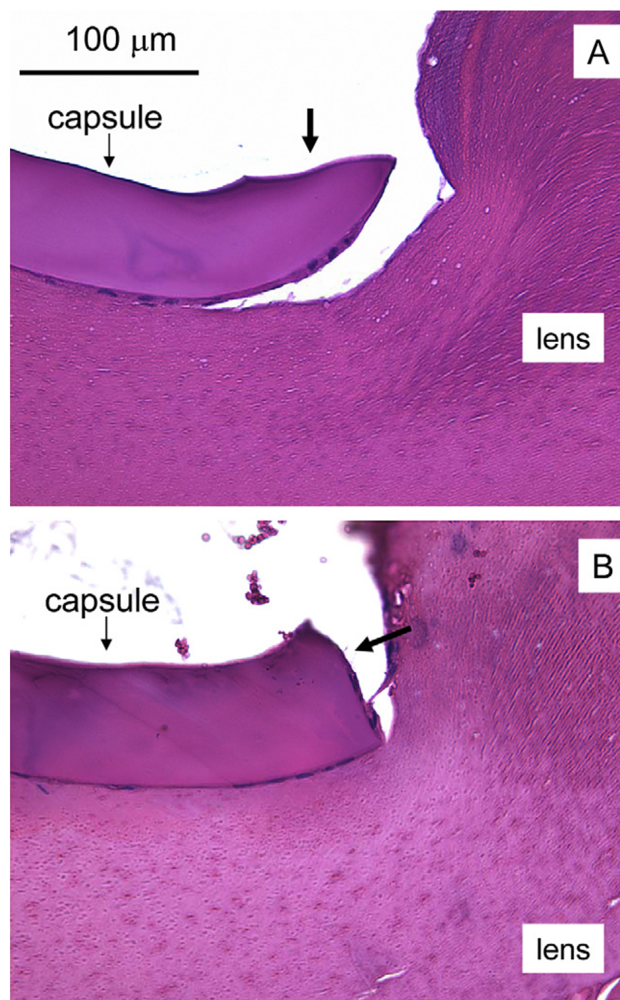

Figure 3. Histologic sections of a porcine capsule after mechanical (*A*) and cutting probe (*B*) CCC creation. The arrows show the surface of the cut edge.

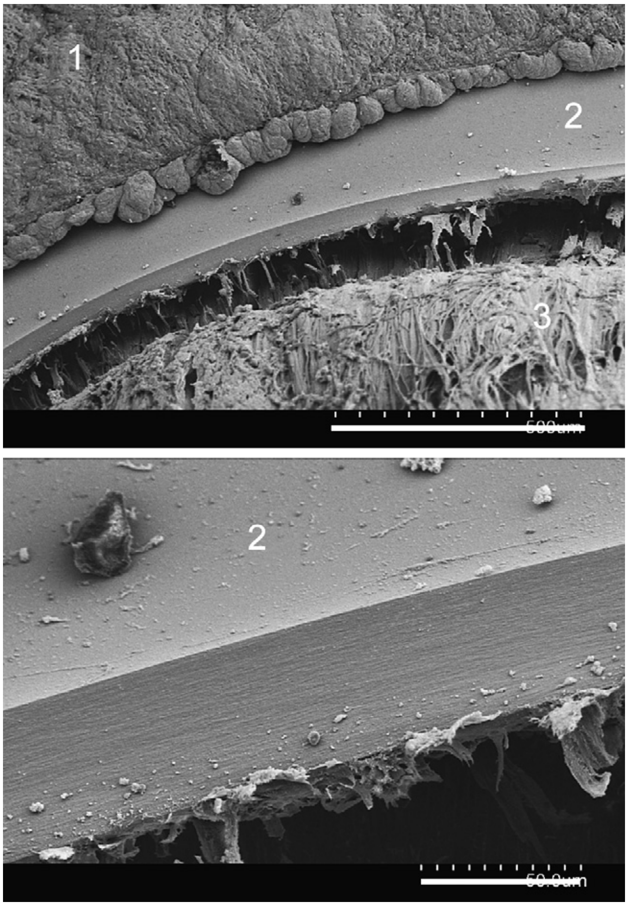

Figure 4. Scanning electron micrographs of the porcine capsule after mechanical capsulorhexis. The scale bar in the upper image is 500 μm and in the lower image, 50 μm (1 = iris; 2 = lens capsule; 3 = lens cortex).

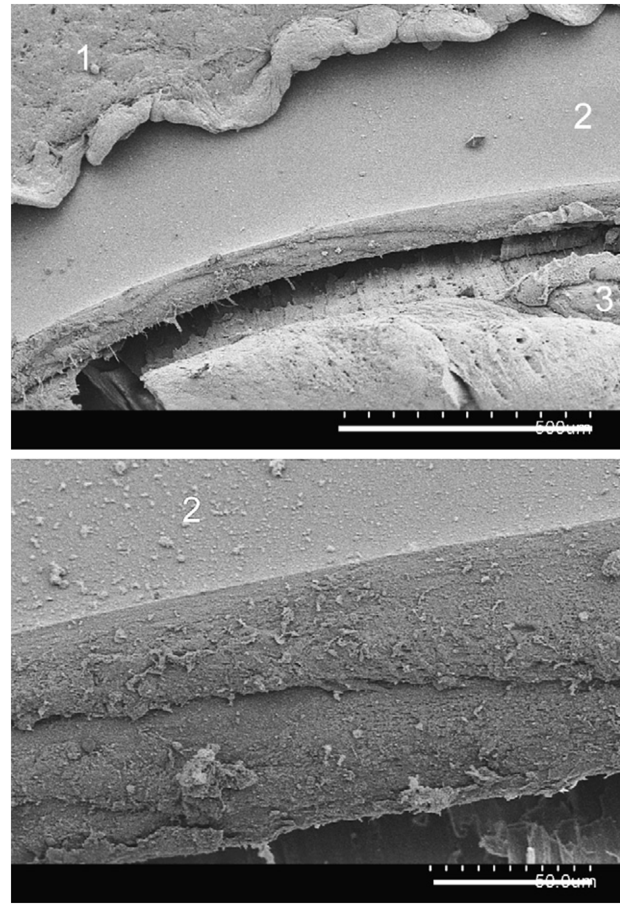

Figure 5. Scanning electron micrographs of the porcine capsule after a CCC created with the probe. Note the very sharp and continuous edges, with some cellular-scale texture on the cut side surface. The scale bar in the upper image is 500 μm and in the lower image, 50 μm (1 = iris; 2 = lens capsule; 3 = lens cortex).

to cut rather than tear the capsular margin would be advantageous. Another challenge is rescuing the errant tear, which is typically due to one of the aforementioned risk factors. Again, the precise control of a cutting probe might allow surgeons to better redirect the path of the tear. Finally, secondarily enlarging a smaller than desired CCC would be advantageous once the IOL has been implanted. A precise and highly maneuverable capsule-cutting instrument would facilitate this step.

Several other methods to allow surgeons to trace or draw a capsulorhexis have been tried.[19–21] The high-frequency capsulotomy[22] has been associated with a higher risk for capsule tears and intraoperative complications than the conventional mechanical CCC.[19,22] Histologic examination of high-frequency capsulotomy cuts show thermal tissue damage that decreases the biomechanical stability of the anterior capsular edge.[19,20,22] The vitrectorhexis, a mechanized anterior capsulotomy technique combined with an IOL implantation in pediatric cataract surgery, was first described in the 1990s.[23] In a retrospective analysis of 208 eyes,[24] the incidence of radial tears was as high as 7.7%. This technique has not been used for adult anterior capsulotomy. The Fugo blade was introduced several years ago for resistance-free incision of the anterior lens capsule.[21,25] The instrument is bulkier and heavier than a conventional cystotome, which creates a substantial surgical learning curve. A higher percentage of radial tears with this method were found in a clinical study comparing different methods of making a CCC.[24] Although it is U.S. Food and Drug Administration approved, surgeons have not adopted the Fugo blade for creating the anterior capsulotomy to a significant degree.

The pulsed-electron avalanche knife system, originally developed for vitreoretinal surgery, was used in a few human eyes to create a capsulotomy for cataract surgery[26,27]; however, the system's retinal probe was not properly configured for creating capsulotomy, and no histological evaluation of the cut capsule edge was performed. In addition, the system's power supply did not have continuous control of the burst repetition rate and the relatively low radio frequency (400 kHz) generated a noticeable amount of gas bubbles.[26,27]

We evaluated a modification of the pulsed-electron avalanche knife system; this new anterior segment system has an optimized probe shape, continuous footpedal control of cutting rate, and a higher radiofrequency (2 MHz) to reduce the amount of gas bubbles. The new probe configuration for anterior capsule cutting incorporates a lighter, more maneuverable handle and an intraocular design that emulates a bent 25-gauge cystotome or capsulotomy needle. This makes the tip easy to insert through a 1.0 mm paracentesis and easy to maneuver in the anterior chamber.

Our study using the new pulsed-electron avalanche knife system showed that it consistently created a histologically smooth continuous capsule edge without evidence of collateral thermal damage or weakening nicks. In addition, the electrosurgical parameters were successfully optimized for cutting without excessive view-impairing bubbles.

In conclusion, the new capsulotomy instrument has the potential to provide cataract surgeons with a more precise and reproducible way to create a CCC. This might improve successful completion of this step in the face of surgical risk factors, such as weak zonules or poor visibility. Finally, better surgical control may improve proper capsulorhexis sizing and centration, the consistent attainment of which will be a prerequisite for the next generation of accommodating and refractive IOLs. The successful application and evaluation of the pulsed-electron avalanche knife capsulotomy in porcine cadaver eyes and in live rabbits, particularly given the difficulty of completing a rabbit anterior capsulorhexis, provides promise for appropriately designed human clinical trials.

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