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Precision Pulse Capsulotomy

Preclinical Safety and Performance of a New Capsulotomy Technology

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Purpose: To assess the preclinical safety and performance of a new precision pulse capsulotomy (PPC) method.

Design: Human cadaver eye studies and surgical, slit-lamp, and histopathologic evaluation in a consecutive series of 20 live rabbits.

Participants: Human cadaver eyes and New Zealand white rabbits.

Methods: Precision pulse capsulotomy uses a highly focused, fast, multipulse, low-energy discharge to produce a perfectly round anterior capsulotomy instantaneously and simultaneously along all 360°. Capsulotomies are performed using a disposable handpiece with a soft collapsible tip and circular nitinol cutting element. Miyake-Apple imaging and scanning electron microscopy (SEM) of PPC were conducted in human cadaver eyes. Surgical, postoperative slit-lamp, and histopathologic assessments of PPC were performed in 20 live rabbits and were compared with manual continuous curvilinear capsulorrhexis (CCC) in the fellow eye. Anterior chamber (AC) thermocouple temperature measurements were evaluated in a subset of rabbit eyes.

Main Outcome Measures: Capsulotomy edge circularity, SEM morphologic features and zonular movement with PPC in human cadaver eyes. Anterior chamber temperature during PPC and grading of ocular inflammation, corneal endothelial damage, anterior capsular opacification (ACO), and posterior capsular opacification (PCO).

Results: Miyake-Apple imaging showed minimal zonular stress, and thermocouple measurements demonstrated negligible AC temperature changes during PPC. Precision pulse capsulotomy produced round, complete capsulotomies in all 20 rabbit eyes, leading to successful in-the-bag intraocular lens (IOL) implantation. Slit-lamp examinations at 3 days and 1, 2, and 4 weeks after surgery showed no significant differences between PPC and CCC in corneal edema, AC inflammatory reaction, capsular fibrosis, ACO, and PCO. Postmortem studies showed no difference in the corneal endothelium between PPC and CCC eyes. All IOLs were well centered in PPC eyes, and histopathologic analysis showed no greater inflammatory infiltrates.

Conclusions: Precision pulse capsulotomy is a new method to automate consistent creation of a perfectly circular anterior capsulotomy with a disposable handheld instrument that can be used in the normal phacoemulsification surgical sequence. Compared with CCC in fellow rabbit eyes, PPC was equally safe and showed no greater zonular stress compared with CCC in human cadaver eyes. Human cadaver eye SEM showed a much smoother capsulotomy edge compared to those produced by femtosecond laser. *Ophthalmology 2016;123:255-264 © 2016 by the American Academy of Ophthalmology.*

Continuous curvilinear capsulotomy (CCC) is one of the most important components of cataract surgery because of the numerous surgical and anatomic advantages it confers. The continuous edge facilitates hydrodissection, cortical aspiration, intraocular lens (IOL) implantation and fixation and renders the capsular bag more resistant to tearing during surgery.[1,2] Circumferential anterior capsular overlap of the optic edge optimizes IOL centration, reduces posterior capsular opacification, decreases unwanted optical edge dysphotopsias, and may enhance predictability of the effective lens position.[3−6] In contrast, radial anterior capsular tears increase the risk of surgical complications, reduce refractive accuracy, and may preclude using certain IOL designs.[7,8]

The ability to automate a perfectly circular capsulotomy of a consistently precise diameter has driven interest in and adoption of femtosecond laser-assisted cataract surgery.[9−12] However, femtosecond laser-assisted cataract surgery necessitates significant capital and per-case costs, alters and slows the normal operative workflow, and cannot be used on every patient because of affordability or regulatory limitations. In addition, there is evidence that a capsulotomy created with the femtosecond laser may not resist tearing as well as the manual capsulorrhexis.[13−15]

We describe a new precision pulse capsulotomy (PPC) technology that is able to create a quick, precise circular capsulotomy using a disposable handheld instrument called the Zepto (Mynosys, Fremont, CA). The PPC Zepto device

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is introduced during surgery in the conventional surgical sequence and potentially can be centered on the visual axis to produce a capsulotomy of a predetermined diameter.

Methods

Description of Precision Pulse Capsulotomy Device

Precision pulse capsulotomy is performed using a disposable handpiece and capsulotomy tip called the Zepto (Fig 1A) that is connected to a control console for operation (Fig 1B). The capsulotomy tip consists of a soft, transparent, silicone suction cup approximately 6 mm in diameter that houses a circular ring element made of the shape memory alloy nitinol. This nitinol ring element has been refined precisely at the micrometer scale to enable consistent and uniform 360° capsulotomies. The superelastic properties of nitinol allow the capsulotomy tip to be deformed mechanically into a narrower elongated shape for entry through a clear corneal incision. The ring can then re-expand automatically to its native circular shape within the anterior chamber (AC). The elongation of the capsulotomy tip is produced by the extension of a push rod, which then is retracted from the tip to allow it to reassume its original circular state.

The PPC handpiece and system were designed through extensive testing in rabbit eyes, porcine eyes, and in human cadaver eyes from donors in the 50- to 90-year age range. The PPC handpiece substitutes for capsulorrhexis forceps and is inserted into the AC after it is filled with an ophthalmic viscosurgical device. Handpiece operation is controlled by buttons on the control console. The PPC methodology in a human cadaver eye is illustrated in Figure 2. Precision pulse capsulotomy is based on a rapid and precisely controlled method of tissue cleavage specifically developed for the efficient cutting of thin collagen membranes such as the human anterior lens capsule. This precision pulse method uses the capsulotomy device's circular, shape memory alloy nitinol ring element to convert a very brief train of fast electrical pulses efficiently over 4 ms (approximately 1 joule) into mechanical cutting energy (Fig 3). The extremely fast millisecond timeframe of PPC limits any heat dissipation beyond the layer of water surrounding the nitinol ring. The resulting cutting effect essentially is a mechanical one, similar to that with a manual tear. Unlike with a manual or femtosecond laser capsulotomy, however, the entire circumference of the PPC capsulotomy is created at the very same instant because of the use of a circular conducting capsulotomy element. The use of suction delivered through the suction cup ensures optimal apposition of the nitinol ring with the lens capsule surface. Small amounts of tilt are compensated for automatically. A circular capsulotomy is created, duplicating the shape of the circular nitinol element.

Human Cadaver Eye Studies

Cadaver eyes were obtained from eye banks in the United States and were used within 72 hours of death for the Miyake-Apple imaging of zonular structures during PPC and for the analysis of PPC capsulotomy edge morphologic features using scanning electron microscopy. Precision pulse capsulotomy was performed after disinserting the iris tissue from cadaver eyes and centering the PPC device at the approximate center of the anterior capsule using the limbus as the circumferential boundary.

Zonular forces during performance of PPC were compared with those with manual CCC using Miyake-Apple imaging in paired human cadaver eyes. The eyes were prepared as previously described[16,17] and placed into an imaging system consisting of a head model, the underside of which contained a 5-megapixel Universal Serial Bus (USB) video camera. The dissected eye preparation was mounted into the modified eye socket of the head model, and video recordings of PPC or manual CCC were made from below to view the zonular structures during the performance of these 2 different capsulotomy methods.

The morphologic features of the anterior capsulotomy edge produced by PPC in human cadaver eyes was examined using scanning electron microscopy. Precision pulse capsulotomy was performed on the anterior capsule after open sky eye preparations. The globes then were transferred into a glass vessel and submerged in 0.9% saline for hydrodissection, phacoemulsification, and cortical aspiration. A rim of capsule encompassing the capsulotomy opening was dissected free and placed in 2.0% glutaraldehyde in 0.1 M phosphate buffer, pH 7.4, overnight at 4° C. The capsule specimens underwent dehydration using a graded ethanol series and were placed in between steel filter discs with the capsulotomy edge exposed. After processing in a critical point dryer, the specimens were gold-palladium sputtered and imaged using an Quanta 3D FEG scanning electron microscope (FEI, Hillsboro, OR) with the beam voltage set at 5 kV.

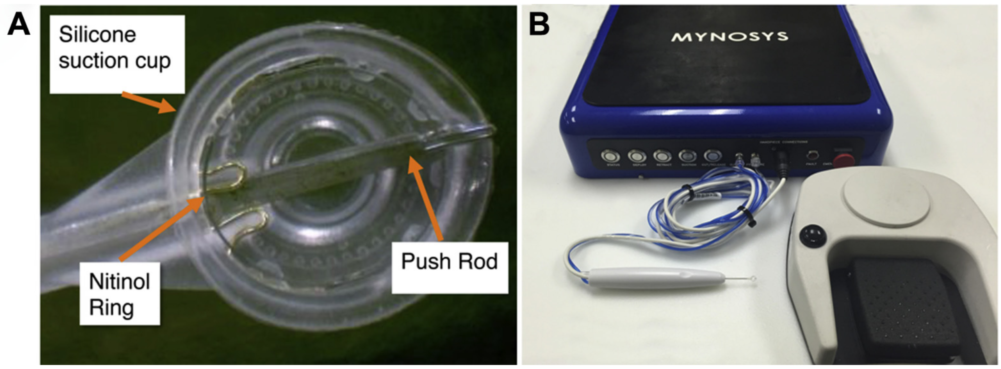

Figure 1. Photographs of the precision pulse capsulotomy (PPC) handpiece capsulotomy tip, handpiece, control console, and foot switch. **A**, View of the PPC capsulotomy tip from below. A circular ring made of the superelastic shape memory alloy nitinol is housed within a soft silicone housing that serves as a suction cup. An extendable and retractable push rod assists in device entry. **B**, View of the PPC handpiece, control console, and foot switch. The foot switch serves as to initiate PPC and also acts as an emergency stop.