ARTICLE

Precision pulse capsulotomy: Initial clinical experience in simple and challenging cataract surgery cases

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Purpose: To evaluate precision pulse capsulotomy (PPC) in simple and challenging cataract surgery cases.

Setting: Clínica Quesada, San Salvador, El Salvador.

Design: Prospective case series.

Methods: This single-center prospective study assessed cataract surgeries with anterior capsulotomy performed using a PPC device through a 2.2 mm corneal incision in the presence of an ophthalmic viscosurgical device. This was followed by phacoemulsification and intraocular lens implantation. Outcomes included capsulotomy appearance and diameter, surgical complications, and postoperative visual acuity.

Results: The study comprised 38 eyes. All cases resulted in 360-degree complete, round capsulotomies averaging 5.5 mm in diameter with intracapsular IOL fixation. No PPC-related complications were observed intraoperatively or on follow-up at 3 to 8 months. The PPC was useful in challenging cases with corneal opacities that obscured the capsulotomy path or with poorly dilated pupils. Precision pulse capsulotomy occurs instantaneously everywhere along the capsulotomy path, which allowed safe release of subcapsular pressure in intumescent cataracts with consistent creation of a round, appropriately sized capsulotomy. The PPC edge quality was shown in a case with 6 clock hours of zonular dialysis in which iris hooks held the capsulotomy edge for over 45 minutes for removal of a 4+ cataract.

Conclusions: Precision pulse capsulotomy had a short learning curve and was integrated seamlessly into the surgical routine. The combination of suction with ultrafast capsulotomy provided capsulotomy roundness, sizing, safety, and edge quality that significantly facilitated difficult cases. The ease of use, consistency, and efficiency of PPC capsulotomy might support its use under many practice scenarios.

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Online Video

Anterior lens capsulotomy is one of the most important steps in cataract phacoemulsification surgery because it significantly affects the success of the rest of the procedure and the patient's visual outcomes. Capsulotomy size, shape, and centration also play a role in the prevention of posterior capsule opacification[1–4] and likely influence intraocular lens (IOL) performance, in particular premium IOLs.[5–8] Capsulotomies can be challenging in eyes with zonular dialysis and other ocular pathologies, and the consistent creation of a dimensionally perfect capsulotomy is the desired goal in routine cases as well as in difficult cases.

Capsulotomy is typically performed using a continuous curvilinear capsulorhexis (CCC) to preserve the capsular bag for intracapsular IOL fixation. Automated capsulotomy creation using a femtosecond laser has been added in recent years as an alternative capsulotomy method.[9,10] Although the femtosecond laser can deliver round and appropriately sized capsulotomies,[11–14] the use of this technology typically requires significant investment in equipment cost, space as well as personnel and adds extra time to the cataract procedure.[15,16] There are also patient contraindications to laser use, such as corneal opacities, small pupils, unfavorable orbital anatomy,[9,17] and increased capsule tear rates as well as other complications have been reported.[18–22]

Recently, an disposable capsulotomy device using precision pulse technology was introduced for automated, quick, and consistent capsulotomy creation during surgery.[23,24] The precision pulse capsulotomy (PPC) device consists of a soft silicone suction cup covering a microfabricated

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superelastic nitinol capsulotomy ring. The device is collapsed for entry through a small corneal incision to unfold within the anterior chamber. Following suction to appose the capsulotomy ring to the capsule, a 4 millisecond electrical waveform is applied to the ring to cause the rapid phase transition of trapped water molecules to create the capsulotomy effect. Preclinical surgical testing, Miyake-Apple imaging, thermocouple measurements, endothelial cell staining and histopathology have shown the device to have excellent ocular safety.[23] Testing using paired human cadaver eyes resulted in a capsulotomy edge tear strength that was 2 to 4 times greater than that produced by the femtosecond laser and CCC.[24] We report on the initial clinical experience of the use of the PPC device in patients having cataract surgery with phacoemulsification. The results from both routine as well as challenging cataract surgery cases are presented.

PATIENTS AND METHODS

This study assessed the use of a PPC device (Zepto, Mynosys Cellular Devices, Inc.) during cataract removal with phacoemulsification performed between February and June 2016. All surgeries were authorized by the El Salvador Supervisory Board of the Medical Profession, the Monitoring Board of the Nursing Profession, and the Republic of El Salvador Board of Public Health. All patients provided informed consent.

This study involved the first clinical use of the newly developed PPC device; therefore, experienced surgeons were involved. One surgeon had performed roughly 8000 cataract surgeries, while the other 2 had performed roughly 20 000 cases each. Cataracts were graded using the Lens Opacities Classification System II (LOCS II) system.[25]

After standard topical anesthesia and dilating eyedrops were administered, a paracentesis was created and the anterior chamber filled with 3.0% hyaluronate (Healon Endocoat). A primary 2.2 mm clear corneal incision was used in all cases. The PPC device was elongated manually by the surgeon extending a slider forward on the PPC handpiece. After ocular stabilization using a Thornton ring, the elongated PPC tip was inserted through the incision into the anterior chamber. The slider was then moved backward by the surgeon to retract the push rod from the PPC tip, allowing the tip to regain its native circular state. After the tip was at the desired capsulotomy location, suction was applied via the PPC control console to evacuate ophthalmic viscosurgical device (OVD) from underneath the PPC suction cup ($\sim$20 μL) and appose the capsulotomy ring against the capsule. A second button on the PPC console was then engaged to provide the 4 milliseconds multipulse capsulotomy waveform to create the capsulotomy. Suction was reversed, and the OVD originally evacuated from the suction cup was reintroduced into the cup to gently float it off the capsule. The collapsible PPC tip was manually withdrawn from the anterior chamber, and the free-floating capsule button was retrieved by the surgeon using a forceps. The surgeon then continued with the remainder of the surgery. Phacoemulsification was performed using the Infiniti system (Alcon Laboratories, Inc.).

Surgeries were videorecorded using an Optronics camera mounted onto a Zeiss surgical microscope. All patients had implantation of a single-piece acrylic IOL (Tecnis ZCB00, Abbott Medical Optics, Inc., or iSert250, Hoya Surgical Optics, Inc.) with postoperative follow-up visits at 1 day, 2 to 6 weeks, and 3 to 8 months.

RESULTS

The study comprised 38 patients aged 49 to 86 years. Twenty-eight were women, and 10 were men (Table 1). The cataract grade on the LOCS II system was 2 in 10 eyes, 3 in 6 eyes, and 4 in 12 eyes. Patients had a variety of comorbidities that presented challenges during surgery. These included significant pterygium that interfered with capsulotomy path visualization CCC (n = 2), poorly dilated pupils of 4.0 mm or smaller (n = 3), grade 4 cataracts with corrected distance visual acuity (CDVA) of 20/200 or less (n = 12), and 6 clock hours of zonular dialysis (n = 1).

Figure 1 and Video 1 (available at http://jcrsjournal.org) show a PPC capsulotomy in a patient having cataract surgery with phacoemulsification. Suction generated by the control console automatically apposed the device's capsulotomy ring to the capsule without the surgeon pressing down on the capsule or twisting the neck of the suction cup. The roof of the suction was optically clear, allowing the surgeon to monitor the application of suction by observing the flow of small air bubbles in the OVD. Cessation of OVD flow indicated completion of suction and that the capsulotomy could then proceed. Suction reversal and retrieval of the PPC device were indicated when a small amount of OVD was observed to escape at the corneal incision after OVD reintroduction through the suction cup to lift the device off the capsule.

In all 38 cases, a complete, 360-degree free-floating capsulotomy was created without complications followed by intracapsular IOL fixation. The anterior chamber depth (ACD) ranged from 2.30 to 3.63 mm. The surgeons maintained their normal surgical routine in all cases and did not alter any of their standard procedures, instruments, or OVD. The use of PPC for anterior capsulotomy did not change any of the subsequent steps of hydrodissection, phacoemulsification, irrigation/aspiration, or IOL placement. No difficulties with hydrodissection were encountered.

In the first 10 patients, trypan blue was used to enhance visualization of the capsule and did not pose problems during capsulotomy creation using the PPC device. The majority of the remaining 28 surgeries were performed without trypan blue staining because the PPC device performs an automated capsulotomy that does not require surgeon visualization and manipulation of the capsule. No differences were observed in the behavior of trypan blue–stained capsules and unstained capsules during PPC or in the completeness of capsulotomy.

Poorly Dilated Pupils

In several cases, the dilated pupil was smaller than the desired size of the capsulotomy and prevented direct visualization of the capsulotomy path. The PPC was performed in these cases using the thin, soft, flared lip of the silicone suction cup to ease sealing of the suction cup onto the capsule. The flared lip was maneuvered under the iris to allow placement of the PPC device through a small pupil (Figure 2) (Video 2, available at http://jcrsjournal.org). First, the anterior lip of the PPC device was slid under the iris (Figure 2, *A* and *B*). This was followed by sliding the posterior lip under the iris (Figure 2, *C* and *D*), accompanied by a gentle sideways sweeping motion. The manipulations essentially caused the PPC

Table 1. Patient data and surgical outcomes.

Pt	Age (Y)	Sex	Eye	Cataract Grade	ACD (mm)	Capsulotomy	Intracapsular IOL Fixation	CDVA	
								Preop	Postop
1	86	F	RR	2	2.84	Complete	Yes	20/50	20/30
2	74	F	R	2	2.88	Complete	Yes	20/70	20/50
3	64	F	L	4	2.54	Complete	Yes	20/400	20/30
4	81	F	R	2	2.61	Complete	Yes	20/100	20/100
5	68	F	R	4	2.93	Complete	Yes	20/400	20/20
6	73	F	L	3	2.97	Complete	Yes	20/200	20/20
7	75	F	R	3	3.09	Complete	Yes	20/100	20/30
8	86	F	L	4	3.02	Complete	Yes	20/400	20/70
9	74	M	R	3	2.38	Complete	Yes	20/100	20/25
10	49	F	R	4	3.14	Complete	Yes	20/400	20/40
11	58	F	R	4	3.54	Complete	Yes	20/800	20/40
12	71	M	L	3	3.29	Complete	Yes	20/50	20/25
13	73	F	R	3	2.87	Complete	Yes	20/50	20/20
14	75	F	L	4	3.21	Complete	Yes	20/200	20/30
15	57	F	R	2	3.57	Complete	Yes	20/40	20/30
16	58	F	L	4	3.47	Complete	Yes	20/400	20/25
17	68	F	L	2	2.65	Complete	Yes	20/40	20/25
18	78	M	R	3	3.03	Complete	Yes	20/60	20/30
19	76	M	R	2	2.46	Complete	Yes	20/70	20/30
20	69	F	L	2	3.14	Complete	Yes	20/40	20/25
21	57	M	R	3	2.68	Complete	Yes	20/200	20/20
22	60	M	L	2	3.07	Complete	Yes	20/30	20/20
23	80	M	L	3	3.29	Complete	Yes	20/40	20/70
24	76	M	L	3	3.28	Complete	Yes	20/60	20/50
25	83	F	R	4	2.77	Complete	Yes	20/200	20/80
26	66	F	L	4	3.18	Complete	Yes	20/200	20/40
27	57	F	L	4	3.06	Complete	Yes	LP	20/200
28	62	F	L	3	3.23	Complete	yes	20/70	20/25
29	68	F	R	2	3.10	Complete	Yes	20/70	20/25
30	62	F	L	4	3.47	Complete	Yes	20/400	20/60
31	58	M	R	3	3.13	Complete	Yes	20/100	20/20
32	60	F	R	3	3.29	Complete	Yes	20/80	20/25
33	57	F	L	3	3.14	Complete	Yes	20/800	20/20
34	80	F	L	3	2.58	Complete	Yes	20/100	20/40
35	76	M	R	3	2.97	Complete	Yes	20/60	20/50
36	57	F	L	2	3.53	Complete	Yes	20/40	20/25
37	69	F	R	2	3.43	Complete	Yes	20/30	20/30
38	62	F	L	4	3.63	Complete	Yes	20/800	20/400

ACD = anterior chamber depth; CDVA = corrected distance visual acuity; IOL = intraocular lens; LP = light perception; Pt = patient

device to expand the pupil (Figure 2, *E*) for creation of a capsulotomy of approximately 5.5 mm. Successful phacoemulsification with intracapsular IOL fixation was achieved in each case. No other pupil expansion device was necessary.

Intumescent Cataract

Figure 3 and Video 3 (available at http://jcrsjournal.org) show an example of lens capsulotomy using the PPC device on an intumescent cataract. In this case, the capsule was pressurized and taut with underlying milky white material, presenting the setup for development of radial tear extension and an Argentinian flag sign. The chamber was also shallow, as is typical with an intumescent cataract. After a 2.2 mm main incision was created, the PPC device was inserted into the anterior chamber and placed through the pupil, which was smaller than the outer diameter of the PPC device. Suction was applied via the PPC device; this was followed by delivery of the capsulotomy waveform. The instantaneous completion of a round capsulotomy caused the white intumescent cataract to immediately become brown as the white milky material was removed by the suction. There was no capsule tear, and the PPC capsulotomy was round and strong. The surgeon proceeded safely with phacoemulsification with a secure capsulotomy.

Pressure Relief and Fluid Aspiration in Intumescent Cataract

The PPC provided instant relief of pressure in intumescent cataracts, and immediate aspiration of fluid from beneath the capsule was seen in a frame-by-frame analysis of the video captured at 30 frames per second during PPC. The application of suction caused the roof of the PPC silicone

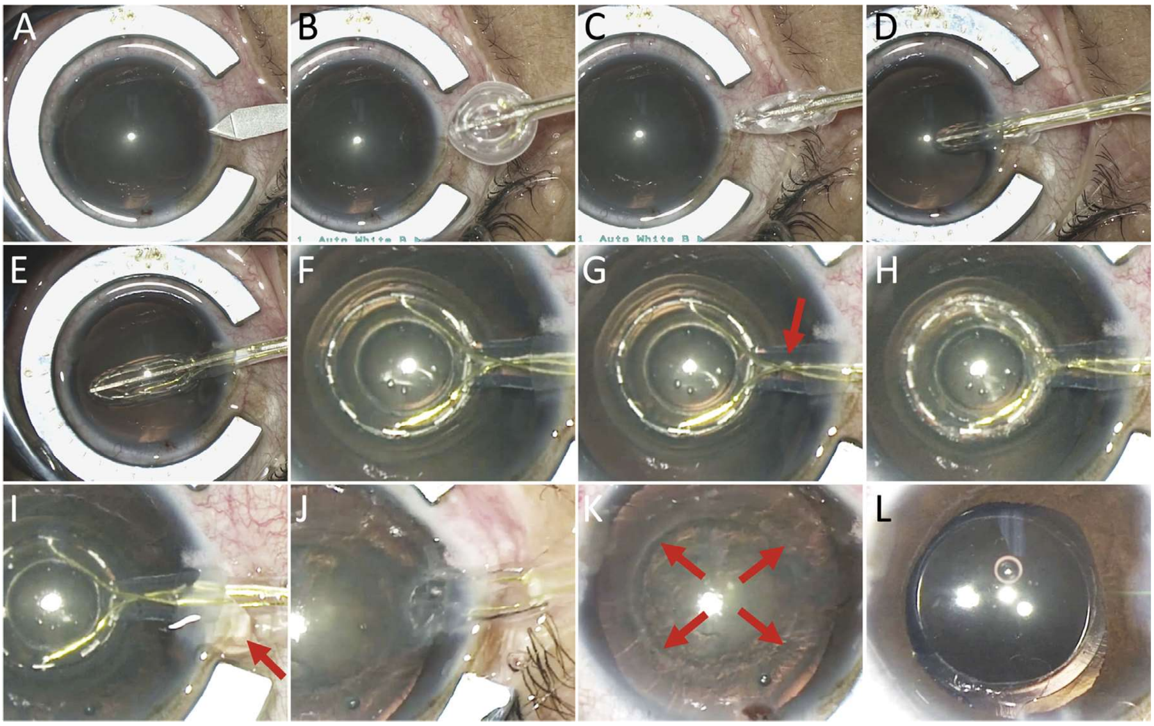

Figure 1. Precision pulse capsulotomy in a patient having cataract surgery with phacoemulsification. This is the surgeon's first use of the PPC device (Video 1, available at http://jcrsjournal.org). *A*: A 2.2 mm corneal incision is made. *B*: The precision pulse handpiece is removed from its sterile packaging. The capsulotomy tip is in its ready position before extension. *C*: The surgeon pushes a finger slider forward on the handpiece to elongate the capsulotomy tip, causing it to be compressed in its lateral dimension. *D*: The elongated capsulotomy tip is eased through the corneal incision into the anterior chamber. *E* and *F*: Once the tip is fully within the anterior chamber, the push rod is retracted to allow the capsulotomy tip to regain its native uncompressed circular state. *G*: An assistant is instructed to press the suction button on the PPC control console. As suction is delivered to the capsulotomy suction cup, small air bubbles in the OVD move (*arrow*) as the OVD is temporarily evacuated out of the suction cup into the stem. *H*: The assistant is then instructed to press the cut/release button on the PPC control console. The capsulotomy is performed in 4 milliseconds followed by automatic reversal of the suction. *I*: As the OVD is reintroduced into the anterior chamber to release and lift the suction cup off the capsule and lens, some OVD escapes through the corneal incision (*arrow*). This is a sign the suction cup is fully lifted off the lens. *J*: The capsulotomy tip is withdrawn from the anterior chamber. The free-floating capsulotomy button is retrieved from the anterior chamber using a forceps. *K*: Complete circular PPC (*arrows*) before phacoemulsification and IOL implantation. *L*: Intracapsular IOL fixation after PPC.

suction cup to indent downward into direct contact with the capsule, thereby providing a "window" to view the relief of pressure and fluid aspiration during PPC. The 4-millisecond capsulotomy was observed as a small reflex in the PPC tip. Within 33 milliseconds (1 frame) after the capsulotomy and while the suction remained on, the white milky fluid under the capsule was aspirated out and the central viewing window assumed a paler color. More fluid continued to be aspirated at 66 milliseconds; 99 milliseconds after the capsulotomy, all fluid had been removed, leaving the remaining lens material visible.

Zonular Dialysis

Anterior capsulotomy was successfully performed using PPC in a case with approximately 6 clock hours of zonular dialysis nasally resulting from trauma (Figure 4) (Video 4, available at http://jcrsjournal.org) and with 4+ nuclear sclerosis and 3+ cortical changes. After the PPC device was inserted into the anterior chamber, the surgeon first used the device to recenter the lens. After selecting the appropriate location for the capsulotomy, suction was delivered through the PPC device to stabilize the lens in the absence of zonular fiber countertraction. The PPC suction and capsulotomy action placed no apparent stress on the peripheral capsule and resulted in the creation of a round 5.5 mm capsulotomy that was well centered on the capsular bag. Capsule hooks and capsule tension rings were not available; therefore, 2 iris hooks were used to retract and hold the capsular bag in place during phacoemulsification and the remaining steps of the procedure (Figure 4, *E* to *I*). The nucleus and cortex were removed with care over 45 minutes with the iris hooks in place against the capsulotomy edge. The capsular bag remained intact and in position throughout lens removal while restrained by the iris hooks. The IOL was secured and centered in the bag by suturing 1 haptic to the sclera through the capsule fornix. This was performed without difficulty and without tears radiating from the suture passes. Two months after surgery, the IOL remained in the capsule. The patient had uncorrected distance visual acuity of 20/70 with very little corneal edema. The patient had CDVA of approximately 20/30.

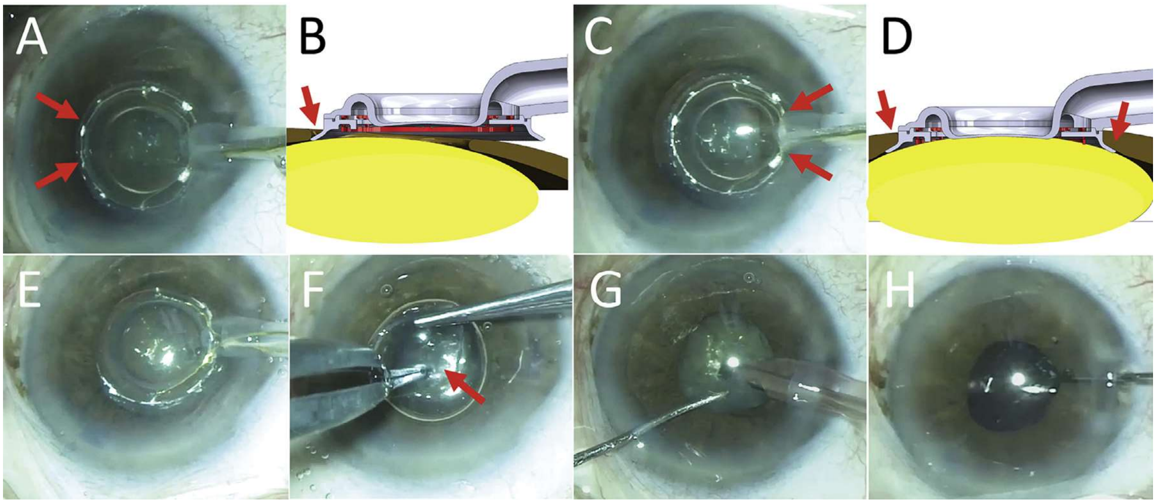

Figure 2. Precision pulse capsulotomy performed in a case with a pupil smaller than the intended capsulotomy size (Video 2, available at http://jcrsjournal.org). *A*: The flared lip at the suction cup's distal portion is first slipped under the iris tissue (*red arrows*). *B*: Schematic showing the PPC device in cross-section as the distal lip of the PPC suction cup (*red arrow*) is slid under the iris (depicted as *brown structure*). *C*: While the distal lip is maintained under the iris tissue, the lip at the suction cup's proximal portion is slipped under the iris (*red arrows*). *D*: Schematic showing the PPC device in cross-section as the proximal lip of the PPC suction cup (*red arrow*) is slid under the iris. *E*: With similar sideways sweeping motions, the suction cup lip is completely inserted under the iris, expanding the pupil for capsulotomy. *F*: The free-floating capsule button (*arrow*) is retrieved and confirmed. *G*: Phacoemulsification is performed after PPC device removal. *H*: Adjustment of IOL position in the capsular bag.

Follow-up at 8 Months

The appearance of the capsule was examined in 30 patients using slitlamp microscopy at intervals from 3 to 8 months after surgery. Several patients received sequential assessment of the capsulotomy edge 2, 3, and 8 months after surgery. No capsule contraction was observed in any patient at any timepoint. Figure 5 shows representative photographs of the appearance of the PPC capsulotomy edge 3 to 8 months after surgery.

DISCUSSION

This study reports on the first clinical experience of PPC in patients having cataract surgery with phacoemulsification. The Zepto PPC device was easy to use and integrated seamlessly into cataract surgery with phacoemulsification. Instead of a capsulorhexis forceps, the surgeon used the PPC device with no change in OVD use or hydrodissection technique. The capsulotomies produced were consistently round, averaged 5.5 mm in diameter,

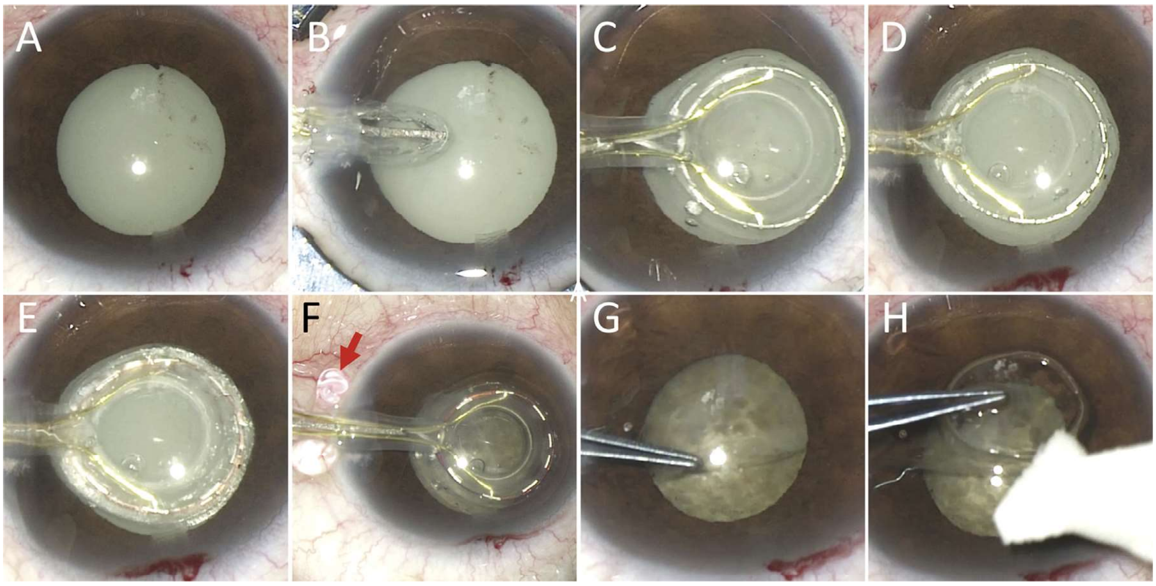

Figure 3. Precision pulse capsulotomy in a patient with an intumescent cataract and poor pupil dilation (Video 3, available at http://jcrsjournal.org). *A*: Appearance of eye at the beginning of surgery. *B*: Compressed elongated capsulotomy tip entering the anterior chamber. *C*: The distal portion of the suction cup lip is first slid under the iris. *D*: With additional sliding action in the other quadrants of the suction cup, the entire circumference of the suction cup lip is slid under the iris, expanding the pupil. *E*: Following suction, the capsulotomy is performed. *F*: Suction is reversed, the OVD is pushed out of the corneal incision (*arrow*), and the capsulotomy tip is withdrawn from the anterior chamber. *G*: The capsulotomy button is retrieved using a forceps. *H*: Unfolded capsulotomy button.

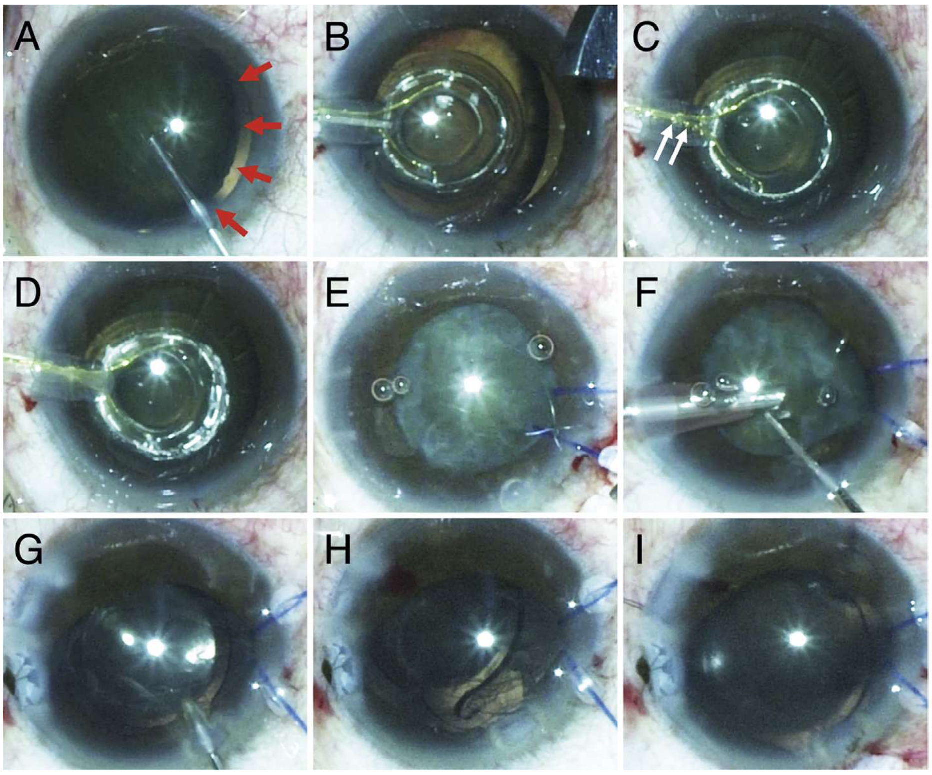

Figure 4. Precision pulse capsulotomy in an eye with 4+ cataract and zonular dialysis (Video 4, available at http://jcrsjournal.org). *A*: Intraoperative photograph shows approximately 6 clock hours of zonular dialysis (*red arrows*). *B*: Precision pulse capsulotomy device is introduced and used to reposition the lens. *C*: Once the lens is repositioned and the desired central capsulotomy position identified, suction is applied to appose the device. Completion of suction is verified by cessation of movement of small air bubbles within the OVD in the suction cup and the device neck (*white arrows*). *D*: Precision pulse capsulotomy is performed. *E*: Capsulotomy device is removed, and 2 iris hooks are used to secure the capsulotomy edge and hold the capsular bag for phacoemulsification. *F*: Phacoemulsification. *G*: A 1-piece is IOL implanted. *H* and *I*: The IOL is secured by suturing it to the sclera.

and could be positioned for centration on the pupil or anywhere on the capsular bag. All 38 PPC capsulotomies were complete 360 degrees circumferentially with free-floating capsule buttons. The capsulotomy edges were clean with no evidence of tissue burning or cauterization. There was typically uniform symmetrical capsulotomy edge overlap with the IOL optic. No collateral thermal changes were present in the underlying cortex. No complications related to PPC capsulotomy were noted intraoperatively, and no capsule contraction was observed in the 30 patients who had a follow-up examination 3 to 8 months after surgery.

The surgical experience from this initial set of patients tested several functional aspects of the PPC device. First, during entry and exit through the corneal incision, the soft silicone suction cup folded onto itself and enveloped the capsulotomy element to prevent contact with corneal tissue, increasing safety and effectiveness. In the fully expanded circular configuration within the anterior chamber, the suction cup provided a soft shield and insulation for the capsulotomy element. Even when fully expanded, the PPC device is small and can fit within some pupil expansion devices on the market. No cases of corneal touch were observed. Although corneal endothelial cell counts were not obtained in this study, a previous study[23] found the PPC device use did not cause significant thermal changes in the anterior chamber of rabbits, which have a smaller ACD than humans. This previous study also showed no difference in the endothelial cell condition or morphology between eyes having a PPC and those having a manual CCC.

The application of suction firmly apposed the capsulotomy element against the capsule and in doing so stabilized the lens during capsulotomy, and it did not exert centripetal traction on zonular fibers. The lens was stabilized against the PPC device; thus, there was no need to exert downward pressure on the lens, which can cause zonular stress. This was shown in the case in which 6 clock hours of zonular fibers were missing. In this case, the PPC method resulted in a well-centered, undistorted, and completely round capsulotomy (Figure 4). This clinical experience was also consistent with previously reported Miyake-Apple imaging of zonular fibers in paired cadaver eyes, which showed a stable lens with no traction on zonular fibers during PPC.[23] In addition to absent zonular effects, the use of suction provided automation and consistency in every case, preventing the variability that can potentially occur if manual downward pressure is applied to the lens, especially in eyes that differ significantly in anatomy.

In cases with poorly dilated pupils, the flared lip of the suction cup, which was originally designed to facilitate sealing of the suction cup onto the capsule, was effective in positioning the PPC device through a small pupil under the iris, thereby acting as a pupil expander and a capsulotomy device. This was shown for pupils that were approximately 4.0 mm in size, the smallest pupils in our series. The use of the PPC device in these cases was safe because the silicone material forming the suction cup is soft and insulates against heat. A previous study[23] found only a slight temperature change (1 to 2 degrees) immediately adjacent to the suction cup during capsulotomy. A similar device

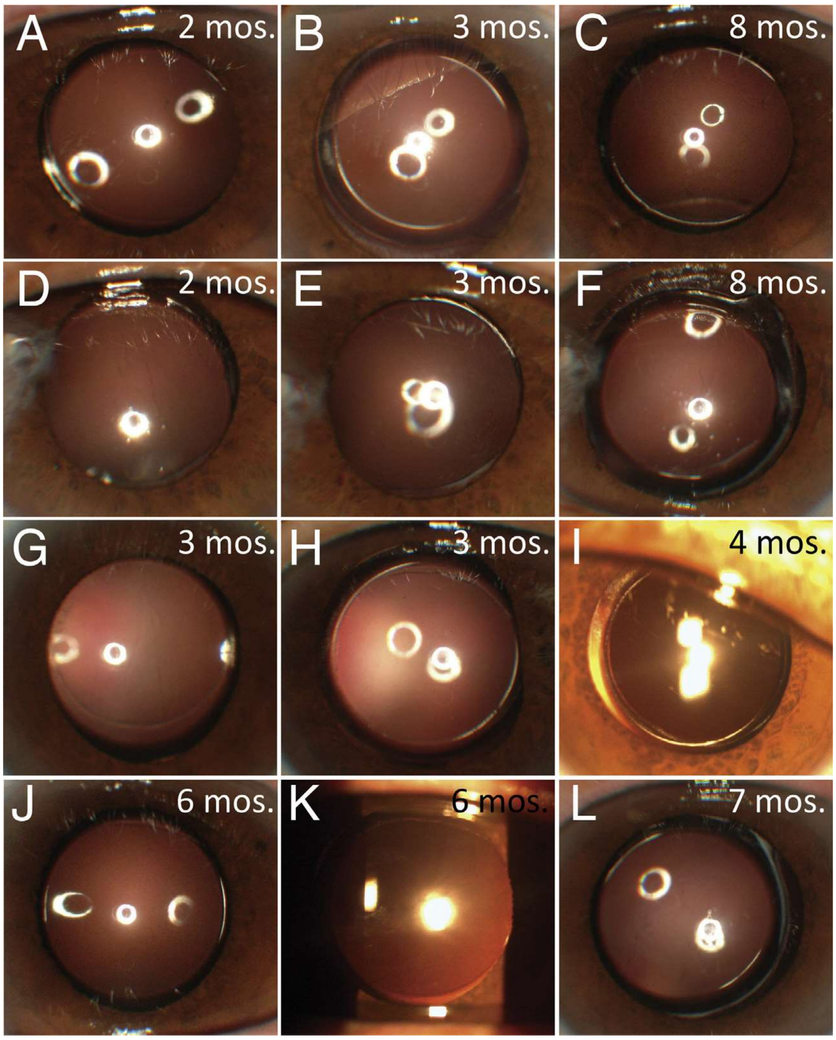

Figure 5. Appearance of PPC edge 3 to 8 months after capsulotomy. *A* to *C*: The same patient examined at 2, 3, and 8 months. *D* to *F*: A second patient examined at 2, 3, and 8 months. *G*: The PPC 3 months after surgery. *H*: Three months after surgery. *I*: Four month after surgery. *J*: Six months after surgery. *K*: Six months after surgery. *L*: Seven months after surgery.

without a silicone suction cup would be unsuitable for use in eyes with a small pupil.

Intraoperatively, the roof of the suction cup was optically transparent, giving the surgeon clear visualization of the application of suction and the capsulotomy and allowing patients to fixate on a specific light on the surgical microscope. This opens the possibility of using simple patient fixation that is coaxial with surgeon viewing on the Chang and Waring[26] axis to intraoperatively determine a patient's functional visual axis. Placement of the center of the PPC device on the appropriate Purkinje image would allow centration of a PPC capsulotomy on the patient's visual axis. Although visual axis centration was not used in the cases presented in the current study, visual centration of the capsulotomy might be beneficial to the performance of advanced-technology IOLs.

A second important feature of the PPC device is the instantaneous creation of a 360-degrees capsulotomy with a 4-millisecond pulse train. The capsulotomy principle is based on a new water phase transition method[23,24] and is not based on radiofrequency cutting, burning, or cauterization, which are known to create a relatively weak and less extensible capsulotomy edge.[27–30] This quick capsulotomy technique occurs for 360 degrees simultaneously, safely relieving the pressure in intumescent cataracts. The PPC capsulotomy at 4 milliseconds requires 1/100 of the 400 milliseconds required for a human eye blink.[31,32] Unlike the femtosecond laser, which must be programmed to cut into the cortex to ensure the capsule is cut, PPC is limited to the capsule, and no cortical difficulties were encountered during hydrodissection and cortical removal.

In summary, our initial surgical experience showed that the PPC device provided consistent precise capsulotomies during lens phacoemulsification surgery. Its design can be useful in challenging cases, such as in those involving poorly dilated pupils, intumescent cataracts, and zonulopathy. Patients with these and other comorbidities can account for as many as 22% of patients having cataract surgery.[33–37] Although not shown here, the potential to place a capsulotomy on the visual axis might also be an advantage of the PPC in cataract surgery. Last, given its ease of use and consistency in providing a secure capsulotomy, the PPC device might provide automated efficiency in capsulotomy creation in many practice scenarios.

WHAT WAS KNOWN

- Previous studies of PPC in rabbits found consistent creation of round capsulotomies with no differences in the endothelial cell condition, ocular recovery, capsule response, inflammation, or histopathology compared with contralateral eyes in which a CCC was created.
- Miyake-Apple imaging shows the PPC exerts minimal stress on zonular structures.
- The PPC capsulotomy edge tear strength is 2 to 4 times greater than that produced by the femtosecond laser and CCC in paired human cadaver eyes.

WHAT THIS PAPER ADDS

- Initial experience in 38 patients showed that PPC enabled consistent automated creation of round, complete, and free-floating capsulotomies.
- The PPC device was useful in challenging cases in which it was slipped under poorly dilated pupils to perform capsulotomy. It enabled instantaneous capsulotomies to relieve pressure in intumescent cataracts and stabilize the lens and provided a secure capsulotomy edge for the management of zonular dialysis.

REFERENCES

1. Smith SR, Daynes T, Hinckley M, Wallin TR, Olson RJ. The effect of lens edge design versus anterior capsule overlap on posterior capsule opacification. Am J Ophthalmol 2004; 138:521–526
2. Dewey S. Posterior capsule opacification. Curr Opin Ophthalmol 2006; 17:45–53
3. Awasthi N, Guo S, Wagner BJ. Posterior capsular opacification; a problem reduced but not yet eradicated. Arch Ophthalmol 2009; 127:555–562. Available at: http://archopht.jamanetwork.com/article.aspx?articleid=422987. Accessed March 21, 2017
4. Kramer GD, Werner L, Mamalis N. Prevention of postoperative capsular bag opacification using intraocular lenses and endocapsular devices maintaining an open or expanded capsular bag. J Cataract Refract Surg 2016; 42:469–484
5. Liu JW, Haw WW. Optimizing outcomes of multifocal intraocular lenses. Curr Opin Ophthalmol 2014; 25:44–48
6. Woodward MA, Randleman JB, Stulting RD. Dissatisfaction after multifocal intraocular lens implantation. J Cataract Refract Surg 2009; 35:992–997
7. de Vries NE, Webers CAB, Touwslager WRH, Bauer NJC, de Brabander J, Berendschot TT, Nuijts RMMA. Dissatisfaction after implantation of multifocal intraocular lenses. J Cataract Refract Surg 2011; 37:859–865
8. Braga-Mele R, Chang D, Dewey S, Foster G, Henderson BA, Hill W, Hoffman R, Little B, Mamalis N, Oetting T, Serafano D, Talley-Rostov A, Vasavada A, Yoo S, for the ASCRS Cataract Clinical Committee. Multifocal intraocular lenses: Relative indications and contraindications for implantation. J Cataract Refract Surg 2014; 40:313–322. Available at: http://ascrs.org/sites/default/files/resources/Multifocal%20IOLs_0.pdf. Accessed March 21, 2017
9. Nagy ZZ, McAlinden C. Femtosecond laser cataract surgery. Eye Vis 2015; 2:11. Available at: https://www.scienceopen.com/document_file/693f4f1a-b12a-42ab-af74-695babdc89c9/PubMedCentral/693f4f1a-b12a-42ab-af74-695babdc89c9.pdf. Accessed March 21, 2017
10. Grewal DS, Schultz T, Basti S, Dick HB. Femtosecond laser–assisted cataract surgery—current status and future directions. Surv Ophthalmol 2016; 61:103–131
11. Friedman NJ, Palanker DV, Schuele G, Andersen D, Marcellino G, Seibel BS, Batlle J, Feliz R, Talamo JH, Blumenkranz MS, Culbertson WW. Femtosecond laser capsulotomy. J Cataract Refract Surg 2011; 37:1189–1198; erratum, 1742
12. Naranjo-Tackman R. How a femtosecond laser increases safety and precision in cataract surgery? Curr Opin Ophthalmol 2011; 22:53–57
13. Mastropasqua L, Toto L, Mattei PA, Vecchiarino L, Mastropasqua A, Navarra R, Di Nicola M, Nubile M. Optical coherence tomography and 3-dimensional confocal structured imaging system–guided femtosecond laser capsulotomy versus manual continuous curvilinear capsulorhexis. J Cataract Refract Surg 2014; 40:2035–2043
14. Reddy KP, Kandulla J, Auffarth GU. Effectiveness and safety of femtosecond laser–assisted lens fragmentation and anterior capsulotomy versus the manual technique in cataract surgery. J Cataract Refract Surg 2013; 39:1297–1306
15. Bartlett JD, Miller KM. The economics of femtosecond laser-assisted cataract surgery. Curr Opin Ophthalmol 2016; 27:76–81
16. Abell RG, Vote BJ. Cost-effectiveness of femtosecond laser-assisted cataract surgery versus phacoemulsification cataract surgery. Ophthalmology 2014; 121:10–16
17. Donaldson KE, Braga-Mele R, Cabot F, Davidson R, Dhaliwal DK, Hamilton R, Jackson M, Patterson L, Stonecipher K, Yoo SH, for the ASCRS Refractive Cataract Surgery Subcommittee. Femtosecond laser–assisted cataract surgery. J Cataract Refract Surg 2013; 39:1753–1763. Available at: http://www.ascrs.org/sites/default/files/resources/Femtosecond%20Cataract%20Surgery%20Review_0.pdf. Accessed March 21, 2017
18. Abell RG, Darian-Smith E, Kan JB, Allen PL, Ewe SYP, Vote BJ. Femtosecond laser–assisted cataract surgery versus standard phacoemulsification cataract surgery: outcomes and safety in more than 4000 cases at a single center. J Cataract Refract Surg 2015; 41:47–52
19. Abell RG, Davies PEJ, Phelan D, Goemann K, McPherson ZE, Vote BJ. Anterior capsulotomy integrity after femtosecond laser-assisted cataract surgery. Ophthalmology 2014; 121:17–24
20. Chang JSM, Chen IN, Chan W-M, Ng JCM, Chan VKC, Law AKP. Initial evaluation of a femtosecond laser system in cataract surgery. J Cataract Refract Surg 2014; 40:29–36
21. Ewe SYP, Oakley CL, Abell RG, Allen PL, Vote BJ. Cystoid macular edema after femtosecond laser–assisted versus phacoemulsification cataract surgery. J Cataract Refract Surg 2015; 41:2373–2378
22. Yu Y, Hua H, Wu M, Yu Y, Yu W, Lai K, Yao K. Evaluation of dry eye after femtosecond laser–assisted cataract surgery. J Cataract Refract Surg 2015; 41:2614–2623
23. Precision pulse capsulotomy; preclinical safety and performance of a new capsulotomy device. Ophthalmology 2016; 123:255–264
24. Thompson VM, Berdahl JP, Solano JM, Chang DF. Comparison of manual, femtosecond laser, and precision pulse capsulotomy edge tear strength in paired Human Cadaver Eyes. Ophthalmology 2016; 123:265–274
25. Chylack LT Jr, Leske MC, McCarthy D, Khu P, Kashiwagi T, Sperduto R. Lens Opacities Classification System II (LOCS II). Arch Ophthalmol 1989; 107:991–997
26. Chang DH, Waring GO IV. The subject-fixated coaxially sighted corneal light reflex: a clinical marker for centration of refractive treatments and devices. Am J Ophthalmol 2014; 158:863–874
27. Morgan JE, Ellingham RB, Young RD, Trmal GJ. The mechanical properties of the human lens capsule following capsulorhexis or radiofrequency diathermy capsulotomy. Arch Ophthalmol 1996; 114:1110–1115
28. Wilson ME Jr. Anterior lens capsule management in pediatric cataract surgery. Trans Am Ophthalmol Soc 2004; 102:391–422. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1280111/pdf/tao102pg391.pdf. Accessed March 21, 2017
29. Trivedi RH, Wilson ME Jr, Bartholomew LR. Extensibility and scanning electron microscopy evaluation of 5 pediatric anterior capsulotomy techniques in a porcine model. J Cataract Refract Surg 2006; 32:1206–1213
30. Luck J, Brahma AK, Noble BA. A comparative study of the elastic properties of continuous tear curvilinear capsulorhexis versus capsulorhexis produced by radiofrequency endodiathermy. Br J Ophthalmol 1994; 78:392–396. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC504795/pdf/brjopthal00029-0068.pdf. Accessed March 21, 2017
31. Kwon K-A, Shipley RJ, Edirisinghe M, Ezra DG, Rose G, Best SM, Cameron RE. High-speed camera characterization of voluntary eye blinking kinematics. J R Soc Interface 2013; 10:20130227. Available at: http://rsif.royalsocietypublishing.org/content/royinterface/10/85/20130227.full.pdf. Accessed March 21, 2017
32. Mak FHW, Harker A, Kwon K-A, Edirisinghe M, Rose GE, Murta F, Ezra DG. Analysis of blink dynamics in patients with blepharoptosis. J R Soc Interface 2016; 13:20150932. Available at: http://rsif.royalsocietypublishing.org/content/royinterface/13/116/20150932.full.pdf. Accessed March 21, 2017
33. Artzén D, Lundtröm M, Behndig A, Stenevi U, Lydahl E, Montan P. Capsule complication during cataract surgery: case-control study of preoperative

and intraoperative risk factors; Swedish Capsule Rupture Study Group report 2. J Cataract Refract Surg 2009; 35:1688–1693

34. Jaycock P, Johnston RL, Taylor H, Adams M, Tole DM, Galloway P, Canning C, Sparrow JM, and the UK EPR User Group. The Cataract National Dataset electronic multicentre audit of 55 567 operations: updating benchmark standards of care in the United Kingdom and internationally. Eye 2009; 23:38–49. Available at: http://www.nature.com/eye/journal/v23/n1/pdf/6703015a.pdf. Accessed March 1, 2017
35. Muhtaseb M, Kalhoro A, Ionides A. A system for preoperative stratification of cataract patients according to risk of intraoperative complications: a prospective analysis of 1441 cases. Br J Ophthalmol 2004; 88:1242–1246. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1772833/pdf/bjo08901143.pdf. Accessed March 21, 2017
36. Zare M, Javadi M-A, Einollahi B, Baradaran-Rafii A-R, Feizi S, Kiavash V. Risk factors for posterior capsule rupture and vitreous loss during phacoemulsification. J Ophthalmic Vis Res 2009; 4:208–212. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3498858/pdf/JOVR-04-208.pdf. Accessed March 21, 2017
37. Chang DF, Campbell JR. Intraoperative floppy iris syndrome associated with tamsulosin. J Cataract Refract Surg 2005; 31:664–673

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