Comparison of postoperative axial stability of intraocular lens and capsulotomy parameters between precision pulse capsulotomy and continuous curvilinear capsulotomy

A prospective cohort study

Seung Pil Bang, MD, Jong Hwa Jun, MD, PhD

Abstract

Objectives: The aim of this study was to verify the safety and stability of precision pulse capsulotomy (PPC) by comparison of the axial stability of the intraocular lens (IOL) and the capsulotomy parameters during 6 months of follow-up after cataract surgery using PPC or the conventional method (continuous curvilinear capsulorhexis, CCC).

Design: Prospective observational study.

Setting: Tertiary referral center.

Subjects: Fifty nine eyes of 59 candidates for cataract surgery.

Interventions: PPC (33 eyes) or CCC (26 eyes).

Outcome measures: The anterior capsule opacification grade and effective lens position (ELP) were measured 1 week and 1, 3, and 6 months postoperatively.

Results: No significant difference in the mean anterior capsule opacification grade or the effective lens position was found between the PPC and CCC groups at any time point; however, the standard deviation and root mean square of the effective lens position were significantly lower in the PPC group than in the CCC group during follow-up (P = 0.002 and P = 0.011, respectively). There was a significantly lower discrepancy between the intended vs achieved capsulotomy area and better circularity in the PPC group than in the CCC group at all time points.

Conclusions: The overall variability in effective lens position was less when cataract surgery was performed using PPC than when performed using CCC. Circularity was better and had a more predictable size with PPC than with CCC.

Abbreviations: ACO = anterior capsule opacification, BCVA = best corrected visual acuity, CCC = continuous curvilinear capsulorhexis, CMT = central macular thickness, ELP = effective lens position, FLACS = femtosecond laser-assisted cataract surgery, IOL = intraocular lens, OVD = ophthalmic viscosurgical device, PPC = precision pulse capsulotomy, RMS = root mean square, SD = standard deviation, SE = spherical equivalent.

Keywords: continuous curvilinear capsulorhexis, effective lens position, intraocular lens, precision pulse capsulotomy.

1. Introduction

In addition to precise ocular biometry and appropriate intraocular lens (IOL) power calculation, accurate determination of the position of the IOL postoperatively is integral to optimal postoperative refractive outcomes. The postoperative axial position of the IOL, widely defined as the effective lens position (ELP), is affected by various parameters, especially the capsulotomy features. A small capsulorhexis can lead to...
development of excessive anterior capsular fibrosis associated with residual lens epithelial cells, leading to an anteroposterior axial shift or decentration of the IOL with the passage of time because of asymmetric contraction of the capsular bag. In contrast, IOL tilting, decentration, and posterior capsule opacification are more common with an excessively large capsulorhexis.

Continuous curvilinear capsulorhexis (CCC) is the technique most widely used for anterior capsulotomy in standard cataract surgery using phacoemulsification. Nevertheless, the shape, size, and centration of the CCC vary widely according to the type of cataract and the skill of the surgeon. The advent of femtosecond laser-assisted cataract surgery (FLACS) has led to high reproducibility and predictability of anterior capsulotomy with a more accurate shape and size than achieved with conventional CCC. A uniform anterior capsulotomy that completely overlies the IOL optic area contributes to precise positioning of the IOL during the early postoperative period and to long-term symmetric capsular fibrosis. However, FLACS incurs substantial per-case costs, slows and interrupts the routine operative workflow, and cannot be available to every patient for affordability reasons.

Recently, a new precision pulse capsulotomy (PPC) device with a disposable handheld apparatus (Zepto; Mynosys, Fremont, CA, USA) that produces rapid and precise uniform capsulotomy has been introduced. Several experimental and clinical studies have demonstrated the ability of this thermal capsulotomy device to generate complete, consistent, and reproducible symmetric capsulotomies as well as its safety. Given the possibility of anterior capsular contraction induced by thermal delivery using this device, we hypothesized that PPC may have the potential to cause anterior capsule fibrosis or phimosis, which can cause postoperative IOL tilting or axial movement. The aims of this study were to

1. to determine the safety and stability of PPC by comparing the axial movements of the IOL and associated refractive changes during 6 months of follow-up after cataract surgery performed using PPC or CCC and

2. the variability in capsulotomy features, including circularity and capsulotomy size using these 2 techniques.

2. Methods

2.1. Patients

Fifty nine patients (59 eyes) who were scheduled for cataract surgery were enrolled in this prospective cohort study between May and October 2018. The research was performed in the Ophthalmology Department at Dongsan Medical Center, which is affiliated with the Keimyung University in Daegu, Republic of Korea. The study protocol was approved by the Ethics Committee of Dongsan Medical Center (Keimyung University Dongsan Medical Center Institutional Review Board, approval number DSMC 2018–07–007) and conducted in accordance with the tenets of the Declaration of Helsinki. Before the surgery, the concept of PPC and CCC was explained to the patient. PPC was then performed if the patient agreed to pay the additional cost for PPC. Informed consent was obtained from all patients.

The inclusion criteria were age-related cataract, good general health, and uneventful in-the-bag IOL implantation in the operated eye. To avoid double-organ bias, only 1 eye was enrolled from each patient. The exclusion criteria were as follows:

- a history of intraocular surgery or corneal laser surgery, history of ocular trauma or uveitis, poor pupil dilation, pseudoxfoliation syndrome, axial length <22.0 mm or >24.5 mm, zonular weakening or tension ring insertion, radial tear of the anterior capsule, brunescent or mature cataract, and anterior subcapsular opacity.

2.2. Surgical procedure

Patients underwent the necessary laboratory tests and a physical examination. IOL power was determined to obtain postoperative refraction between ±0.25 and ±0.25 diopter (D) using optical low-coherence reflectometry (Lenstar LS900, Haag-Streit AG, Bern, Switzerland). Preoperative best corrected visual acuity (BCVA) was measured and converted to the logMAR scale. Anterior chamber depth, axial length, and lens thickness were measured with the Lenstar preoperatively. Approximately half an hour before surgery, 0.5% tropicamide + 0.5% phenylephrine combination eye drops (Tropherine, Hanmi Pharm, Seoul, Korea) were instilled twice in 5 minutes in each eye to maximize pupil dilation. All surgeries were performed with a 2.85 mm co-axial incision (Infini vision system, Alcon Laboratories, Fort Worth, TX, USA) by the same surgeon (JHJ). After topical anaesthesia induced with 0.5% proparacaine eye drops (Paracaine, Hanmi Pharm), a clear corneal incision was made at 9 o’clock in the right eye and 2 o’clock in the left eye. The anterior chamber was filled with DisCoVisc (a 1:1 mixture of 4% sodium chondroitin sulfate + 1.65% sodium hyaluronate, Alcon Laboratories).

In the PPC group, the nitinol cutting component was introduced into the anterior chamber via a 2.85-mm incision and located on the center of the anterior capsule via alignment of the circular nitinol ring with the corneal capsulotomy marker. Next, an assistant activated suction to promote fixation of the nitinol ring on the capsule by negative pressure. When sufficient suction was achieved, recognized by a decrease in detectable movement of minute air bubbles via the tubing, electrical energy was released along the ring. The assistant then released the suction, and the tip of the device was withdrawn from the eye. In the CCC group, a 5.5 mm-diameter centered CCC was performed with capsulorhexis forceps after marking of the capsulotomy. The intended CCC size was determined on the basis of a previous report indicating that the average PPC capsulotomy diameter was 5.5 mm. To achieve a uniform CCC size, we used a 6-mm diameter capsulorhexis marker (K3–7850, Katena, Denville, NJ, USA) to achieve a 5.5-mm diameter rhexis. Meticulous hydrodissection was then performed to rotate the nucleus smoothly, and phaco-chop nucleofractis was then performed for emulsification and removal of the nucleus. In all cases, after removal of the remaining cortical material, insertion of the hydrophilic 1-piece IOL (AcrySof IQ SN60WF, Alcon Laboratories), and removal of the ophthalmic viscosurgical device, the corneal incision was hydrated. All patients were treated with 0.5% moxifloxacin eyelids (Vigamox, Alcon Laboratories) and 1% prednisolone acetate ophthalmic suspension (Pred Forte, Allergan, Irvine, CA, USA), which were instilled every 2 hours after surgery for 3 days, and then tapered to 4 times a day for a further 3 weeks.

2.3. Postoperative examinations

Anterior capsule opacification (ACO) was assessed using the scale devised by Werner et al (grade 0, clear (transparent) anterior capsule; grade I, opacification localized at the edge of the
capsulotomy; grade II, moderate, diffuse opacification, sometimes with areas of capsule folding; grade III, intense opacification with areas of capsule folding; grade IV, constriction (phimosis) of the capsulotomy opening (capsulotomy diameter \( \leq 3.5\) mm/capsulotomy area \( \leq 9.62\) mm\(^2\)). To augment precision, the ACO was evaluated in 4 quadrants (superior, inferior, nasal, and temporal). The ACO grade recorded was the average value for the 4 quadrants. Anterior chamber cells and flare were also graded clinically using the Standardization of Uveitis Nomenclature classification.\(^{21}\)

The ELP was determined as the interval from the anterior surface of the cornea to the anterior surface of the IOL on the optical axis. The ELP was assessed using the Galilei G4 dual-Scheimpflug Analyzer (Ziemer, Port, Switzerland) at 1 week and 1, 3, and 6 months after surgery. Cross-sectional scans were acquired from each patient, and scans with the optimum quality in terms of perceptibility of the anterior segment were selected to evaluate the ELP using the anterior segment dual-line scan mode. The ELP was measured using embedded image software that includes a ruler. All scans were taken, and all data were measured by a single examiner (SPB) from the best of a series of 3 images. The images were blinded for patient information and randomized prior to analysis. Central corneal thickness was measured with the dual-Scheimpflug Analyzer.

Comparison of the mean ELP was considered inappropriate because forward and backward movements could only be partly neutralized; therefore, we compared the mean standard deviation (SD) for the 4 ELP values, calculated at 6 months after surgery, between the 2 groups. Furthermore, on the basis of our previous report,\(^{17}\) the root mean square (RMS) of the change in ELP at each follow-up visit (ELP\(_{RMS}\)) was also calculated for each group at 6 months after surgery.

The preoperative BCVA and postoperative uncorrected visual acuity were recorded in logMAR units, and autorefractometry (RK-F2, Canon Inc., Tokyo, Japan) was performed at each visit. To demonstrate the discrepancy between the refraction calculated preoperatively by the Lenstar and that achieved postoperatively at each time point, we calculated the postoperative refraction error as the achieved postoperative spherical equivalent (SE) minus the preoperatively calculated SE (SE = sphere + cylinder/2). The intraocular pressure was measured using a non-contact tonometer (NT-530P, Nidek, Tokyo, Japan).

The central corneal endothelial cell density was measured with a specular microscope (SP-9000, Konan Medical, Nishinomiya, Hyogo, Japan) at baseline before surgery and at each postoperative time point.

The central macular thickness (CMT), defined as the mean thickness from Bruch membrane to the inner retinal border within the central 1-mm circle of the ETDRS grid, was measured using swept-source optical coherence tomography (DRI OCT Triton, software version 10.0, Topcon, Tokyo, Japan). For each participant, 2 replicate scans were acquired for measurement of CMT and the average of the 2 values was recorded.

Capsulorhexis/capsulotomy assessments were performed using retroillumination photographs obtained with maximum pupil dilation at each time point. The images were blinded for patient information and randomized prior to analysis. All digital images were imported and analyzed using ImageJ (http://imagej.nih.gov/ij/; National Institutes of Health, Bethesda, MD, USA).\(^{22}\) The software was used to measure the PPC capsulotomy or CCC size after the capsulotomy. The edge visible over or outside the anterior IOL surface was manually drawn with seed points using the Polygon Selection Tool (Fig. 1). Circularity was determined using a function built-in into the software; the area of the capsulotomy or capsulorhexis was also measured using this function. Given that the value of this area is arbitrary, we calculated the absolute value of the area by obtaining an arbitrary value for the IOL optic area, the absolute value of which was already known.

### 2.4. Statistical analysis

Quantitative variables are summarized as the mean and standard deviation and the qualitative variables as the frequency and percentage. Data normality was assessed using the Kolmogorov-Smirnov test. The quantitative variables were compared between the groups using the Student \( t \) test for unpaired data and qualitative variables using the Mann–Whitney \( U \) test. Linear mixed-effects models for repeated measurements were used to analyze the effect of surgery on continuous outcome variables (ELP, refractive parameters, circularity, and capsulorhexis area). Models were used to regress measures with patients as a random sample.
Table 1  
Preoperative patient demographic and ophthalmic data.  

| Variable                 | PPC (n = 33) | CCC (n = 26) | P valuea  |
|--------------------------|-------------|--------------|-----------|
| Sex (M/F)                | 18/15       | 10/16        | .445b     |
| Age (years)              | 67.79 ± 12.34 | 69.69 ± 10.59 | .534     |
| Laxatority (OD/OS)       | 15/18       | 14/12        | .59c      |
| Best corrected visual acuity (logMAR) | 0.65 ± 0.22 | 0.62 ± 0.29 | .708      |
| Spherical equivalent (D) | -0.95 ± 3.40 | -1.33 ± 2.46 | .695      |
| Intracocular pressure (mm Hg) | 14.49 ± 3.52 | 15.79 ± 3.97 | .195     |
| Central corneal thickness (µm) | 544 ± 36 | 545 ± 29 | .922     |
| Anterior chamber depth (mm) | 3.20 ± 0.56 | 3.30 ± 0.59 | .664      |
| Axial length (mm)        | 23.16 ± 0.76 | 23.16 ± 0.75 | .904      |
| Lens thickness (mm)      | 4.30 ± 0.52 | 4.27 ± 0.50 | .876      |
| Central macular thickness (µm) | 232 ± 47 | 211 ± 32 | .103     |
| Intraocular lens power (D) | 20.93 ± 2.21 | 21.69 ± 2.42 | .331    |
| Predicted refraction (D) | 0.08 ± 0.12 | 0.09 ± 0.15 | .924      |

a Probability that the effect of procedure on the addressed variable was in.
b Probability that the effect of surgery on the addressed variable was in.
c Probability that the effect of time was greater in 1 group (interaction group × time).

Table 2  
Postoperative effective lens position.  

| Group     | Mean ELP (mm) ± SD | P valuea  |
|-----------|--------------------|-----------|
|           | 1 week             | 1 month   | 3 months | 6 months | Mean SD (mm) | Mean ELP_{PACS} (mm) |
| PPC       | 4.09 ± 0.13        | 4.10 ± 0.12 | 4.10 ± 0.13 | 4.10 ± 0.15 | 0.057 ± 0.034 | 0.060 ± 0.030 |
| CCC       | 4.09 ± 0.15        | 4.14 ± 0.16 | 4.12 ± 0.14 | 4.09 ± 0.24 | 0.118 ± 0.091 | 0.119 ± 0.081 |
| P valuea  | .968               | .354      | .561      | .870      | .002         | .001       |

a Independent t-test.

Table 3  
Outcome variables in the 2 study groups during follow-up.  

| Variable                | 1 week | 1 month | 3 months | 6 months | P valuea  |
|-------------------------|--------|---------|----------|----------|-----------|
| ELP (mm)                | 4.09 ± 0.13 | 4.09 ± 0.15 | 4.10 ± 0.12 | 4.14 ± 0.16 | 4.10 ± 0.13 | 4.12 ± 0.14 | 4.10 ± 0.15 | 4.09 ± 0.24 | .011 | .706 | .071 |
| SE (D)                  | 0.26 ± 0.71 | 0.08 ± 0.73 | 0.10 ± 0.52 | 0.29 ± 0.84 | 0.05 ± 0.56 | 0.30 ± 0.78 | 0.08 ± 0.47 | 0.17 ± 0.46 | .007 | .991 | .007 |
| Circularity             | 0.99 ± 0.01 | 0.98 ± 0.02 | 0.99 ± 0.01 | 0.98 ± 0.02 | 0.99 ± 0.01 | 0.98 ± 0.01 | 0.99 ± 0.01 | 0.97 ± 0.01 | .726 | <.001 | .873 |
| Cap area (mm²)          | 19.92 ± 0.44 | 20.59 ± 0.57 | 19.85 ± 0.41 | 20.13 ± 2.54 | 19.51 ± 0.62 | 18.87 ± 2.05 | 19.54 ± 0.53 | 18.22 ± 2.28 | <.001 | .770 | .001 |

a Probability that the effect of procedure on the addressed variable was in.
b Probability that the effect of surgery on the addressed variable was in.
c Probability that the effect of time was greater in 1 group (interaction group × time).

The values are presented as the mean ± standard deviation. CCC = continuous curvilinear capsulorhexis, PPC = precision pulse capsulotomy.
Comparison of postoperative safety parameters between the study groups.

| Parameter                              | PPC (n = 33) | CCC (n = 26) | P value* |
|----------------------------------------|--------------|--------------|---------|
| Anterior capsule fibrosis (grade)      |              |              |         |
| 1 week                                 | 0.67 ± 0.47  | 0.65 ± 0.49  | .862    |
| 1 month                                | 1.73 ± 0.76  | 1.58 ± 0.67  | .483    |
| 3 months                               | 1.68 ± 0.82  | 1.73 ± 0.61  | .671    |
| 6 months                               | 1.86 ± 0.69  | 1.13 ± 0.85  | .153    |
| Anterior chamber cells (grade)         |              |              |         |
| 1 week                                 | 0.29 ± 0.38  | 0.14 ± 0.33  | .184    |
| 1 month                                | 0.04 ± 0.13  | 0             | .161    |
| 3 months                               | 0             | 0             | N/A     |
| 6 months                               | 0             | 0             | N/A     |
| Anterior chamber flare (grade)         |              |              |         |
| 1 week                                 | 0.15 ± 0.35  | 0.13 ± 0.34  | .852    |
| 1 month                                | 0.02 ± 0.10  | 0             | .412    |
| 3 months                               | 0             | 0             | N/A     |
| 6 months                               | 0             | 0             | N/A     |
| Uncorrected visual acuity (logMAR)     |              |              |         |
| 1 week                                 | 0.20 ± 0.16  | 0.20 ± 0.35  | .995    |
| 1 month                                | 0.19 ± 0.20  | 0.18 ± 0.31  | .977    |
| 3 months                               | 0.18 ± 0.17  | 0.15 ± 0.11  | .539    |
| 6 months                               | 0.15 ± 0.11  | 0.14 ± 0.13  | .889    |
| Corneal endothelial cell density        |              |              |         |
| (cells/mm²)                            |              |              |         |
| 1 week                                 | 2350 ± 692   | 2483 ± 344   | .432    |
| 1 month                                | 2354 ± 389   | 2344 ± 424   | .930    |
| 3 months                               | 2378 ± 407   | 2254 ± 444   | .303    |
| 6 months                               | 2345 ± 524   | 2382 ± 425   | .647    |
| Central corneal thickness (µm)         |              |              |         |
| 1 week                                 | 581 ± 56     | 591 ± 52     | .554    |
| 1 month                                | 570 ± 52     | 560 ± 34     | .499    |
| 3 months                               | 541 ± 34     | 553 ± 38     | .413    |
| 6 months                               | 537 ± 46     | 559 ± 42     | .595    |
| Central macular thickness (µm)         |              |              |         |
| 1 week                                 | 242 ± 36     | 216 ± 36     | .554    |
| 1 month                                | 252 ± 46     | 226 ± 33     | .449    |
| 3 months                               | 234 ± 29     | 222 ± 47     | .413    |
| 6 months                               | 231 ± 20     | 216 ± 28     | .595    |

*Independent t-test.
The values are presented as the mean ± standard deviation. CCC = continuous curvilinear capsulotomy, PPC = precision pulse capsulotomy.

Table 4 compares the results for the safety parameters, including ACO, between the PPC and CCC groups. Evaluation of these parameters did not identify any safety concerns in either study group at any time point.

4. Discussion
To the best of our knowledge, this is the first study to evaluate axial movements of the IOL for 6 months after PPC and conventional CCC, to assess the impact of capsulotomy characteristics on these movements, and to evaluate the prediction error for both techniques. In this study, the ELP showed a greater change in terms of mean SD and ELP RMS in the CCC group than in the PPC group during postoperative follow-up. The mean circularity was significantly better in the PPC group than in the CCC group at all time points. The SD of the capsulotomy area produced by PPC was significantly lower than the area of the capsulotomy obtained manually at all time points. The capsulotomy area showed a tendency to decrease with time in both groups.

Given that the same model of IOL (SN60WF) was implanted in both groups and that there was no statistically significant between-group difference in ACO, age, preoperative BCVA, SE, intraocular pressure, central corneal thickness, anterior chamber depth, axial length, lens thickness, CMT, IOL power, or predicted refraction, we believe that the reason for the axial changes in the IOL was related to the different features of the capsulotomies/capsulorhexes. A greater deviation between the achieved area and the intended area was detected in the CCC group than in the PPC group. The divergent rhexis size in the CCC group was the result of human error in estimating the measurement of rhexis diameter by the surgeon when performing CCC. In the PPC group, the capsulotomy size was determined by the diameter of the nitinol ring, consistent with a variance of up to 10 µm, thereby minimizing the prediction error.

It is known that the forward IOL shift occurring during the first days postoperatively is caused by the decay of haptic compression force against the capsule contraction. This phenomenon is exacerbated for a period of time because of capsule fibrosis and shrinkage. It is possible to hypothesize that a smaller rhexis counteracts the greater resistance of the haptic compression force and that this phenomenon could increase for a period of time as a result of both fibrosis of the capsule and the natural decay of haptic compression force, whereas a larger rhexis could exert weaker resistance to haptic compression force. While the mean rhexis size in the CCC group was greater at postoperative week 1, the mean rhexis size achieved by CCC was significantly smaller than that achieved by PPC over time, indicating more rapid shrinkage of the capsule. This might result in a marked forward shift of the IOL between 1 month and 6 months postoperatively.

In our study, the mean postoperative refraction error showed a myopic shift in the CCC group from 1 to 6 months after surgery, which could be related in part to the greater anterior-posterior shift of the IOL in the CCC group than in the PPC group. Nevertheless, there was no significant difference in the postoperative refraction error between the 2 techniques at any time point. Further investigation in larger samples is required to understand whether PPC can improve the refractive outcome of cataract surgery.

Several studies have examined the positioning of the IOL after cataract surgery and the related refractive results, focusing on factors determining axial changes in the IOL. One study reported a reduction in anterior chamber depth measured by a Scheimpflug camera and an associated myopic shift in eyes implanted with 3-piece angled IOLs when compared with a single-piece flat haptic (Acrysof) IOL during 12 months of follow-up.[4] Another study analyzed axial movements of the IOL and predicted the refractive error of 3 IOL models during 6 months of follow-
The investigators observed smaller axial movement of the non-angulated C-loop longer overall length IOL (Acrysof IQ SN60WF IOL) than of the other 2 angulated plate haptic shorter overall length IOLs, emphasizing the concept that a shorter angulated haptic cannot fully support the capsular bag during the postoperative period. Other studies have also reported that single-piece flat haptic (Acrysof) IOLs are more stable and show better refraction than 3-piece IOLs. Our results are in good agreement with these earlier clinical studies.

Previous studies of PPC in cadaveric and rabbit eyes have found the device to be as safe as conventional phacoemulsification cataract surgery with improved capsulotomy tear strength when compared with that of FLACS capsulotomy and CCC. In a previous small case series of 38 selected eyes, all eyes had successful free-floating capsulotomies with no complications. In our study, extensive testing of postoperative safety parameters did not raise important safety signals, and our findings are comparable with those previously reported for FLACS and conventional phacoemulsification cataract surgery. We also achieved 100% success in delivering free-floating capsulotomies without any anterior radial tear. As suggested in a previous study, we avoided using a dispersive ophthalmic visscousal device (OVD) but utilized a DisCoVisc, which has an intermediate cohesive/dispersive index. Given the relatively higher viscosity and electroconductivity of the OVD and our safety results, we believe that the DisCoVisc may be a good choice of OVD.

Our study showed that the overall variability of ELP was lower with PPC capsulotomy than with conventional CCC for a period of time with superior circularity and more consistent capsulotomy size. Given the low affordability of FLACS in view of high of time with superior circularity and more consistent capsulotomy size. Given the low affordability of FLACS in view of high cost, PPC may be an appropriate alternative to FLACS for obtaining symmetricity of capsulotomy and axial stability of the IOL without risks of anterior capsule fibrosis or phimosis.

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