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Comparison of clinical outcomes between cystotome-assisted prechop phacoemulsification surgery and conventional phacoemulsification surgery for hard nucleus cataracts
A CONSORT-compliant article

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Abstract

Background: This study aimed to investigate the safety and efficacy of the cystotome-assisted prechop phacoemulsification surgery (CAPPS) and conventional phacoemulsification surgery (CPS) in patients with IV degree nucleus cataract.

Methods: The prospective, randomized, consecutive, comparative cohort study consecutively recruited Chinese age-related cataract patients, CAPPS and CPS were performed by a seasoned surgeon. Postoperative follow-up was at 1 day, 1 week, 1 month, 3 months, 6 months, and 1 year, and the outcome measures comprised ultrasound power, effective phacoemulsification time (EPT), corrected distance visual acuity (CDVA), endothelial cell density (ECD), corneal endothelium loss rate (ECL), central corneal thickness (CCT), and intraoperative and postoperative complications.

Results: Patients in both groups gained a better CDVA postoperatively. The ultrasound power and EPT in the CAPPS group were lower than the CPS group ($P < .001$). ECD value decreased at each follow-up visit and did not return to the preoperative level; CPS resulted in greater endothelial cell loss than CAPPS did, which was significant. CCT increased immediately after the surgery, and decreased thereafter. The mean CCT values returned to preoperative levels at 3 months after surgery in the CAPPS group while it took 6 months in the CPS group. The differences in cornea edema and anterior chamber flare between the 2 groups were not significant at 1 day postoperatively ($P = .070$ and $.094$, respectively), while at the 1-week time point, the differences were statistically significant ($P = .002$ and $.001$, respectively).

Conclusion: CAPPS appears to be an excellent method for treating hard nucleus cataract.

Abbreviations: CAPPS = cystotome-assisted prechop phacoemulsification surgery, CCC = continuous curvilinear capsulorhexis, CCT = central corneal thickness, CDVA = corrected distance visual acuity, CPS = conventional phacoemulsification surgery, ECD = endothelial cell density, ECL = endothelium cell loss, EPT = effective phacoemulsification time, IOL = intraocular lens, PCO = posterior capsule opacification.

Keywords: cataract surgery, cystotome-assisted prechop, hard nucleus, phacoemulsification

1. Introduction

The first cataract surgery can be traced back more than 4000 years to Ancient Egypt.[1] Now, cataract surgery is the most commonly performed surgical procedure in the world. Forty years ago, phacoemulsification (ultrasound) was first introduced to clinical practice by Charles Kelman[2]; it has since become the standard method of cataract surgery in many countries. There are 5 main steps in conventional phacoemulsification surgery (CPS), as follows: the creation of the corneal incisions, capsulotomy, lens fragmentation, removal of the fragmented crystalline lens, and insertion of the intraocular lens (IOL). Lens fragmentation is considered as the critical component. Surgeons have developed several methods of fracturing the nucleus, such as the in situ fracture,[3] divide-and-conquer,[4] phaco-chop,[5] and stop-and-chop techniques.[6] All these approaches require the conversion between ultrasound and negative pressure, as well as coordination and cooperation between the operator's hands and feet during the surgery. However, many studies have indicated that, although the application of the aforementioned technologies can result in the gain of excellent postoperative visual acuity, the incidence rates of endothelial cell loss, corneal edema, anterior capsule tears, and posterior capsule ruptures are relatively high. It is thought that, in age-related cataract cases, with increasing nuclear density, more ultrasound power and phacoemulsification time are often required.[7] Thus, developing a new method that can reduce the effective ultrasound power and shorten the

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effective phacoemulsification time (EPT) in hard nucleus cases has become a promising research field.

Recently, we have used a surgeon-bent cystotome along with the traditional Nagahara chopper to fracture the nucleus in the capsular bag, then remove the fragmented crystalline lens and insert the IOL. This method, which we call cystotome-assisted prechop phacoemulsification surgery (CAPPS), is easy to learn and master, and it works especially well for patients with a hard nucleus. To our knowledge, no study has compared the clinical outcomes of CAPPS and CPS in patients with a hard nucleus. Hence, we conducted a prospective, randomized, consecutive, and comparative cohort study to evaluate the surgical effect of the 2 cataract procedures.

2. Methods

2.1. General information

This prospective, randomized, consecutive, comparative cohort study involving CAPPS cases (study group) and CPS cases (control group) was performed at Xiangya Hospital, Central South University, Changsha, China, between January 2016 and August 2017. The study protocol was reviewed and approved by Central South University Xiangya Hospital Medical Ethics Committee and followed the guidelines set forth in the Declaration of Helsinki.

2.2. Inclusion and exclusion criteria

A total of 102 patients were enrolled into the study; after excluding 6 of them, 96 IV degree nucleus age-related cataract patients were randomly assigned to undergo CAPPS and CPS using a random number table (Fig. 1). The degree of nuclear hardness was classified according to the Emery–Little classification.[8] Exclusion criteria included the following: age younger than 18 years; endothelial cell density (ECD) < 2000 cells/mm^2, severe dry eye, corneal scars, corneal dystrophy, or any other corneal pathologies; manifest glaucoma treated with antiglaucoma drugs or past glaucoma filtration surgery; history of intraocular trauma or surgery; and poor cooperation in diagnostic tests or noncompliance at follow up.
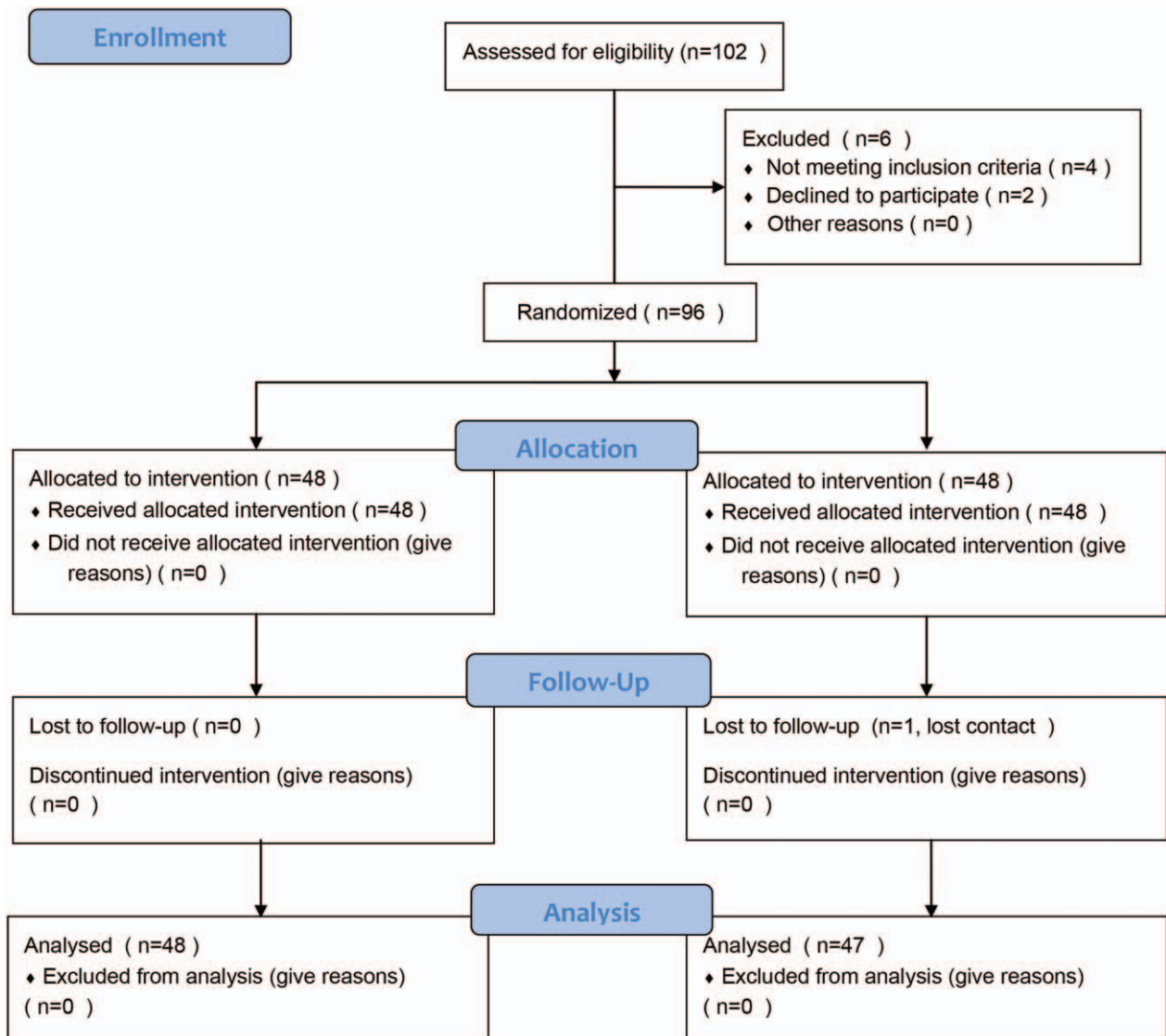

Figure 1. CONSORT flow diagram of patient selection and allocation.

2.3. Patient evaluation

Before surgery, all the patients underwent a detailed ophthalmic evaluation. The parameters comprised corrected distance visual acuity (CDVA) measurement using the standard logarithmic visual acuity chart; corneal, lens, cataract grade, and fundus status evaluation using a slitlamp (K Series, Keeler Instruments, Inc, Malvern, PA); corneal topography (Pentacam, Oculus Optikgerate GmbH); axial length and biometry with an IOL Master biometer (Carl Zeiss Meditec AG, Jena, Germany); and OCT (CIRRUS HD-OCT 500, Carl Zeiss Meditec AG). A noncontact specular microscope (SP 2000P; Topcon, Tokyo, Japan) with the IMAGE-NET imaging system (version 4.0; Topcon) was used to analyze the ECD and percentage of hexagonal cells.

2.4. Surgical technique

All patients had implantation of aspheric monofocal IOLs of the same brand (Tecnis ZCB00 intraocular lens, Abbott Medical Optics, Inc., Santa Ana, CA).The patients' pupils were dilated with 1 drop of tropicamide every 10 minutes 3 times before the surgery. All patients were prescribed Tobradex 4 times a day for 2 weeks and pranoprofen 4 times a day for 1 month.

2.4.1. Cystotome-assisted prechop phacoemulsification.
The surgeon used a needle holder to bend one-fourth to one-half of a 27-gauge needle tip down while holding the bevel up; the needle was then bent near the hub while maintaining the needle orientation. According to personal experience, the angle of the tip can vary from 60° to 90°. A 3.0-mm single-plane main incision and a 0.8-mm side-port corneal incision were made with a 3.2-mm keratome and 1.2-mm sideport blade. A cystotome or capsule forceps can also be used to complete a 5.0-mm continuous curvilinear capsulorhexis (CCC). The surgeon used a keratome to complete the corneal incisions. Figure 2 shows the key procedure of CAPPS. After the capsulorhexis was completed, without hydrodissection or hydrodelineation, the cystotome and chopper were inserted into the anterior chamber through the paracentesis: The chopper in the surgeon's left hand was slid under the cortex and capsule, ensuring the chopper blade was perpendicular to the equator of the nucleus, resting at 5 o'clock in the bag. The hook tip needed to be oriented toward the optical nerve, while the cystotome was repositioned and inserted into the endonucleus just inside the capsular rim at 11 o'clock. The chopper and cystotome were kept in apposition at the same radial meridian. Squeeze force was used to reach the center of the nucleus; once the chopper and cystotome met, they needed to be separated and pulled on both sides, causing the nucleus to split completely into 2 hemispheres. The nucleus was rotated 90°, and then the appeal method was used to split the nucleus again. Ultimately, the nucleus was split into 4 pieces. Subsequently, the surgeon removed the fragmented crystalline lens using a Stellaris phaco-machine (Bausch and Lomb, Rochester, NY) and inserted the IOL.

2.4.2. Conventional phacoemulsification surgery.
Following the standard CPS protocol, after the creation of CCC, the surgeon performed lens fragmentation using the stop-and-chop technology. Then, the fragmented crystalline lens was removed, and the IOL was inserted.

2.5. Outcome measures

During the operation, the ultrasound power and EPT were recorded, as well as intraoperative complications. Postoperative
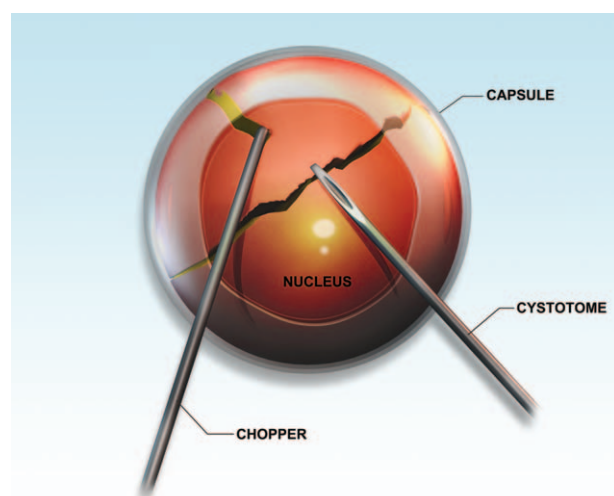

Figure 2. The key procedure of cystotome-assisted prechop phacoemulsification surgery. The chopper in the surgeon's left hand was resting 5 o'clock in the bag while the cystotome in the right hand just inside the capsular rim at 11 o'clock. Once the chopper and the cystotome met, the nucleus splited completely into 2 hemispheres. Then the nucleus was rotated 90°, and the aforementioned procedure was used to split the nucleus again.

outcome measurements included the CDVA, ECD, corneal endothelium cell loss (ECL) rate, central corneal thickness (CCT), eye number of different grades of cornea edema, grade of anterior chamber flare, and intraoperative and postoperative complications. The patients and those who performed preoperative and postoperative evaluations were blinded to the study.

2.6. Statistical analysis

Statistical analyses were performed using SAS software (version 9.4; SAS, Cary, NC). To compare the demographic data and baseline characteristics, continuous data were analyzed using the independent t test, while categorical data were assessed using the chi-squared test. Postoperative parameters between the 2 groups were analyzed using repeated measures-analysis of variance (ANOVA); when there was a significant difference between the groups, a further ANOVA process was required to determine the time point at which these differences occurred compared with the baseline. The differences at postoperative follow-up time points in each group were analyzed using 1-way ANOVA with Dunnett multiple comparison. A P value $< .05$ was considered statistically significant.

3. Results

One patient (CPS group) was lost to follow up, and 95 eyes were evaluated. Table 1 shows the preoperative characteristics of the 2 groups. There was no statistically significant difference in the demographic data or baseline characteristics of the study population.

The mean ultrasound power was $13.554 \pm 1.488\%$ in the CAPPS group and $21.368 \pm 1.063\%$ in the CPS group. There was a significant difference between the 2 groups ($P < .001$). EPT was also significantly lower in the CAPPS group than in the CPS group ($P < .001$; Fig. 3).

Table 2 displays the preoperative and postoperative CDVA values of the 2 groups. The CDVA values were significantly

Demographic data and baseline characteristics of the study population.

Parameters	CAPPS	CPS	*P*
Age, y	69.375 ± 6.794	69.723 ± 6.375	.797[*]
Female, n (%)	20 (41.67)	26 (55.32)	.183[**]
IOP, mm Hg	14.313 ± 2.451	14.511 ± 2.166	.677[*]
Axial length, mm	23.927 ± 0.576	23.885 ± 0.507	.812[*]
Mean K, D	44.010 ± 0.715	43.899 ± 0.569	.357[*]
ACD, mm	2.796 ± 0.215	2.779 ± 0.167	.500[***]

ACD = anterior chamber depth, CAPPS = cystotome-assisted prechop phacoemulsification surgery, CPS = conventional phacoemulsification surgery, IOP = intraocular pressure.
Data are mean ± standard deviation unless otherwise noted.
[*] Independent *t* test.
[**] Chi-squared analysis.
[***] Mann–Whitney *U* test.

improved from 1 day postoperatively to 1 year postoperatively in both groups, and the differences were statistically significant (all $P < .001$). No significant differences were observed between the 2 groups at any follow-up visit.

Before surgery, the mean ECD was 2540.027 ± 158.561 cells/mm^2 in the CAPPS group and 2481.466 ± 149.632 cells/mm^2 in the CPS group ($P = .067$). The ECD decreased in both groups postoperatively, with statistically significant differences (all $P < .001$), and the differences in the ECD at each follow-up visit between the 2 groups were statistically significant. In addition, the percentage of ECL was higher in the CAPPS group than it was in the CPS group at each follow-up visit (Fig. 4).

The preoperative CCT values were similar (529.188 ± 13.467 and 527.787 ± 12.446 μm, respectively; $P = .600$) and increased immediately 1 day after surgery in both groups. At the 3-month time point, the CCT returned to the baseline level in the CAPPS group ($P = .999$), while the central cornea was still thicker than at the preoperative level in the CPS group. CCT took 6 months to return to the preoperative level in the CPS group ($P = .975$) (Fig. 5).

Table 3 displays the intraoperative and postoperative complications in the 2 groups. During the surgery, Descemet's membrane local detachment occurred in 1 eye in the CPS group, and this was treated with gas injection to the anterior chamber. Miosis occurred in 1 eye in the CAPPS group, while 2 cases occurred in the CPS group; the difference was not statistically significant ($P = .547$). No other adverse events, such as zonular

Comparison of preoperative and postoperative corrected distance visual acuity between groups.

CDVA (logMAR)	CAPPS	CPS	*P*
Baseline	0.906 ± 0.239	0.960 ± 0.316	.671[*]
1 d	0.095 ± 0.119	0.128 ± 0.154	.240[**]
1 wk	0.064 ± 0.083	0.058 ± 0.093	.737[**]
1 mo	0.039 ± 0.073	0.034 ± 0.083	.760[**]
3 mo	0.033 ± 0.076	0.031 ± 0.086	.921[**]
6 mo	0.033 ± 0.075	0.034 ± 0.084	.915[**]
1 y	0.034 ± 0.072	0.043 ± 0.083	.564[**]
P (1 d)	<0.001[***]	<0.001[***]	
P (1 wk)	<0.001[***]	<0.001[***]	
P (1 mo)	<0.001[***]	<0.001[***]	
P (3 mo)	<0.001[***]	<0.001[***]	
P (6 mo)	<0.001[***]	<0.001[***]	
P (1 y)	<0.001[***]	<0.001[***]	

ANOVA = analysis of variance, CAPPS = cystotome-assisted prechop phacoemulsification surgery, CDVA = corrected distance visual acuity, CPS = conventional phacoemulsification surgery, logMAR = logarithm of the minimum angle of resolution.
[*] Mann–Whitney *U* test.
[**] Repeated measures ANOVA (difference at each follow-up visit postoperatively compare to baseline between the 2 groups).
[***] One-way ANOVA with Dunnett multiple-comparison (difference in the baseline and each postoperatively visit values of each group).

dehiscence or vitreous prolapse, occurred during the surgeries in either group.

After surgery, corneal edema was observed in both groups. There was less corneal edema in the CAPPS group than in the CPS group at 1 week, and the difference between the 2 groups was statistically significant ($P = .002$). Similarly, the difference in anterior chamber flare between the 2 groups was not significant at 1 day postoperatively ($P = .094$), while at the 1-week time point, the difference was statistically significant ($P = .001$). Two of the 49 CAPPS cases developed posterior capsule opacification (PCO) after the surgery, while 3 developed PCO in the CPS group; the difference was not statistically significant ($P = .630$).

4. Discussion

Cataract patients are demanding better postoperative visual acuity following cataract surgery. Breaking up the hard nucleus into emulsate for aspiration is the prerequisite for the removal of
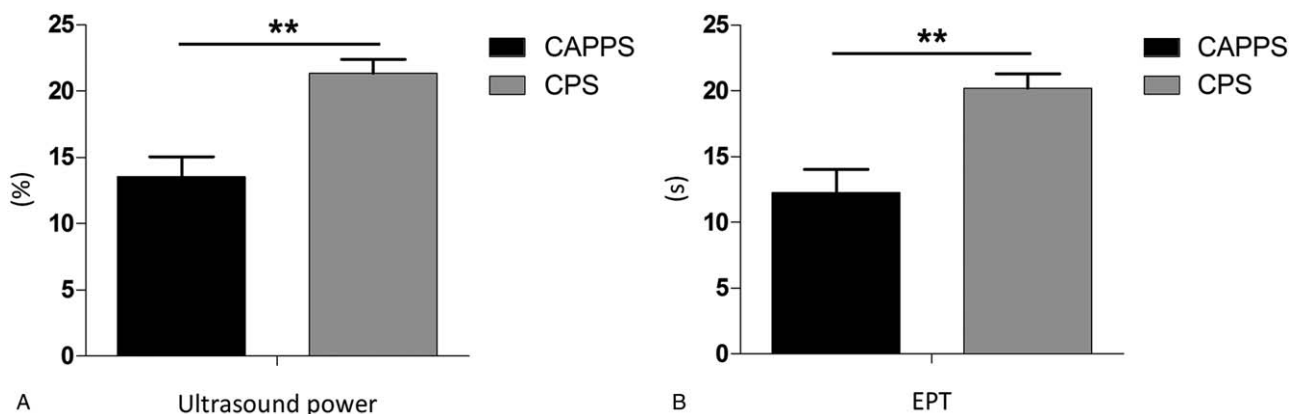

Figure 3. Intraoperative parameters between the 2 groups. (A) Mean ultrasound power; (B) effective phacoemulsification time.
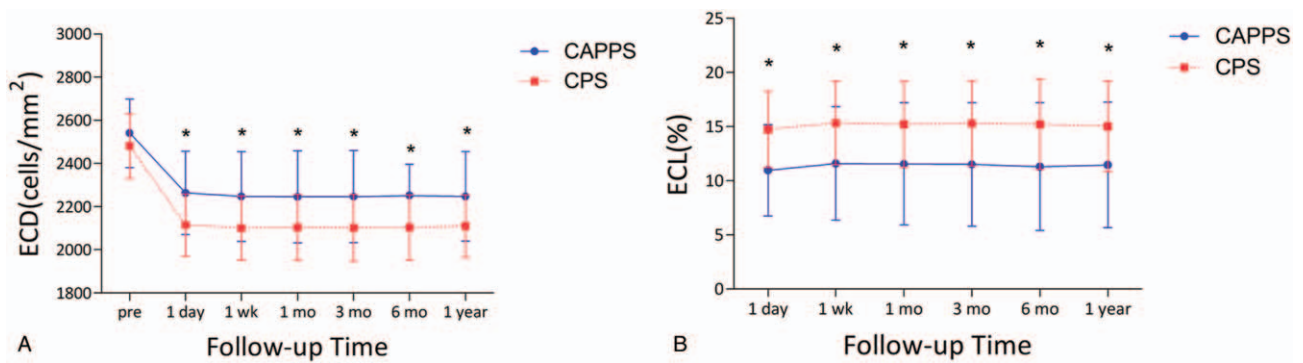
Figure 4. Preoperative and postoperative endothelial cell density and corneal endothelium loss rate. (A) Endothelial cell density; (B) corneal endothelium loss rate. "*" denotes there is significant statistical difference between CAPPS group (blue) and CPS group (red). CAPPS = cystotome-assisted prechop phacoemulsification surgery, CPS = conventional phacoemulsification surgery.

a cataract. The basic principle of phacoemulsification consists of direct action of the vibrating tip against the tissue and indirect cavitational effects. The phacoemulsification handpiece incorporates a transducer for converting high-frequency alternating current into mechanical vibrations[9]: Certain crystals produce an electric current, and then the electric current causes the crystal to contract. These mechanical vibrations are conducted to the phaco-needle along the handpiece to complete the emulsification.

The human lens includes 3 distinct structures, namely the capsule, cortex, and nucleus. As the fibers are laid down over time, the fetal nucleus turns into a hard central nucleus.[10] The crystal opacity begins to increase in density, gradually increasing in the surrounding area. The treatment for hard nucleus cataracts remains a challenge for surgeons. The hard nucleus creates surgical difficulties for several reasons, as follows: First, the radial suture plane of these lenses tends to have a strongly adhesive quality around the posterior epinucleus, forming a dense posterior nuclear plate.[11,12] Second, since the nucleus is thick and strong, posterior capsule rupture is more likely to occur during the surgery. Third, excessive ultrasound energy is often required to form a deep crater to accomplish complete fragmentation.[13]
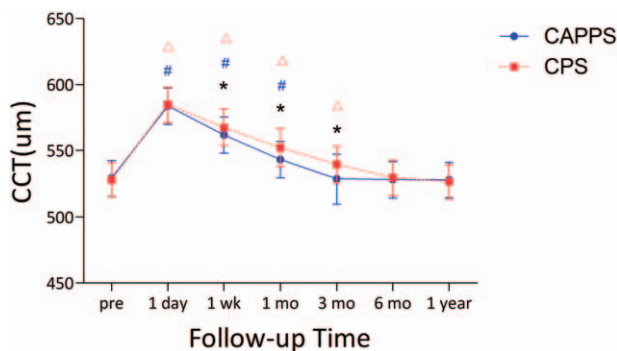

Figure 5. CCT before and after cystotome-assisted prechop phacoemulsification surgery and conventional phacoemulsification surgery. "*" denotes there is significant statistical difference between CAPPS group (blue) and CPS group (red); # denotes the differences at each follow-up visit postoperatively compare to baseline in CAPPS group; "△" denotes the differences at each follow-up visit postoperatively compare to baseline in CPS group. CAPPS = cystotome-assisted prechop phacoemulsification surgery, CCT = central corneal thickness, CPS = conventional phacoemulsification surgery.

When using stop-and-chop phacoemulsification technology in the surgery, the phacoemulsification needle generates energy and buries the needle into the nucleus; then, the posterior plate of the nucleus is cracked in half by laterally moving the chopper and phacoemulsification probe in opposite directions.[14] Compared with the other technologies, the stop-and-chop phacoemulsification technology can reduce the ultrasound power and shorten the EPT to some extent. However, in hard nucleus cases, the cost

Table 3

Between-group comparison of intraoperative and postoperative complications.

Complications	CAPPS	CPS	P
Intraoperative			
Miosis, n (%)	1 (2.08)	2 (4.26)	.547*
Descemet's membrane local detachment, n (%)	0	1 (2.13)	.312*
Postoperative			
Posterior capsule opacification, n (%)	2 (4.17)	3 (6.38)	.630*
Corneal edema, n (%)			
1 d			.070**
Grade 0	14 (29.17)	9 (19.15)	
Grade 1	22 (45.83)	14 (29.79)	
Grade 2	7 (14.58)	16 (34.04)	
Grade 3	5 (10.42)	8 (17.02)	
1 wk			.002*
Grade 0	25 (52.08)	15 (31.92)	
Grade 1	20 (41.67)	17 (36.17)	
Grade 2	3 (6.25)	12 (25.53)	
Grade 3	0	3 (6.38)	
Anterior chamber flare			
1 d			.094**
0	16 (33.33)	10 (21.28)	
1+	20 (41.67)	14 (29.79)	
2+	8 (16.67)	18 (38.29)	
3+	4 (8.33)	5 (10.64)	
1 wk			.001*
0	36 (75.00)	16 (34.04)	
1+	8 (16.67)	19 (40.42)	
2+	4 (8.33)	10 (21.28)	
3+	0	2 (4.26)	

CAPPS = cystotome-assisted prechop phacoemulsification surgery, CPS = conventional phacoemulsification surgery.
* Fisher exact test.
** Chi-squared analysis.

of ultrasound power in the process of burying the needle and fixing the nucleus is relatively high.

Prechop technology is a kind of technology that fractures the nucleus with special instruments or methods before the conventional aspiration. It was first introduced by Akahoshi in 1998[15]; since then, multiple prechop technologies have been introduced to clinical practice, such as the Fukasaku hydro-chopping cannula[16] and 2 modified cystotomes for middle prechop.[17] In our study, we used a surgeon-bent cystotome to fracture the nucleus prior to the phacoemulsification step; as there was no release of ultrasonic power throughout the process, the ultrasound power and EPT in the CAPPS group were much lower than those in the CPS group, which is consistent with previous, similar research.[18]

Endothelial cell damage frequently occurs in cataract surgery. Generally, ECL ranges from 4% to 25%[19]; nevertheless, this number can be as high as 42% in hard nucleus cases.[20] Our result showed ECD decreases in both groups postoperatively, and the ECL in the CAPPS group was much lower than it was in the CPS group. We account for this in terms of the lower ultrasound power in the CAPPS group: Many studies have indicated that phaco energy is the main risk factor for trauma after surgery, especially concerning corneal endothelial cell injury or dysfunction,[21] and there is a linear relationship between ultrasound power and ECL.[22–24]

An increasing CCT often accompanies ECL.[25,26] This is mainly because of the postoperative corneal swelling. In our study, it took less time for the CAPPS group to return to the preoperative CCT value, suggesting that patients in the CAPPS group could achieve a faster recovery. Hence, CAPPS can effectively reduce corneal swelling and shorten the recovery time.

Transient corneal edema is usually observed after phacoemulsification surgery, suggesting effects on the corneal endothelial pump function.[27] In our study, there was no significant difference in corneal edema 1 day postoperatively between the CAPPS and CPS groups; however, at the 1-week follow-up visit, there was more corneal edema in the CAPPS group than the CPS group. A previous study showed that postoperative corneal edema is strongly associated with a clinically significant corneal endothelial cell loss[28]; we can conclude that CAPPS can provide faster relief from corneal edema postoperatively.

The postoperative release of anterior chamber cells and flare are challenges for patients who desire rapid visual recovery and minimal associated pain. Previous studies have shown that the mean flare values peak at 1 day and then decline rapidly 1 week after cataract surgery.[29,30] Our study confirmed the same outcome; the grade of anterior chamber flare was high in the postoperative period immediately after surgery and declined thereafter. We also found that the grade of anterior chamber flare in the CAPPS group was much lower than that in the CPS group.

Visual acuity remains cataract patients' most important concern. In our study, the CDVA improved greatly in both the CAPPS and CPS groups. Although the differences were not significant, the CDVA at 1 month, 3 months, 6 months, and 1 year were better than they were at 1 day and 1 week. This was mainly because of the recovery from corneal edema.

We found some advantages in using CAPPS. First, there is no need for additional specialized instruments, such as the Akahoshi Combo Prechopper. Surgeons can complete the prechop with the same cystotome to transfer in and out of the anterior chamber after creating the capsulorhexis. Second, the CAPPS procedure requires only 2 hands to operate the equipment during the lens fragmentation procedure; it does not require building the occlusion in the endonucleus with precise pedal control and a high vacuum, which is associated with a relatively long-learning curve for phacoemulsification beginners. Moreover, it is much easier to carry out compared with other prechop procedures. The learning curve is relatively short.

There is limitation to this study. With the development of technology and the popularity of cataract surgery, it is difficult to enroll more patients with hard nucleus. Hence, future studies are still needed.

5. Conclusion

In conclusion, both surgeries can attain excellent visual acuity postoperatively. Compared with CPS, CAPPS uses less ultrasound power, shortens the EPT during the surgery, and reduces the potential for corneal edema and endothelial cell loss. In addition, it requires no specialized instruments except a surgeon-bent cystotome, and the learning curve is relatively short. Hence, CAPPS appears to be an excellent method for treating hard nucleus cataract.

Author contributions

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Funding acquisition: Weitao Song.
Methodology: Weitao Song.
Project administration: Weitao Song.
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Supervision: Xiaobo Xia, Weitao Song.
Writing – original draft: Xin Li, Ye He.
Writing – review & editing: Weitao Song.

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