Comparison of the reverse chopper-assisted prechop and phaco-chop nucleotomy techniques during phacoemulsification for cataracts with grade III nuclei: a randomized controlled trial

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Background: Phacoemulsification surgery is the standard treatment for cataract. However, excessive ultrasound (US) energy may cause injury to the corneal endothelium and other ocular tissues. Recently, a new prechop technique assisted with the reverse chopper is showed to be more efficient and safe, by splitting the nuclei in situ without using any US energy. However, it is verified only in treating some kinds of complex cataracts such as grade IV hard nuclei cataract, small-pupil cataract, and ultra-high myopia cataract. Since grade III nuclei cataract is the most common type of cataract, it is necessary to evaluate the efficacy and safety of prechop technique with reverse chopper in routine cataract surgery.

Methods: This prospective, two-parallel, randomized controlled trial was conducted in Beijing Tongren Hospital from January 2022 to September 2022. A total of 89 cataract patients (89 eyes) were enrolled and then randomly assigned to either the reverse chopper-assisted prechop group (n=45) or the phaco-chop group (n=44). The patients were followed for 3 months postoperatively. The best-corrected visual acuity (BCVA), cumulative dissipated energy (CDE), corneal endothelial cell loss (ECL), and degree of corneal edema were evaluated and compared between these 2 groups. Data were analyzed using SPSS 23.0 and GraphPad Prism 8.0.

Results: The CDE of the reverse chopper-assisted prechop group was significantly less than that of the phaco-chop group (P=0.011). Compared with the phaco-chop group, the corneal edema in the reverse chopper-assisted prechop group was milder (P=0.026) and the BCVA was better (P=0.0012) at 1 day after surgery. No significant difference was found in the count or rate of corneal ECL between the 2 groups at 1 month after surgery (corneal ECL count: P=0.090; corneal ECL rate: P=0.053). The BCVA of the 2 groups at 1 week, 1 month, and 3 months after surgery was equivalent (P=0.052, 0.26, and 0.41, respectively).

Conclusions: The prechop technique assisted with the reverse chopper in treating cataract with grade III nuclei enables less phaco energy consumption, milder ocular structural damage, and faster recovery of vision, compared with traditional phaco-chop technique.

Keywords: Prechop; reverse chopper; phaco-chop; cataract

Submitted Oct 21, 2022. Accepted for publication Jan 10, 2023. Published online Jan 31, 2023.
doi: 10.21037/atm-22-6163
View this article at: https://dx.doi.org/10.21037/atm-22-6163

Introduction

Cataract is the leading cause of world blindness (1,2). Currently, phacoemulsification surgery is the standard treatment for cataract and lens fragmentation is considered the critical step in the surgery (3). In recent years, several different lens splitting techniques in phacoemulsification have been developed, such as *in situ* fracture, divide-and-conquer, stop-and chop, and phaco-chop techniques, among which phaco-chop is the most classic and popular one (4,5). However, the learning curve of phaco-chop nucleotomy technique is long, as it requires good hand-foot coordination from the surgeon and frequent conversion between ultrasound (US) and negative pressure (6). In addition, there are risks of corneal endothelium injury and other ocular tissue damage resulting from the US energy (7,8).

The prechop techniques, firstly reported by Akahoshi in 1998 (9), have been shown to make the cataract surgery easier to learn and to reduce the US energy. The prechop techniques use special instruments to split the nuclei. These instruments include the Akahoshi Combo and modified device, the capsulotomy needle, the capsulorhexis forceps, the double-hook, and the femtosecond laser, among others. However, these prechop techniques have several limitations, including the excessive stress on posterior capsule or zonules, potential iatrogenic injury when the cystotomes go through the incision, difficulty in complete division of the lens due to the fibrous or leathery posterior nuclear plate, or the requirement of expensive equipment such as the femtosecond laser (10-14).

In previous study from Beijing Tongren Eye Center, a new prechop technique was introduced (15). With the assistance of the reverse chopper, the lens nuclei could be effectively split *in situ*, which greatly shortened the subsequent phacoemulsification time and reduced the use of US energy. However, the advantages were manifested only in treating some kinds of complex cataracts such as the grade IV hard nuclei cataract, the small-pupil cataract, and the high myopia cataract in small samples (16-18). Since grade III nuclei cataract is the most common type of cataract, it is necessary to evaluate the use of the new prechop technique in routine cataract surgery. The purpose of current study is to compare the efficacy and safety between the reverse chopper-assisted prechop and phaco-chop nucleotomy techniques, during phacoemulsification for cataracts with grade III nuclei. We present the following article in accordance with the CONSORT reporting checklist (available at https://atm.amegroups.com/article/view/10.21037/atm-22-6163/rc).

Highlight box

Key findings

- Compared with phaco-chop technique, the prechop technique using the reverse chopper in treating cataract with grade III nuclei enabled less phaco energy consumption, milder ocular structural damage, and faster recovery of vision.

What is known and what is new?

- The US energy during phacoemulsification increases the risks of corneal endothelium injury and other ocular tissue damage. The reverse chopper-assisted prechop technique can effectively split the nucleus in situ and reduce the US energy, but the advantages are confirmed only in some complex types of cataract surgeries.
- This study firstly evaluates the use of the prechop technique with a reverse chopper in grade III nuclei cataract surgery.

What is the implication, and what should change now?

- In comparison with the traditional phaco-chop technique, it provides a more simple, safe, and efficient nucleotomy method to use the reverse chopper-assisted prechop techniques for cataract with grade III nuclei.

Methods

Trial design and participants

This two-paralleled, randomized controlled trial was conducted between January 2022 to September 2022 in Beijing Tongren Hospital. To satisfy the two-sample *t*-test with a significance level of 0.05 and a power of 0.8, 40 subjects were required in each group. With about a 10% dropout rate, it resulted in a total of 89 subjects. A total of 89 patients (89 eyes) with age-related cataracts were enrolled, of ages from 42 to 84 years old. These patients were randomly assigned (1:1) to either the reverse chopper-assisted prechop group (hereinafter referred to as the reverse chopper group) (n=45) or the phaco-chop group (n=44) using a randomization table. The inclusion criteria were as follows: (I) age-related cataracts with lens opacity grade 3 (based on the Lens Opacities Classification System; LOCS III); (II) cataracts indicated for phacoemulsification cataract surgery and intraocular lens (IOL) implantation; and (III) good compliance to the treatments and follow-up visits. The exclusion criteria were as follows: (I) corneal lesions including corneal leukoplakia, keratoconus, and/or corneal endothelium <1,000/mm^2; (II) active ocular inflammation in the past 6 months; (III) lens luxation or subluxation; (IV)

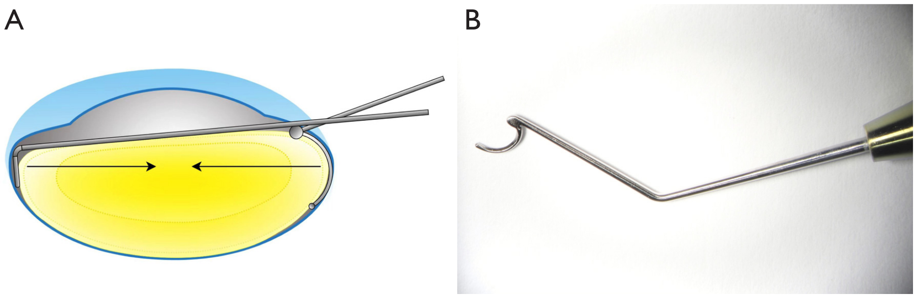

Figure 1 The schematic diagram of the reverse chopper-assisted prechop technique and photograph of the reverse chopper. (A) The cross-section of the lens illustrating the locations and the shearing force produced by the relative movement of the two choppers, which were the reverse chopper (in the right hand) and the Nagahara chopper (in the left hand). (B) The reverse chopper consisted of an inverted circular arc containing an inner blade with a blunt tip.

other severe ocular conditions affecting vision (e.g., macular diseases, glaucoma, optic atrophy, and/or ocular trauma); (V) a history of any intraocular surgery; and (VI) aged ≤40 years. The investigational procedures were in accordance with the Declaration of Helsinki (as revised in 2013), and the study was approved by the Institutional Review Board of Beijing Tongren Hospital (No. TRECKY2017-028). All patients provided written informed consents before enrollment.

Preoperative evaluation

All patients received a full ophthalmic examination preoperatively. Best-corrected visual acuity (BCVA) of the operative eye was recorded in the logarithm of minimal angle of resolution (logMAR) values. Slit-lamp examination was used to grade the severity of nuclear sclerosis according to the LOCS III (19). The corneal endothelial cell density (ECD) was measured with a non-contact endothelial specular microscopy (SP-3000P, Topcon, Tokyo, Japan). IOL Master 500 (Carl Zeiss Meditec AG, Jena, Germany) was used for the axial length measurement and IOL calculation. Other preoperative examinations for cataract surgery, including the intraocular pressure (IOP), color fundus photography, ophthalmic ultrasonography, and macular optical coherence tomography (OCT), were also routinely performed.

Surgical technique

All the surgeries were performed by a single experienced surgeon (JT). Under topical anesthesia, superior phaco incisions were used for all the surgeries. The Infiniti® phacoemulsification unit (Alcon Laboratories, Fort Worth, TX, USA) and the 0.9 mm mini-flared, 45-degree ABS Kelman microtip (Alcon) were applied for each cataract surgery. The phaco machine settings were as follows: infusion bottle height of 95 cm, the torsional continual model with 100% amplitude, vacuum 450 mmHg, and aspiration flow rate of 40 mL/min. The settings used in the 2 groups were identical.

The surgeries were performed using standard surgical procedures, which were identical in the 2 groups, except for the step of nucleus fracturing. Each cataract surgery began with a 3.0 mm clear corneal incision at the 10 o'clock position, and a lateral incision at the 2 o'clock position, then viscoelastics (EYEFILL® S.C; Bausch & Lomb, Montpellier, France) was injected into the anterior chamber, and a 5–6 mm continuous curvilinear capsulorhexis was performed.

The following nucleus-splitting steps were different between the 2 groups: in phaco-chop group, the phaco tip was buried into the core of the endonucleus companied with energy being exerted. Then, the lens nucleus was sucked by the phaco tip with high vacuum, in the meantime, the Nagahara chopper was pulled toward the phaco tip splitting the endonucleus into two halves. This process was repeated, resulting in the right half of nucleus being bisected.

For the reverse chopper-assisted prechop technique, the steps were described in detail in previous study (15). In brief, a manual prechop technique was applicated before phacoemulsification, assisted with the shearing force produced by the relative motion of the reverse chopper and a Nagahara chopper, which could achieve efficient *in situ* nucleus-splitting without releasing ultrasonic energy (*Figure 1A*). The reverse chopper consisted of an inverted circular arc containing an inner blade with a blunt tip (*Figure 1B*). The steps of the reverse chopper-assisted

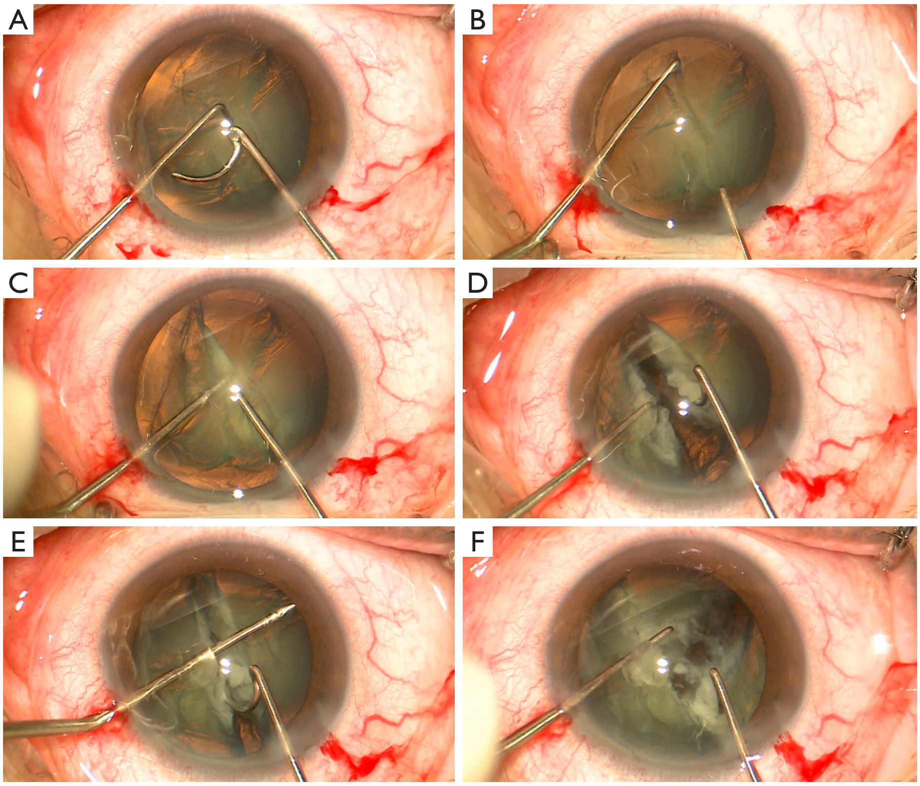

Figure 2 The procedures of the reverse chopper-assisted prechop technique during the surgery. (A) The reverse chopper was inserted from the main incision and inclined laterally, and the Nagahara chopper was inserted from the lateral incision. (B) The reverse chopper was gradually erected until its arc was set in the cortex between the capsule and the nucleus at the 11 o'clock position. The Nagahara chopper was slid into the space between cortex and capsule membrane at the 5 o'clock position, which was opposite to the radial direction of the reverse chopper. (C) The reverse chopper and the Nagahara chopper were horizontally pushed toward the core of the lens simultaneously. (D) The nucleus was divided into two semi-ellipsoids. (E) The reverse chopper was pressed close to the right semiellipsoid, while the Nagahara chopper was slid to the 8 o'clock position and pulled to the center, leading to bisect the right semiellipsoid into two parts. (F) The lens nucleus was divided into three parts finally.

prechop technique during the surgery were implemented as follows (*Figure 2*). After continuous curvilinear capsulorhexis, the reverse chopper was inserted from the main incision and inclined laterally (*Figure 2A*), then slid into the capsule, and gradually erected until its arc was set in the cortex between the capsule and the nucleus at the 11 o'clock position. The Nagahara chopper was inserted from the lateral incision, and slid into the space between capsule and cortex at the 5 o'clock position, which was opposite to the radial direction of the reverse chopper (*Figure 2B*). Then, the reverse chopper and the Nagahara chopper were horizontally pushed toward the core of the lens simultaneously (*Figure 2C*) to divide the nucleus into two semiellipsoids (*Figure 2D*). After that, the reverse chopper was pressed close to the right semiellipsoid, while the Nagahara chopper was slid to the 8 o'clock position and pulled to the center, leading to bisect the right semiellipsoid into two parts (*Figure 2E*). At last, the lens nucleus was divided into three parts (*Figure 2F*).

After the fragmentation of the nuclei, the subsequent steps of the surgeries were similar between 2 groups. The nucleus fragments were crushed and sucked away by phacoemulsification at the iris plane. After removing the remaining epinucleus and cortex, a foldable monofocal IOL was implanted into the capsular bag. After the surgery, the operated eye received tobramycin/dexamethasone eye ointment immediately, and tobramycin/dexamethasone eye drops 4 times a day for 3 weeks.

Intraoperative measurement

Total cumulative dissipated energy (CDE) was measured and recorded intraoperatively, displayed automatically on the interface of the Infiniti system. It was the total US energy in foot pedal position 3 (torsional and longitudinal) measured in percent-seconds. CDE = (torsional time × 0.4 × average torsional amplitude) + (longitudinal time × average longitudinal power) (20).

Intraoperative complications (e.g., capsular rupture with or without vitrectomy, corneal endothelial injury by the instruments, dropped lens, zonular dialysis, Descemet's membrane detachment) were also documented.

Postoperative evaluation

Complications during the 3 months postoperative period were evaluated, including corneal endothelial dysfunction, secondary glaucoma, endophthalmitis, subluxated IOL, and so on.

The postoperative examinations were performed by a single examiner at 1 day, 1 week, 1 month, and 3 months after surgery. The outcome assessment included testing for BCVA, degree of corneal edema, corneal ECD, and other necessary postoperative examinations.

Corneal edema on the first postoperative day was graded as follows: (I) grade 0: transparent cornea; (II) grade 1 (mild edema): a slight increase in corneal thickness with no Descemet's folds and clear iris details were seen; (III) grade 2 (moderate edema): increased stromal thickness, fewer than ten Descemet's folds and hazy iris details; (IV) grade 3 (severe edema): more than 10 Descemet's folds and marked increase in the corneal thickness, the iris details were not visible (21).

The rate of corneal ECL was calculated as follows: ECL (%) = (ECDpre − ECDpost)/ECDpre. Pre is the abbreviation of pre-operative and post is the abbreviation of post-operative. Postoperative complications were also documented, including corneal decompensation, secondary glaucoma, uveitis, IOL displacement, and so on.

Statistical analyses

Statistical analyses were performed using SPSS 23.0 (IBM Corp., Armonk, NY, USA) and GraphPad Prism 8.0 (GraphPad Software Inc., San Diego, CA, USA). Shapiro-Wilk test was performed firstly to show the normality of data. Comparisons between the reverse chopper group and the phaco-chop group were made by the Mann-Whitney U test (when the variables were not normally distributed) or by unpaired Student's *t*-tests (when the variables were normally distributed). The associations between the parameters were evaluated by the Spearman's correlation coefficient. All statistical tests were two-sided, and P values of less than 0.05 were considered statistically significant.

Results

Demographic and clinical characteristics of the participants

Figure 3 depicted the study flow of participants. All 89 participants completed the intervention and follow-up, and were included in the analysis for the study, comprising 43 men (48.3%) and 46 women (51.7%). The mean age of the participants was 67.5±8.2 years (mean ± SD), ranging from 42 to 84 years. The detailed demographic and clinical characteristics of the participants of the 2 groups were presented in *Table 1*. The age, gender, axial length, and preoperative BCVA and corneal ECD were all matched between the 2 groups before surgery (age: P=0.15; gender: P>0.99; AL: P=0.12; BCVA: P=0.58; corneal ECD: P=0.11) (*Table 1*).

Complications evaluation

There were no intraoperative and postoperative complications in both groups.

Comparison of CDE, postoperative corneal edema, BCVA, and corneal ECD

The mean CDE was 7.53±3.21 in the reverse chopper group and 9.60±3.98 in the phaco-chop group (*Table 2*). The CDE of the reverse chopper group was significantly less than that of the phaco-chop group (P=0.011). Various degrees of corneal edema were observed in the operated eyes at the first day after operation, which gradually decreased over time. Compared with the phaco-chop group, the corneal edema of the reverse chopper group was milder at one day postoperatively (P=0.026) (*Table 2*). The BCVA at the first day after operation was 0.12±0.12 logMAR in the reverse chopper group and 0.22±0.16 logMAR in the phaco-chop group. BCVA of the reverse chopper group was better than that of the phaco-chop group significantly (P=0.0012) at the first day after operation, but no significant difference was found between the 2 groups in BCVA at 1

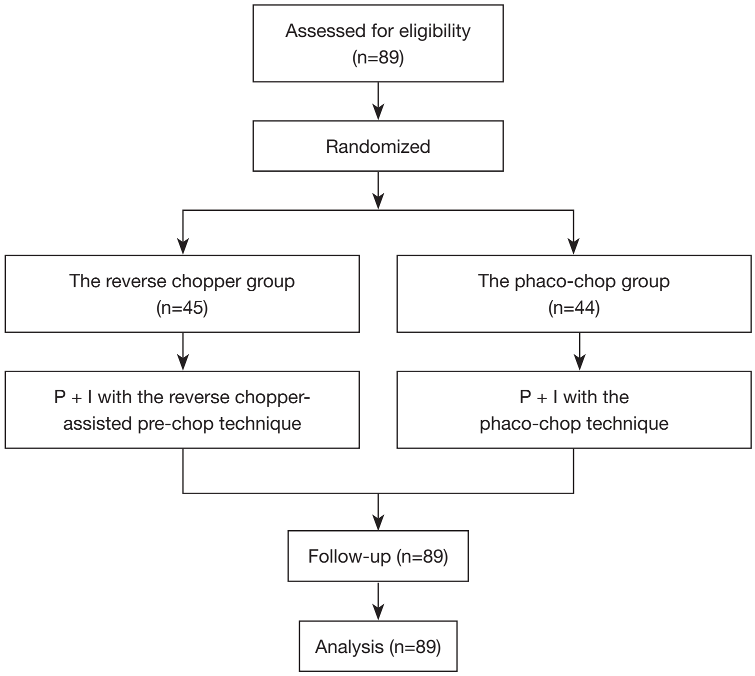

Figure 3 Participant flow of this study. P + I, phacoemulsification and intraocular lens implantation.

Table 1 Comparison of clinical profile of the reverse chopper group and the phaco-chop group (mean ± SD)

Groups	Eyes	Male/female	Age (years)	AL (mm)	Preoperative BCVA (logMAR)	Preoperative corneal ECD (cells/mm^2)
Reverse chopper group	45	22/23	66.2±9.7	24.0±1.6	0.60±0.34	2,633.0±333.5
Phaco-chop group	44	21/23	68.8±6.1	23.5±1.0	0.65±0.39	2,553.6±363.3
P value		>0.99	0.15	0.12	0.58	0.11

SD, standard deviation; AL, axial length; BCVA, best-corrected visual acuity; ECD, endothelial cell density.

Table 2 Comparison of intraoperative and postoperative parameters of the reverse chopper group and the phaco-chop group (mean ± SD)

Groups	CDE	Postoperative corneal edema grade (1-day)	Postoperative BCVA (logMAR)				Postoperative corneal ECL count (cells/mm^2) (1-month)	Postoperative corneal ECL rate (%) (1-month)
			1-day	1-week	1-month	3-month		
Reverse chopper group	7.53±3.21	0.36±0.48	0.12±0.12	0.05±0.09	0.03±0.05	0.02±0.04	428.3±305.8	15.9±10.3
Phaco-chop group	9.60±3.98	0.62±0.53	0.22±0.16	0.08±0.10	0.04±0.07	0.03±0.05	479.3±227.0	18.6±7.7
P value	0.011*	0.026*	0.0012**	0.052	0.26	0.41	0.090	0.053

*, significant at the 0.05 level (two-tailed); **, significant at the 0.01 level (two-tailed). SD, standard deviation; CDE, cumulative dissipated energy; BCVA, best-corrected visual acuity; ECL, endothelial cell loss.

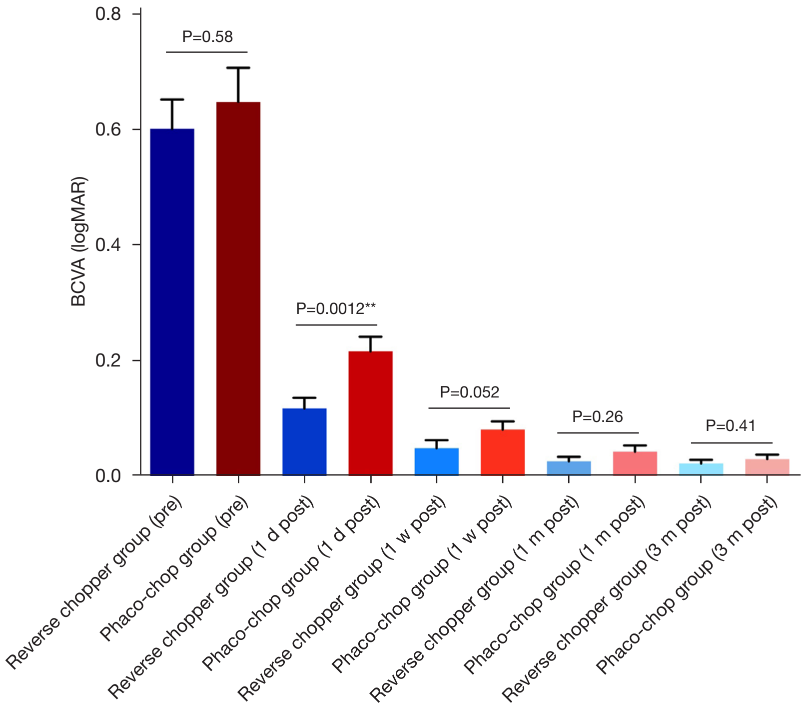

Figure 4 Bar graph showing the difference of the visual acuity between the reverse chopper group and the phaco-chop group (mean ± SEM). **, significant at the 0.01 level (two-tailed). pre, pre-operatively; post, post-operatively; d, day; m, month; SEM, standard error of the mean; BCVA, best-corrected visual acuity.

Table 3 Correlations between the intraoperative and postoperative parameters

Parameters	Spearman correlation coefficient	P value
CDE *vs.* postoperative corneal ECL count	0.581**	<0.01
CDE *vs.* postoperative corneal ECL rate	0.627**	<0.01
CDE *vs.* postoperative corneal edema grade (1 d)	0.499**	<0.01
CDE *vs.* postoperative BCVA (1 d)	0.318**	<0.01
postoperative corneal edema grade *vs.* BCVA (1 d)	0.441**	<0.01

**, significant at the 0.01 level (two-tailed). CDE, cumulative dissipated energy; ECL, endothelial cell loss; d, day; BCVA, best-corrected visual acuity.

week, 1 month, or 3 months postoperatively (P=0.052, 0.26, and 0.41, respectively) (*Figure 4*). The corneal ECL counts at one month after surgery were 428.3±305.8 cells/mm^2 in the reverse chopper group and 479.3±227.0 cells/mm^2 in the phaco-chop group. The corneal ECL rates at one month after surgery were 15.9±10.3(%) and 18.6±7.7(%), respectively (*Table 2*). There were no significant differences in the count or rate of corneal ECL between the 2 groups at one month after surgery (corneal ECL count: P=0.090; corneal ECL rate: P=0.053).

Correlations between the intraoperative and postoperative parameters

Spearman correlation test was applied among the intraoperative and postoperative parameters (*Table 3*). The corneal edema of the operated eye at the first day after operation was significantly related to the CDE (r=0.499, P<0.01). Besides, the count and rate of corneal ECL at 1 month postoperatively were also found to be positively related to the CDE (r=0.581, P<0.01; r=0.627, P<0.01). The BCVA at 1 day after surgery was positively correlated with the degree of corneal edema (r=0.441, P<0.01). There was also a positive correlation between the CDE and the BCVA of the operated eye at the first day after surgery (r=0.318, P<0.01), indicating that the increase of US energy in the surgery leaded to temporary worse vision postoperatively.

Discussion

This study showed that it could be effective to use the reverse chopper-assisted prechop techniques in treating cataracts with grade III nuclei.

Firstly, we found that during lens splitting procedure, the nucleus was divided into two semiellipsoids more completely and efficiently in the reverse chopper group, compared with the phaco-chop group. This advantage benefitted from the design of the reverse chopper. The curvature of the reverse chopper arc was similar to that of the lens equatorial part, which allowed the chopper arc surrounding the lens with its tip under the lens bottom, to ensure complete division of the nucleus. Phaco-chop or other pre-chop techniques might only separate the nucleus upper part, so that certain connections in its lower portion remained especially when the posterior plate was fibrous or leathery (10-14).

Secondly, this was the first study showing the reverse chopper-assisted prechop techniques used less CDE than the phaco-chop techniques in grade III nuclei cataract surgeries, indicating this technique helped to decrease the effective ultrasound energy. The analysis revealed the surgeon used the reverse chopper to perform lens splitting manually without ultrasound energy. In contrast, excessive US energy was required to form a deep crater to bury the needle into the endonucleus for nucleus fragmentation in phaco-chop group (5,22). These results were consistent with the previous reports during grade IV hard nucleus cataract surgery, small pupil cataract surgery and high myopia associated cataract surgery in our eye center (16-18). CDE was chosen as an important parameter to evaluate the US power and time in the surgery. It was the total energy dissipated at the foot pedal position 3, and was calculated as amplitude multiplied by time which was measured in percent-seconds. Thus, effective phacoemulsification time was implicitly embedded in this analysis through CDE (20).

Thirdly, as the effective US energy was an important risk factor for corneal ECL as well as other ocular tissues damage (23), whether the excessive use of energy had an adverse impact on prognosis was investigated in this study. The reverse chopper group was associated with a significantly better visual acuity and milder corneal edema at 1 day after surgery compared with the phaco-chop group. In addition, correlation analysis showed that the corneal edema and the BCVA at postoperative day 1 was positively related to the CDE. The BCVA at postoperative day 1 was positively correlated with the degree of corneal edema. There was a positive correlation between the CDE and the BCVA at postoperative day 1. The CDE was also positively correlated with the count and rate of corneal ECL at 1 month after the surgery.

These results revealed that the increased phacoemulsification energy could increase the risk of surgery induced trauma, especially corneal endothelial dysfunction, and translate to unsatisfactory surgical outcomes. This was consistent with the findings of previous similar studies (24). The application of the reverse chopper-assisted prechop reduced the use of US energy intraoperatively and enabled a faster recovery of vision postoperatively.

It was safe to use the reverse chopper-assisted prechop techniques in treating cataracts with grade III nuclei. There were no intraoperative and postoperative complications in this study. It was known that the most common serious complications for beginners using phaco-chop or the previous prechop techniques were zonular dialysis and posterior capsular rupture (11-14,25,26). The reason was that the splitting force resembled chopping log with an axe, which made it difficult to avoid the unbalanced pressure exerted on the zonule and the downward pressure toward the posterior capsule. The prechop technique used the reverse chopper combined with the Nagahara chopper to wrap around the nucleus, then the two choppers was moved horizontally toward the center with equal force to bisect the nucleus. It was similar to using a clamp with all forces focused on the nucleus itself, enabled the lens remaining *in situ* during the whole splitting process. In addition, it was safe to place the reverse chopper around the equator without damaging the posterior capsule due to its round and blunt tip.

There are a few key points to be noted when performing the reverse chopper-assisted prechop technique. Firstly, in order to ensure the nucleus *in situ* in the prechop step, both the reverse chopper and the Nagahara chopper should be pushed along the same radial meridian with equal amount of forces, with no extra forces against the capsule and zonules, when moving centripetally. Second, once the two choppers encounter in the center of the nucleus, they need to be separated and pulled slowly on both sides, causing the nucleus as well as the posterior plate of the lens to be split completely into two hemispheres.

In future studies, the potential protective effect on corneal endothelial cell of this reverse chopper-assisted prechop technique might be more prominent when the study is conducted in a larger sample or in the cataract patients with corneal endothelial dystrophy.

Conclusions

Compared with phaco-chop technique, the prechop technique using the reverse chopper in treating cataract with grade III nuclei enables less phaco energy consumption, milder ocular tissue damage, and faster recovery of vision. It provides a simple, safe, and efficient nucleotomy method for cataract treatment.

Acknowledgments

We express heartfelt thanks to the inventor and patent-owner of the reverse chopper, Yang Zhao, for providing methods and ideas for this prechop technique.
Funding: None.

Footnote

Reporting Checklist: The authors have completed the CONSORT reporting checklist. Available at https://atm.amegroups.com/article/view/10.21037/atm-22-6163/rc

Data Sharing Statement: Available at https://atm.amegroups.com/article/view/10.21037/atm-22-6163/dss

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://atm.amegroups.com/article/view/10.21037/atm-22-6163/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The investigational procedures were in accordance with the Declaration of Helsinki (as revised in 2013), and the study was approved by the Institutional Review Board of Beijing Tongren Hospital (TRECKY2017-028). All patients provided written informed consents before enrollment.

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Cite this article as: Tao J, Wan Y, Song X. Comparison of the reverse chopper-assisted prechop and phaco-chop nucleotomy techniques during phacoemulsification for cataracts with grade III nuclei: a randomized controlled trial. Ann Transl Med 2023;11(2):105. doi: 10.21037/atm-22-6163

