Effect of pre-fragmentation on efficacy and safety for phacoemulsification in femtosecond laser-assisted cataract surgery: a non-randomized clinical trial

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Background: Ultrasound energy during phacoemulsification results in the endothelial cell loss of cornea. Crystallin lens fragmentation with softening before phacoemulsification can be used with femtosecond laser-assisted cataract surgery (FLACS) device.

Methods: This non-randomized clinical trial included patients who underwent cataract surgery and not had corneal opacity. Patients who were not possible to apply the interface on the ocular surface, were excluded. Each subject was allowed to decide the surgical method by himself/herself. Cataract surgery was performed with FLACS (groups I and II) or conventional surgical technique (group III). The FLACS group was further subdivided into two groups according to whether a lens softening procedure was performed (group I) or not (group II). The nuclear density of cataract was objectively classified by Pentacam nuclear staging (PNS), preoperatively. Surgical parameters including total phacoemulsification time (TPT), cumulative dissipated energy (CDE), and the balanced salt solution (BSS) volume consumed, were measured during the surgery. Postoperative visual outcomes were evaluated at three months after the surgery, and corneal endothelial cell count (ECC) loss were calculated based on ECC measured before the surgery and two months after the surgery.

Results: Eighty-nine eyes from 89 patients were enrolled. Fifty-three were treated using FLACS (groups I; quadrant pattern with softening of pre-fragmentation, n=31 and II; sextant pattern without softening of pre-fragmentation, n=22) and 36 (group III) with the conventional manual technique. The FLACS groups (groups I and II) had statistically significant lower TPT (P<0.001), CDE (P<0.001), and BSS volumes (P<0.001) used in the nucleus removal step compared to group III. Furthermore, ECC loss in groups I (4.59%±2.57%) and II (6.10%±3.30%) were also statistically lower compared to group III (13.49%±10.55%, P<0.001). From subgroup analysis with the PNS 2, group I showed lower pre-fragmentation time, lower CDE, lower BSS volume used during nucleus removal, and lower ECC loss compared to group II (all P<0.001).

Conclusions: Pre-fragmentation using FLACS may reduce intraoperative ultrasound energy and intraocular manipulations compared to conventional cataract surgery.

Keywords: Cataract; intraocular lens implantation; endothelial cells; femtosecond laser

Submitted Mar 10, 2022. Accepted for publication Nov 09, 2022. Published online Dec 13, 2022.
doi: 10.21037/atm-22-1279
View this article at: https://dx.doi.org/10.21037/atm-22-1279

Introduction

The development of conventional cataract surgery has led to faster recovery of vision through the minimally invasive and small incision technique over the last 50 years. There are two principle techniques used for cataract surgery; phacoemulsification of crystalline lens and extracapsular cataract extraction (ECCE). Phacoemulsification has become the most commonly used surgical procedure because this requires smaller incision than the ECCE. Hence, phacoemulsification is less invasive. However, ultrasonic energy dispensed during phacoemulsification results in endothelial cell loss (1).

Corneal endothelial dysfunction is mainly caused by phacoemulsification (2). In the United States, approximately 4 million cataract surgeries are performed each year, and approximately 4,500 keratoplasties are performed to treat corneal edema after cataract surgery, accounting for 9% of annual keratoplasty (3). Thus, several techniques to reduce the intensity of the ultrasound energy during phacoemulsification have been developed to decrease endothelial cell loss including "divide and conquer", "stop and chop", phacochop, and pre-phaco-chop nucleofractis. In addition, the development of viscoelastic devices has facilitated the use of a soft-shell technique to lessen endothelial cell density loss after cataract surgery (4,5). The introduction of a torsional stroke at the tip has reduced thermal dissipation by approximately one-third comparing to standard tips (6). Phacoemulsification with a bevel-down phaco tip minimizes energy transfer to the corneal endothelium (7,8).

An advanced surgical technique using a femtosecond (FS) laser could be the next stage in addressing this problem. The lens pre-fragmentation procedure is one of the steps in the femtosecond laser-assisted cataract surgery (FLACS) system allowing a decrease of used ultrasound energy and intraocular manipulation. There have been several reports on the advantages of FLACS in terms of improving wound architecture, increasing surgery precision, increasing anterior capsulotomy reproducibility, decreasing tissue damage collateral, and decreasing ultrasound power requirements (9-14). A commercially available FS laser system, i.e., the Catalys® Precision Laser System (Abbott Medical Optics Inc., IL, USA) has a lens fragmentation and softening function during lens pre-fragmentation during cataract surgery. It has three segmentation patterns determining how the lens is divided; quadrant, sextant, and octant. A lens softening process can also be added to the individual segmentation patterns.

There have been some reports on the effects of the lens softening procedure during pre-fragmentation. Most of the published reports have mainly focused on the analysis of surgical parameters including effective phacoemulsification time (EPT) or cumulative dissipated energy (CDE) (15-18). Here, this study aimed to prospectively compare pre-fragmentation patterns for FLACS and conventional cataract surgery in terms of both surgical parameters and the safety of corneal endothelial cells. We present the following article in accordance with the TREND reporting checklist (available at https://atm.amegroups.com/article/view/10.21037/atm-22-1279/rc).

Methods

Subjects

This prospective single-center non-randomized clinical trial was performed by a single surgeon at Seoul St. Mary's Hospital. The inclusion criteria were cataract patients without corneal opacities interfering with both optical coherence tomography (OCT) imaging and laser ablation. Patients with small palpebral fissures or small pupil (5 mm in diameter after dilation) were not included. Patients with zonular weakness were also excluded from this study. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study protocol was reviewed and approved by the Seoul St. Mary's Hospital Institutional Review Board (No. KC13DISI0534). Informed consent was obtained from all patients.

As the surgical procedures of FLACS and conventional cataract surgery were clearly differed between them and the measurement outcomes in the present study was not affected by patients' compliance after the surgery, the randomization was not needed to perform the present study. Additionally, considering ethical aspect, each patient decided in terms of the surgical procedures whether they were performed the surgery using FLACS or not. As a result, 89 eyes from 89 patients were enrolled in this study.

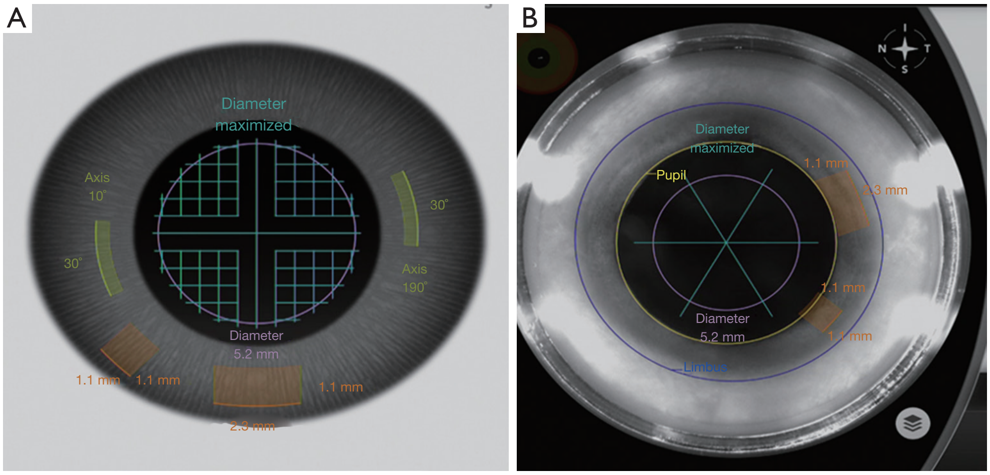

Figure 1 The lens was fragmented using a quadrant segmentation pattern with lens softening, with a 500-μm grid spacing (A) and sextant segmentation without softening procedure (B).

Fifty-three were treated using FLACS (groups I and II) and 36 (group III) with the conventional manual technique. Of the 53 eyes treated by FLACS, 31 eyes were treated using the quadrant pattern with the softening process during lens fragmentation (group I), and 22 eyes were treated using the sextant pattern without softening (group II).

Preoperative examination

The preoperative ocular examination included keratometry, anterior chamber depth (ACD), and axial length to determine intraocular lens power. The abnormal findings were examined with a slit lamp (Huvitz, South Korea) evaluation. The Scheimpflug images for each eye were obtained in all subjects using a Pentacam® (Oculus, Wetzlar, Germany) after the dilation of pupil. The area of interest based on an estimate of nuclear lens density was manually selected as an ellipsoidal shape to encompass as much of the lens nucleus as possible. The automatically estimated value of the nucleus density was expressed as a percentage and graded with pentacam nuclear staging (PNS) from 0 to 5 (19,20). PNS was selected as the method to objectively evaluate the lens density in this study. All patients included in the surgery had a nuclear grade of PNS 0, 1, and 2. Preoperative endothelial cell count (ECC) was also measured using the Keeler Konan specular microscope (Konan, Japan).

Outcome measurements

Total phacoemulsification time (TPT), CDE, and the total volume of balanced salt solution (BSS) used were measured intraoperatively. Additionally, the volume of BSS used during nucleus removal, cortex removal, and viscoelastic removal were recorded, respectively. At 2 months after the surgery, best corrected visual acuity (BCVA, logMAR) and ECC were measured. The ECC loss over a 2-month period was calculated using the following formula, which estimated the corneal endothelial cell damage caused by cataract surgery.

$$\text{Loss of ECC}(\%) = \frac{\text{ECCpre} - \text{ECCpost}}{\text{ECCpre}} \quad [1]$$

Surgical technique

The cataract surgery was performed using either the Catalys® Precision Laser System or a conventional manual technique. The Catalys® Precision Laser System was used for clear corneal incision, anterior capsulotomy, lens fragmentation, and arcuate incision when required. Under the topical anesthesia using 0.5% paracrine hydrochloride (Alcaine®, Alcon Laboratories, Inc., Fort Worth, TX, USA), the patients' eye was immobilized using the liquid immersion interface technique which helps prevent incomplete capsulotomy and the complications related to an increase in intraocular pressure, such as optic nerve damage and retinal vascular occlusion (21). The pre-fragmentation was performed with a 500-μm grid spacing created by scanning, using a FS laser in softening mode. *Figure 1A,1B* showed the lens fragmentation patterns that were used in group I and II, respectively.

Table 1 Characteristics of patients who underwent either FLACS or conventional cataract surgery

Lens pre-fragmentation method	Quadrant fragmentation with softening group (group I)	Sextant fragmentation group (group II)	Conventional group (group III)	P value*
Number	31	22	36	
Age (years)	63.58±8.42	61.32±8.42	65.42±9.93	0.251
Gender (female)	24 (77.4)	13 (59.1)	23 (63.9)	0.443
Nuclear density graded by Scheimpflug image				0.363
0	9	4	6	
1	17	12	18	
2	5	6	12	
Pre-operative measurements				
Axial length (mm)	23.67±1.14	23.73±1.08	24.07±1.81	0.492
ECD (cells/mm^2)	2,625.2±357.1	2,744.2±563.9	2,763.4±419.5	0.408
ACD (mm)	3.19±0.46	3.20±0.55	3.17±0.52	0.978

The patients who received FLACS were divided into two groups—quadrant fragmentation with softening and sextant fragmentation without softening. Data are presented as mean ± standard deviation or n (%). *, statistical analysis was performed using a one-way ANOVA (significance level; P<0.05). FLACS, femtosecond laser-assisted cataract surgery; ECD, endothelial cell density; ACD, anterior chamber depth; ANOVA, analysis of variance.

After delivery of the laser to the target structures, the primary incision site was opened using a blade (2.2-mm bevel-up metal keratome; Kai) and DisCoVisc® (1.6% hyaluronic acid/4.0% chondroitin sulfate; Alcon Laboratories, Fort Worth, TX, USA) was injected into the anterior chamber. The surgeon grasped the anterior capsule that had already been cut by the FS laser, with a circular shaped forceps (Kelman McPherson Typing; Kyoryoeyetech). If there was evidence of a radial tear or an incomplete capsulorhexis, the anterior capsule was carefully removed in a circular motion. BSS was injected beneath the anterior capsule for hydrodissection, taking care to prevent the rupture of the posterior capsular of the lens. Phacoemulsification with torsional mode was performed using the INFINITI® Vision System (Alcon Laboratories, Inc., Fort Worth, TX, USA) and 30° reverse Kelman 0.9 mm Mini-flared phaco tip. Then any remnant cortical material was removed using an I&A probe and followed by intraocular lens implantation into the capsular bag. The patients were prescribed topical antibiotics and steroid eye drops 4 times daily for the following 2 months.

Statistical analysis

All statistical analyses were performed using SPSS software (Version 18.0; SPSS, Inc., Chicago, IL, USA) with the level of statistical significance set at P<0.05 which was two-sided. One-way analysis of variance (ANOVA) for continuous variables and Chi-square test for categorical variables confirmed that there was no difference between the three groups with respect to the baseline characteristics. ANOVA was used to compare intra- and post-operative parameters between the three groups divided according to lens fragmentation methods. Subgroup analysis was performed using Kruskal-Wallis test between three groups according to nuclear density of PNS 0, 1, and 2. Then in terms of subgroups which showed the same PNS, post hoc Mann-Whitney tests with a Bonferroni correction was performed between three groups divided according to lens fragmentation methods.

Results

There was no significant difference in age, sex, axial length, endothelial cell density, and ACD between the groups (*Table 1*). The nuclear density grade of these eyes was ranged from PNS 0 to 2. There was also no statistically significant difference between the groups (P=0.363).

Significant differences between the groups were found for the surgical parameters such as TPT (P<0.001), CDE

Table 2 Summary of surgical parameter values during cataract surgery according to the lens pre-fragmentation methods

Lens pre-fragmentation method	Quadrant fragmentation with softening group (group I)	Sextant fragmentation group (group II)	Conventional group (group III)	P value*
Femtosecond laser ablation				
Fragmentation time (seconds)	43.50±5.34	68.34±12.17	–	<0.001
Phacoemulsification				
TPT (seconds)	16.94±11.09	20.36±11.93	46.23±47.15	<0.001
CDE (percent-seconds)	4.63±3.27	6.30±3.56	14.01±13.02	<0.001
Used BSS volume (mL)	52.97±17.37	61.55±14.98	93.17±45.81	<0.001
Nucleus removal (mL)	30.68±15.23	36.45±13.02	66.03±40.00	<0.001
Cortex removal (mL)	17.84±6.78	19.86±6.43	18.28±14.58	0.780
Viscoelastic removal (mL)	4.45±2.11	5.23±2.96	8.89±16.73	0.213

Data are presented as mean ± standard deviation. *, statistical analysis was performed using a one-way ANOVA (significance level; P<0.05). TPT, total phacoemulsification time; CDE, cumulative dissipated energy; BSS, balanced salt solution; ANOVA, analysis of variance.

Table 3 Summary of post-operative outcomes after cataract surgery according to lens pre-fragmentation methods

Lens pre-fragmentation method	Quadrant fragmentation with softening group (group I)	Sextant fragmentation group (group II)	Conventional group (group III)	P value*
Refractive value and visual outcome				
MAE (D)	0.30±0.24	0.34±0.22	0.42±0.26	<0.001
BCVA (logMAR)	0.05±0.09	0.06±0.11	0.06±0.10	0.985
Endothelial cell loss				
Loss of ECC† (%)	4.59±2.57	6.10±3.30	13.49±10.55	<0.001

Data are presented as mean ± standard deviation. *, statistical analysis was performed using a one way ANOVA (significance level; P<0.05). MAE, mean absolute error; BCVA, best corrected visual acuity; ECC, endothelial cell count; ANOVA, analysis of variance.
†, $\text{Loss of ECC}(\%) = \frac{\text{ECCpre - ECCpost}}{\text{ECCpre}}$.

(P<0.001), and BSS used during nucleus removal (P<0.001). TPT was 16.94±11.09, 20.36±11.93, and 46.23±47.15 sec in groups I, II, and III, respectively. CDE was 4.76±3.27, 6.30±3.56, and 14.01±13.02 in groups I, II, and III, respectively (*Table 2*).

There was no significant difference in the visual outcome between three groups (*Table 3*). Loss of ECC (P<0.001) was found to be statistically and significantly different between groups. Loss of ECC was 4.59%±2.57%, 6.10%±3.30%, 13.49%±10.55% in group I, II, and III, respectively.

CDE was compared between three groups divided according to lens fragmentation methods in each subgroup classified by PNS (*Figure 2A*). Post-hoc analysis of CDE between groups showed that group I (P<0.001) and II (P<0.001) had lower CDE values than group III in both PNS 1 and 2. For PNS 2, group I showed lower CDE than group II (P<0.001). The used BSS volume in the process of nucleus removal was lower in group I (P<0.001) and II (P<0.001) than in group III for both PNS 1 and 2 (*Figure 2B*). For PNS 2, group I showed a lower used BSS volume compared to group II (P<0.001). Loss of ECC was lower in group I (P<0.001) and II (P<0.001) than in group III for both PNS 1 and 2 (*Figure 3*). For PNS 2, group I showed lower loss of ECC than group II (P<0.001).

Discussion

In this study, TPT and CDE were reduced in the FLACS

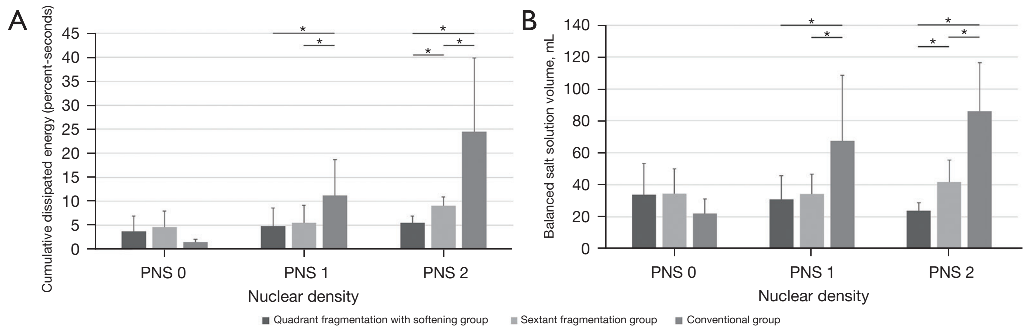

Figure 2 Cumulative dissipated energy (A) and balanced salt solution volume used in nucleus removal step (B). Subgroup analysis for the intraoperative values between three groups according to the nuclear density of PNS calculated from Scheimpflug images. Statistical analysis was performed using Kruskal-Wallis test between three groups in terms of PNS 0, 1, and 2. Then in terms of subgroups which showed the same PNS, post hoc Mann-Whitney tests with a Bonferroni correction was performed between three groups divided according to lens fragmentation methods (*, significance level, P<0.05). PNS, pentacam nucleus staging.

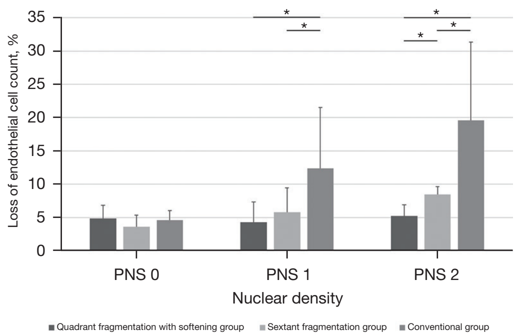

Figure 3 Subgroup analysis for endothelial cell count loss 2 months after cataract surgery compared with pre-surgery. The nucleus density was classified by PNS calculated from Scheimpflug images. Statistical analysis was performed using Kruskal-Wallis test between three groups in terms of PNS 0, 1, and 2. Then, in terms of subgroups which showed the same PNS, post hoc Mann-Whitney tests with a Bonferroni correction was performed between three groups divided by lens fragmentation methods (*, significance level, P<0.05). PNS, pentacam nucleus staging.

group. This was especially evident for the quadrant segmentation with the softening method (group I) when compared with the conventional cataract surgery (group III). This result was consistent with those of previous studies that compared FLACS with the conventional cataract surgery (15-18). Unlike previous studies, this study was performed was analyzed after objectively dividing individual groups based on the nuclear density grade using PNS.

There was no intra- or post-operative complication in any of the groups described in this study. Intraoperative complications become more likely increased as TPT and CDE increase (22-24). The likelihood of endothelial damage can increase with longer TPT and CDE (23,24) and it might lead to postoperative corneal swelling and slower visual recovery. The occurrence of cystoid macular edema can be affected by the ultrasound energy (25). In reducing TPT and CDE by preoperative FS lens fragmentation, these postoperative complications can be prevented (12,22,26).

In terms of reducing TPT, the phaco prechop method introduced by Akahoshi in 1993 was useful in conventional cataract surgery. Elnaby *et al.* (27) reported that the phaco prechop method reduced TPT and total energy and hence, reduced endothelial cell loss. However, performing phaco prechop can be difficult in cases with hard nucleus or weak zonules, and can increase risk of posterior capsular rupture in cases of pseudoexfoliation, trauma, and posterior polar type of cataract. This suggests that in cases where there is a difficulty in performing phaco prechop, FLACS could be a good alternative method (28).

Irrigating fluid can also cause corneal and outer tissue damage (29). FLACS (groups I and II) showed lower BSS volume used during nucleus removal when compared with the conventional cataract surgery group (group III). Additionally, the effect of softening procedure on CDE and used BSS volume was found in dense nucleus such as PNS 2. After lens softening pretreatment especially in soft nucleus, the vacuum may be difficult to completely hold the small size of nuclear fragments on the phaco tip using the peristaltic type of phacoemulsification device which used in this study. For this reason, the requiring volume of BSS showed no difference in the soft nucleus removal between them.

The study was limited to patients with a nuclear density of less than PNS 3. There was a difficulty in performing FLACS for dense nuclear cataract, so we tried to evaluate the surgical parameter and postoperative outcomes from PNS 0 to 2. Another limitation was that groups I and II were performed by different segmentation patterns. Since the sextant pattern is a generally used method when not performing softening procedure in FLACS, it was used in this study.

In summary, the lens fragmentation including the softening procedure, using an appropriate size of grid spacing, with a FS laser has the advantage of reducing CDE especially in cases with dense nucleus. In the softening procedure of the lens, the size of the grid spacing may influence laser ablation time during FS laser treatment. The grid spacing also has an influence on endothelial cell damage because of the amount of micro bubbles that develop during the procedure and the length of ultrasound. Further studies are recommended to establish an appropriate size for the grid spacing by comparing various grid spacing measurements between groups.

FLACS may provide benefits due to decreased ultrasound energy and intraocular manipulations compared with manual cataract surgery. The pre-fragmentation method including the softening procedure in FLACS provided low CDE, low amount of BSS volume used, and decreased ECC loss compared to the conventional cataract surgery.

Acknowledgments

Funding: This work was supported by grants from Basic Science Research Program through the National Research Foundation of Korea funded by the Ministry of Education (No. 2021R1I1A1A01056094).

Footnote

Reporting Checklist: The authors have completed the TREND reporting checklist. Available at https://atm.amegroups.com/article/view/10.21037/atm-22-1279/rc

Data Sharing Statement: Available at https://atm.amegroups.com/article/view/10.21037/atm-22-1279/dss

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://atm.amegroups.com/article/view/10.21037/atm-22-1279/coif). YSY reports that this work was supported by grants from Basic Science Research Program through the National Research Foundation of Korea funded by the Ministry of Education (No. 2021R1I1A1A01056094). The other 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 of integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study protocol was reviewed and approved by the Seoul St. Mary's Hospital Institutional Review Board (No. KC13DISI0534). Informed consent was obtained from all patients.

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Cite this article as: Whang WJ, Yang HJ, Lee SH, Koo MA, Oh HY, Yoo YS, Joo CK. Effect of pre-fragmentation on efficacy and safety for phacoemulsification in femtosecond laser-assisted cataract surgery: a non-randomized clinical trial. Ann Transl Med 2023;11(1):5. doi: 10.21037/atm-22-1279

