Comparison of Surgical Parameters Using Different Lens Fragmentation Patterns in Eyes Undergoing Laser Assisted Cataract Surgery

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ABSTRACT

Purpose: To compare surgical parameters among eyes undergoing laser-assisted cataract surgery (LACS) using different lens fragmentation patterns (LFP).

Methods: Prospective, randomized, unmasked clinical trial. One-hundred eyes underwent LACS and were randomly assigned to 1 of 3 LFP treatment groups: 1) laser capsulotomy only; no lens fragmentation (NLF) (n = 34); 2) three-plane chop (TPC) (n = 33); and, 3) pie-cut pattern (PCP) fragmentation (n = 33). Prechop phacoemulsification (PHACO) was performed on all eyes using the same femtosecond (FS) laser and active fluidics PHACO machine. Main outcome measures: FS laser dock time (seconds), PHACO time (seconds), PHACO power (%), cumulative dissipated energy (CDE) (%-seconds), irrigating fluid volume and operative time.

Results: The 3 treatment groups were comparable in terms of patient age (P = 0.164) and nuclear density (P = 0.669). FS dock time was higher in the PCP group (184.18 ± 25.86) compared to the TPC (145.09 ± 14.15) group (P< 0.001). PHACO time was significantly shorter in the PCP (23.19 ± 17.20 seconds) compared to TPC (35.27 ± 17.70) and NLF (46.15 ± 23.72) groups (P< 0.001). PHACO power was lower in the PCP (11.81 ± 3.71) compared to the NLF (14.41 ± 1.88) and TPC (14.04 ± 2.46) groups (P< 0.001). CDE was lower in the PCP (2.85 ± 2.32) compared to NLF (6.55 ± 3.32) and TPC (6.55 ± 5.45) groups (P<0.001). Fluid volumes and operative times were similar.

Conclusion: LFP can influence PHACO surgical parameters. Extensive fragmentation patterns such as PCP appear to lower PHACO time, power and CDE and may potentially reduce the risk of PHACO related complications.

Keywords: laser-assisted cataract surgery; LACS; phacoemulsification; lens fragmentation

INTRODUCTION

Phacoemulsification (PHACO) is currently the standard of care for cataract surgery in the developed world. Since its introduction in the late 1960s by Kelman [1], PHACO technology has evolved by incorporating improvements in ultrasonic energy delivery [2-4], fluidics [5,6], and instrumentation [7]. Despite these advances, PHACO may still cause vision threatening complications such as corneal endothelial cell (EC) loss, corneal edema, posterior capsular rupture, vitreous loss, and postoperative infection. EC loss may be higher in PHACO compared to extra-capsular cataract extraction (ECCE) when treating higher grade cataracts [8]. The reported range of EC loss varies from 14.5% to 26% in the early days of PHACO [9,10], to as little as 5% with modern PHACO energy modulation software and advanced instrumentation [11].

EC loss is believed to result from heat generated by ultrasonic tips [12], anterior chamber fluid turbulence [13], the impact of cavitation bubbles on the endothelium [14], and reactive oxygen species (free radicals) generated during ultrasonic energy delivery [15-17]. In an attempt to reduce the harmful sequelae of PHACO, the use of laser energy to break up the lens nucleus has been explored. Dodick initially described the use of Nd:YAG and erbium:YAG laser to fragment the lens [18-21]. However, this photolysis technique was not always successful and required conversion to standard ultrasound PHACO in up to 46% of cases [22,23].

Laser-assisted cataract surgery (LACS) uses ultrashort pulse lasers to precisely photodisrupt the crystalline lens [24-26]. Several authors have reported reduction of PHACO time and energy as well as reduction of EC loss among animal and human eyes undergoing laser lens fragmentation (LLF) [27-

32]. These reports consist of a large case series comparing surgical parameters in eyes that underwent conventional PHACO versus LACS [30-32]. There are few randomized clinical trials (RCT) examining the effectiveness of different LACS treatment parameters on PHACO surgical outcomes. Conrad-Hengerer et al reported that using smaller grid softening patterns significantly decreased the amount of effective PHACO time used for cataract surgery [32]. We wanted to compare the effects of using a simple laser chop pattern versus a more extensive chop and lens segmentation pattern on surgical parameters among eyes undergoing (LACS).

PATIENTS AND METHODS

This prospective, randomized, unmasked, clinical trial included 100 consecutive eyes of 100 adults that underwent PHACO surgery at an ambulatory surgical center (Peregrine Eye and Laser Institute, Makati, Philippines) from January 1, 2016 to June 30, 2016. Eyes with opacification within 7 mm of the central cornea, pupillary dilation of less than 6 mm in diameter, zonular weakness, and white cataracts were excluded. The study protocol and informed consent forms were reviewed and approved by an independent review board (Peregrine Eye and Laser Institute - Institutional Review Board, Makati City, Philippines). Potential patients were given an option to enter the study and undergo FS laser treatment with the FS laser cost assumed by Peregrine Eye and Laser Institute. The cost of PHACO surgery and intraocular lens was covered by the patient or their health insurance provider. All patients provided a signed informed consent prior to the start of study procedures.

Diagnostic Procedures

Patient age was recorded. For objective assessment of cataract density, Scheimpflug images were obtained (Pentacam HR, Oculus Optikgerate GmbH, Wetzlar, Germany) under pupil dilatation with 0.5% phenylephrine/tropicamide drops (Sanmyd, Santen, Osaka, Japan). All images were obtained in a consistent environment using the same device, after equipment calibration. The operator visualized a real-time image of the patient's eye on a computer screen and manually focused and aligned the image. The automatic release mode was employed to reduce operator-dependent variables. In this mode, the instrument automatically determined the correct focus and alignment with the corneal apex and then obtained a scan.

The Pentacam Scheimpflug lens densitometry method analyses blue light-scattering intensity of the different lens layers to grade nuclear density objectively. On the three-dimensional plot of the anterior segment with each section running through the corneal vertex, the required lens density was taken as the mean value on the image at 45 degrees in both eyes, using the traditional lens density assessment function available in the software Pentacam Nuclear Staging (PNS) software. In cases in which the image could not be obtained at 45 degrees, the image with better lens visualization was selected. The numerical nuclear density for each was recorded.

Randomization Procedure:

On the day of the surgery, each eye was assigned to receive 1 of 3 treatments based on the results of an online true random number generator (www.random.org) which generates random numbers based on atmospheric noise. Just prior to LACS surgery, the true random number generator assigned "1", "2", or "3" to each eye. The eyes then received the corresponding treatment as follows: (1) laser capsulotomy only, no lens fragmentation (NLF); (2) capsulotomy with 3-plane chop (TPC); or, (3) capsulotomy with pie-cut pattern fragmentation (PCP). Surgical microscope views of each group are shown in Figure 1.

Femtosecond laser procedure

For eyes assigned to undergo LACS, the study eye was docked to the FS laser (Lensar, Orlando, FL) via a suction ring and a non-applanating, index-matching patient interface device. The anterior segment was imaged using the FS laser's built-in high resolution, variable scan rate, augmented reality imaging system. The FS laser was then used to create a 5.25 mm, optical axis-centered (centered on the capsular bag), anterior capsulotomy followed by LLF according to the assigned treatment group (TPC or PCP), and finally, a 3-plane, 2.4 mm wide, temporal, clear corneal incision. Dock time was measured in seconds, from the onset of suction to the removal of the suction ring. The laser energy settings are provided in Table 1.

Phacoemulsification Procedure

All surgeries were completed by a single surgeon (HSU) using the same PHACO machine and PHACO tip (Centurion Vision System, Alcon Surgical, Ft. Worth, TX). After aseptic prepping and draping, the surgeon used a 1.2 mm keratome to create a side port through which unpreserved lidocaine 2% and epinephrine and the ophthalmic viscoelastic device (OVD) (Discovisc, Alcon Surgical, Ft Worth, TX) were sequentially injected into the anterior chamber. A Sinskey hook was used to open the 2.4 mm, 3-plane, laser-created, clear corneal incisions. Capsular forceps were used to remove the capsular button. Careful hydrodissection and hydrodelineation were performed. Coaxial PHACO was then performed using a standard 3-plane, prechop technique. An acrylic IOL was implanted into the capsular bag. At the end of surgery, PHACO time (seconds), PHACO energy (%), CDE (%-seconds), and utilized irrigation fluid (milliliters) were recorded from the PHACO machine screen.

The main outcome measures were: age, nuclear density grading, dock time, PHACO time, PHACO power, cumulative dissipative energy (CDE), irrigating fluid volume, PHACO operative time (minutes), and adverse events. In an effort to avoid confounding the analysis of operative times, we did not create laser side port incisions because of the large variability in ease and duration of opening side port incisions.

Sample Size Calculation

Based on a pilot study, we determined that the mean CDE, using a Centurion machine to perform conventional PHACO, was 8.6 ± 3.45 %-seconds. To detect a 33.3% decrease in CDE at a 5% level of significance, we used the formula for a sample size of three means (sample size = 22s2/d2) to determine the per group sample size. Applying the results from our pilot study, the study sample size was calculated to be: 22 (3.45)2/ (2.86)2 +1 = 33.0 per group.

Statistical Analysis

Data obtained was carefully recorded and analyzed using SPSS version 17.0. Statistical significance was set at 95% confidence intervals, i.e., at a p-value of <0.05. For categorical variables such as nuclear sclerosis grading, the Chi-square test was used. For comparison of means, one-way analysis of variance was used.

RESULTS

The three treatment groups were comparable in terms of patient age (P=0.164) and distribution of cataracts according to nuclear density grading (P= 0.669). The FS dock time was higher in the PCP group (184.18 ± 25.86) compared to the TPC (145.09 ± 14.15 seconds) group (P< 0.001).

PHACO time was significantly shorter in the PCP (23.19 ± 17.20 seconds) compared to TPC (35.27 ± 17.70) and NLF (46.15 ± 23.72) groups (P<0.001). PHACO power was significantly lower in the PCP (11.81 ± 3.71 %) compared to the NLF (14.41 ± 1.88) and TPC (14.04 % ± 2.46) groups (P< 0.001). And, CDE was significantly lower in the PCP (2.85 ± 2.32 %-seconds) compared to NLF (6.55 ± 3.32) and TPC (6.55 ± 5.45) groups (P<0.001).

Fluid volumes (P = 0.887) and operative times (P = 0.619) were similar in all 3 groups. No adverse events were observed among all groups. (Table 1)

DISCUSSION

Minimizing the amount of ultrasonic energy used during cataract surgery reduces anterior chamber turbulence, cavitation bubbles, temperature rise [12], free radical generation [15-17], endothelial cell damage, anterior chamber inflammation, and ultimately, promotes surgical recovery. In LACS, ultra-short pulse lasers fragment the lens prior to cataract surgery, softening the cataract and reducing the energy requirement for nuclear disassembly. However, only a few controlled studies have reported the efficacy of FS laser lens fragmentation for reducing the PHACO energy needed for nuclear disassembly [32].

Modern PHACO machines use sophisticated control software that also measure PHACO power and PHACO time in order to determine absolute energy delivery. In this study, the CDE was calculated by the system software and accounted for utilized torsional and longitudinal PHACO energy, energy modulation, and the percentage of maximal PHACO energy. Together, this information provides the best measure of total energy delivered during the surgery. To determine the effect of laser lens fragmentation, comparison of the PHACO energy used for laser-treated eyes with an untreated control (NLF) group using the same FS laser and PHACO equipment is perhaps the most valid comparison. Because of randomized treatment assignment, a strength of this study is that the 3 treatment groups were comparable in terms of nuclear density.

FS lasers are capable of cutting tissues and may complement PHACO systems to improve the energy efficiency of nuclear disassembly. This study has clearly demonstrated that LLF significantly reduces the amount of ultrasound energy needed for nuclear disassembly. Furthermore, the results demonstrate that the amount of ultrasonic energy reduction is influenced by the type or extent of laser lens fragmentation pattern. The more extensive the fragmentation pattern applied, the less ultrasonic energy is needed for nuclear disassembly. This energy reduction is achieved without increasing irrigation fluid volumes or operative times.

Regarding safety, while substitution with laser energy may reduce ocular exposure to the detrimental effects of PHACO energy, it is important to ensure laser application does not introduce other adverse effects. FS lasers have been used in refractive surgery for many years, and there is no evidence that laser treatment within the cornea has significant effects on endothelium morphology [33,34]. Concern may extend to the effects on the retina since a proportion of the incident energy may pass beyond the structures being treated. The damage may be due to temperature rise, phototoxic effects, or both [35,36]. Experimentation has determined thresholds for retinal damage and calculations of the maximum exposure of retinal tissues to laser radiation passing from the anterior eye during LAC and LLF have been made to ensure that thresholds are not breached [37-39].

In a recently published, non-randomized comparative study, Al-Mohtaseb et al reported that compared to conventional PHACO, LACS treatment significantly decreased the amount of CDE by 33%, and endothelial cell loss by 22.5% [40]. In a similar study, Yesilirmak et al examined the effectiveness of LACS treatment for reducing CDE when different PHACO machines were used. They reported a reduction of CDE by 33% among eyes undergoing LACS and PHACO when an active-fluidics PHACO machine was used compared to a reduction of CDE by 39% when a gravity-fluidics PHACO machine was used [41]. In this study, we observed a reduction of CDE by 11% using a TPC pattern and by 56% when using the more extensive PCP.

There is currently no standard lens fragmentation pattern that all surgeons utilize during LACS treatment. Some surgeons do not use lens fragmentation but only restrict laser application to capsulotomy; some only use the laser to create planar chops to section the nucleus into a few large fragments. Others utilize full fragmentation patterns that divide the nucleus into numerous small fragments. Still, others use a combination of treatment patterns. Theoretically, more extensive fragmentation, (eg. PCP pattern) would lead to the greatest reduction in required energy for nuclear disassembly. Therefore, studies to determine the efficiency of LLF for nuclear disassembly should ideally take into consideration the type of LLF pattern used as well as nuclear density grading, which has been demonstrated to influence the amount of PHACO energy utilization [32,42]. Compared to the TPC pattern, PCP application requires a small increase in FS dock time due to additional time needed to complete the more extensive laser treatment pattern. While this, approximately 20 second, additional laser treatment time does not significantly increase patient discomfort nor total procedural time, the extra period does provide a small window for inadvertent undocking among restless patients. It is likely that future femtosecond laser software of hardware upgrades will result in faster data processing and shorten the additional time it takes to complete the PCP pattern and limit the risk of intraoperative laser undocking.

The limitations of the present study include small sample size and having a single, expert surgeon perform all the surgeries with a single PHACO technique and PHACO machine. These results may not be generalizable to other surgeons, FS laser machines, nor PHACO techniques or machines. Due to the small numbers of patients, we could not perform subgroup analysis per nuclear density grading. Future studies should include surgeons of different skill levels and the use of different PHACO techniques and FS laser machines. Furthermore, as cataracts are of different size and nuclear density, future research should be directed towards customizing LLF pattern to specific cataract types and densities. One shortcoming is that we lack long term endothelial cell count follow up.

The results from this study suggest that the type of lens fragmentation pattern used during LACS influences the amount of ultrasonic energy used during PHACO cataract surgery. Appropriate selection of an LLF pattern can improve surgical efficiency and potentially reduce the risks for surgical complications. These results can also guide manufacturers and surgeons in optimizing LACS technology by customizing treatment patterns to individual cataracts.

COMPLIANCE WITH ETHICAL STANDARDS

Conflict of Interest: Drs. Harvey Uy and Sunil Shah have received research grants from LENSAR, Inc Dr. Raquel Gil-Cazorla was a former employee of LENSAR, Inc. The authors report no other conflict of interest.

Ethical Approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent: Informed consent was obtained from all individual participants included in the study.

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FIGURES

Figure 1A: Surgical microscope view of femtosecond laser restricted to capsulotomy creation without lens fragmentation (Group 1).

Figure 1B: Surgical microscope view of femtosecond laser treated cataract demonstrating three-plane chop pattern (Group 2).

Figure 1C: Surgical microscope view of femtosecond laser treated cataract demonstrating 32-segment, pie-cut pattern lens fragmentation (Group 3).

Table 1: Patient demographics and surgical parameters in eyes receiving different lens fragmentation patterns during laser-assisted cataract surgery

Figure 1a

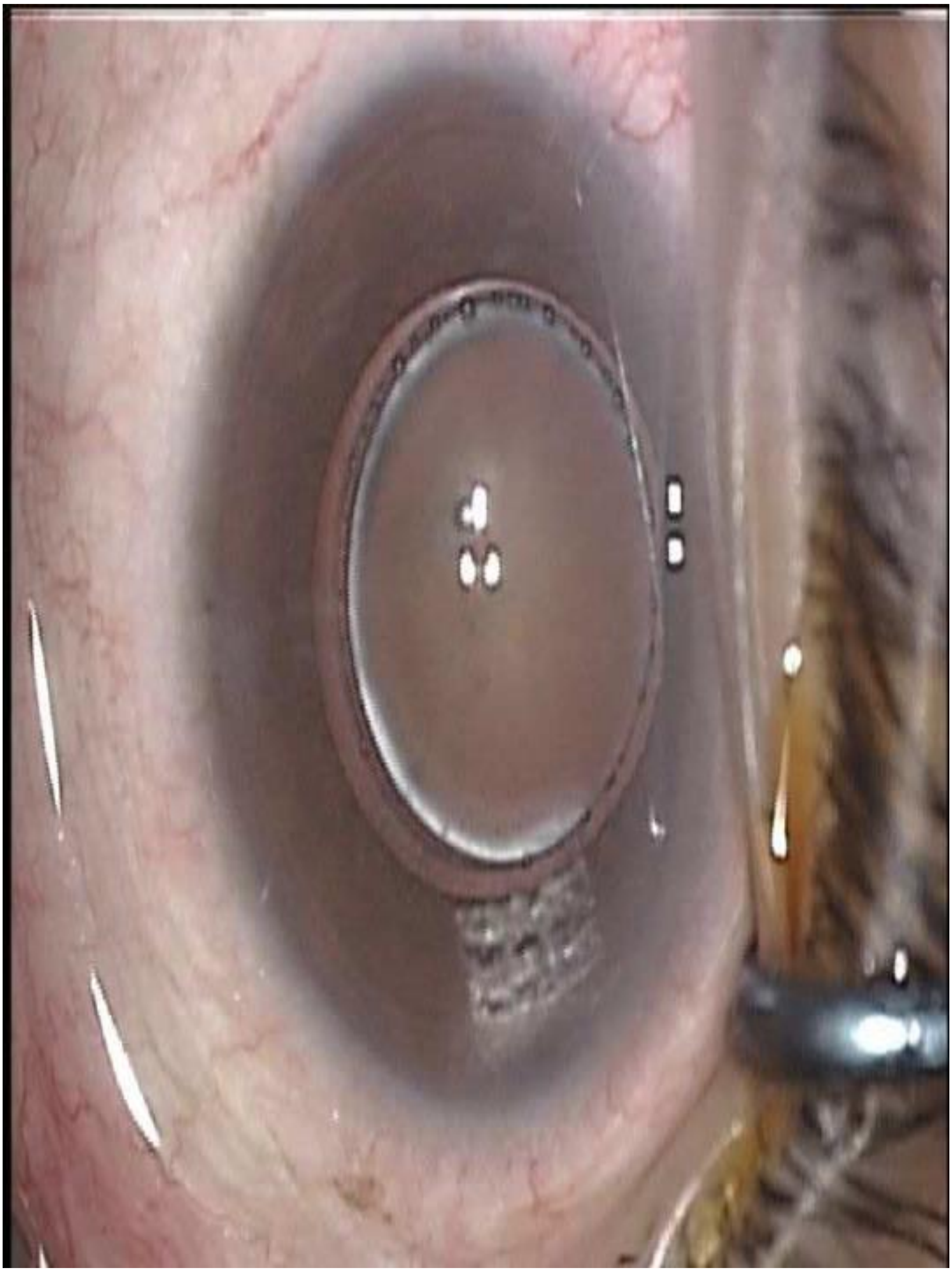

Figure 1b

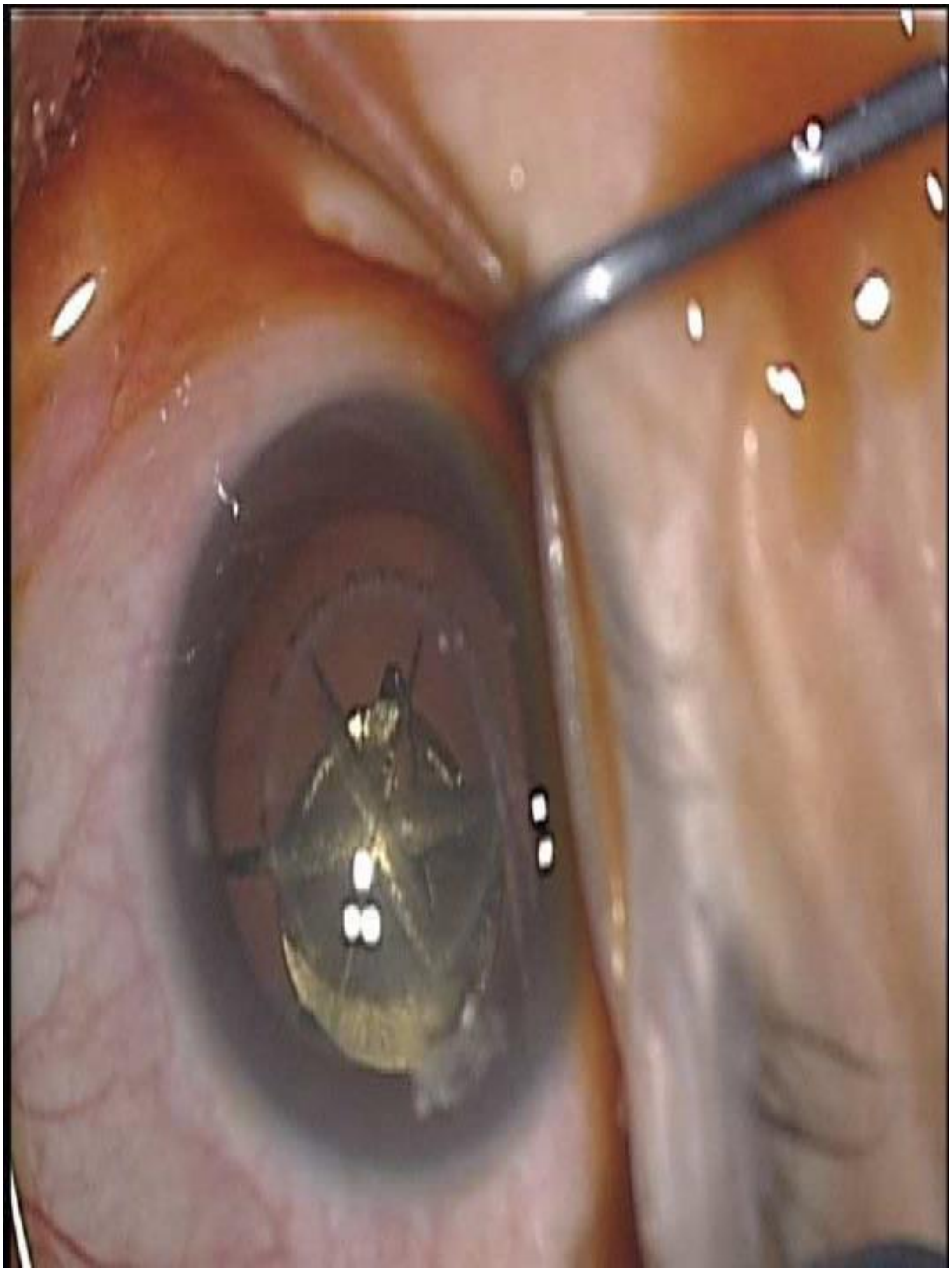

Figure 1c

Table 1: Patient demographics and surgical parameters in eyes receiving different lens fragmentation patterns during laser-assisted cataract surgery.

Table 1: Patient demographics and surgical parameters in eyes receiving different lens fragmentation patterns during laser-assisted cataract surgery.

PARAMETER	**NO LENS FRAGMENTATION Mean ± SD (%)**	**THREE-PLANE CHOP Mean ± SD (%)**	**PIE-CUT PATTERN FRAGMENTATION Mean ± SD (%)**	**P-VALUE***
AGE	70.15 ± 8.49	67.41 ± 9.71	66.36 ± 7.00	0.164
NS GRADE				0.669
GRADE 0	7 (20.6%)	5 (15.2%)	6 (18.2%)	
GRADE 1	18 (52.9%)	18 (54.5%)	18 (54.5%)	
GRADE 2	9 (26.5%)	7 (21.2%)	8 (24.2%)	
GRADE 3	0	3 (9.1%)	1 (3.0%)	
DOCK TIME	N/A	145.56 ± 14.11	184.18 ± 25.86	<0.001
ENERGY	N/A	10.00 ± 0.0	10.00 ± 0.0	N/A
PE TIME	46.15 ± 23.72	35.60 ± 18.82	23.19 ± 17.20	<0.001
PE POWER	14.41 ± 1.88	14.15 ± 2.51	11.81 ± 3.71	<0.001
CDE	6.55 ± 3.32	6.64 ± 5.51	2.85 ± 2.32	<0.001
IRRIGATION FLUID	55.18 ± 21.53	53.78 ± 24.96	52.73 ± 14.84	0.887
OR TIME	10.09 ± 1.40	10.53 ± 2.08	10.30 ± 1.43	0.619

*Legend: NS: nuclear sclerosis grading; PE: phacoemulsification; CDE: cumulative dissipated energy; OR: operative.

**Statistical program used SPSS version 17.0. For categorical variables (e.g NS grade, Seal) Chi-square test was used. For comparison of means, One-Way Anova was used.