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Research Article

Nanosecond Laser and Phacoemulsification Cataract Surgery: Comparison of Intraoperative Parameters and Post-Surgery Outcomes

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Abstract

Background/Aim: To evaluate corneal tissue trauma and effectiveness of cataract surgery using the nanolaser (NL) photofragmentation technique compared to phacoemulsification (US).

Methods: This prospective, randomized, double-masked, clinical interventional study was approved by the regional ethics committee (Aktenzeichen: F - 2013 - 094) and was conducted at the Department of Ophthalmology, Charlottenklinik, Stuttgart, Germany. Sixty-eight consecutive eyes were enrolled and randomized into two groups that underwent cataract surgery using NL or US. The main outcome measure was corneal endothelial cell loss (ECL) at 84 days. Secondary intraoperative (fluidics, effective phacoemulsification/photofragmentation time (EPT), and energy used) and post-operative (central corneal thickness, uncorrected visual acuity, and distance corrected visual acuity) outcome measurements were also evaluated.

Results: Between-group differences in uncorrected and corrected distance visual acuity were not significantly significant. Postoperatively, there were no between-group differences in the endothelial cell count. The largest decrement of endothelial cell count compared to preoperative values was observed in the US group after seven days and after 30 days in the NL group. Statistically significant differences in the central corneal thickness were not observed. The mean EPT was significantly lower in US (59.7 ± 57.0 sec) than in NL (138.7 ± 68.8 sec) ($p < 0.001$). There was a significant difference in the mean energy consumption between the two groups (38.5 ± 29.9J and 1.2 ± 0.7J, respectively) ($p < 0.001$). The difference in fluidics (33.1 ± 37.2 ml and 54.9 ± 30.6 ml, respectively) was statistically significant ($p = 0.015$).

Conclusion: The NL procedures, although requiring a longer EPT and more fluidics, were effective in cataract removal releasing less energy in the eye. It also resulted in an ECL of 3.5% compared to 7.3% with US.

Keywords: *Cataract Surgery; Phaco Energy; Phacoemulsification; Nanosecond Laser; Corneal Endothelial Cell Loss*

Abbreviations

NL: Nanolaser; US: Phacoemulsification (Ultrasound); ECL: Endothelial Cell Loss; EPT: Effective Phacoemulsification/ Photofragmentation Time; Nd:YAG: Neodymium:YAG; ECC: Endothelial Cell Count; GS: Gangolf Sauder; IOP: Intra Ocular Pressure; AL: Axial Length; ACD: Anterior Chamber Depth; CT: Corneal Thickness; LOCS III: Lens Opacities Classification System III; NO: Nuclear Opacity; CCC: Continuous Curvilinear Capsulorhexis; CE: Conformité Européenne; FDA: Food and Drug Administration; UDVA: Uncorrected Distance Visual Acuity; CDVA: Corrected Distance Visual Acuity

Introduction

Most individuals think vision is important for overall health and nearly half rate vision loss is the worst health outcome [1]. Globally cataract is the second most common cause of visual impairment and the first cause of reversible vision loss [2]. Thus, cataract surgery is one of the most frequently performed surgical procedures in many developed countries. Currently, cataract surgery of today is far from perfect and continues to present challenges and risks. Given the large number of procedures performed worldwide, even minor improvements in outcome would have a significant impact.

Ultrasound (US) phacoemulsification has been continuously developed and refined since it was first used in 1967 [3]. Today it represents the method of choice for the effective removal of cataracts.

Progressing evolution of the ophthalmological laser has made the use of systems, such as nanosecond laser, usable in cataract surgery. Since the first report of "phacolysis of a human cataractous lens" using a neodymium:YAG (Nd:YAG) laser in 1991 [4], this technology has evolved immensely over the last decades. Derived from experience with the Nd:YAG laser capsulotomy [5], the Dodick photolysis is based on the physical principles of plasma formation and shock-wave generation from the laser pulse hitting a titanium plate, which are used for fragmentation of the lens nucleus of cataract patients (Figure 1).

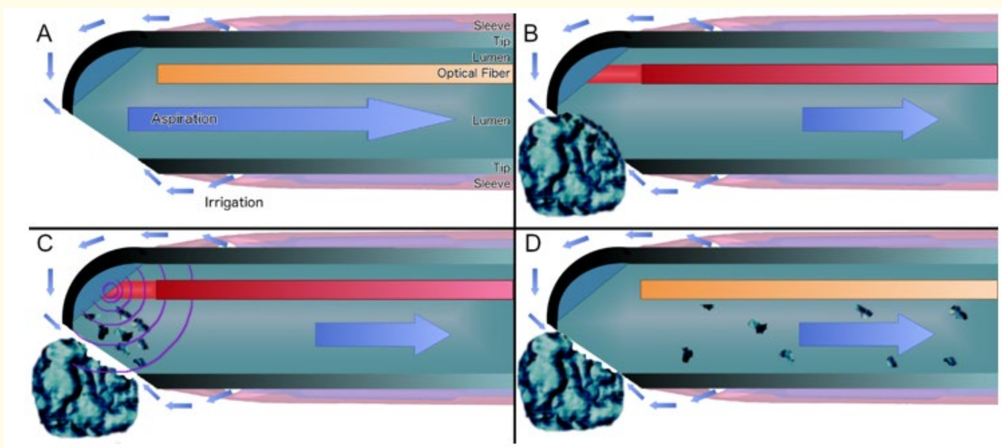

Figure 1: *Schematic diagram of the nanolaser photofragmentation technique.*

A: The tip of the handpiece has a similar design as the phacoemulsification tip except for the optical fiber that carries the laser pulse to the titanium plate. B: once the opening is in contact with the cataract, the laser pulse is activated via the phaco system foot switch. C: When the pulse strikes the titanium plate a shock wave is created that fragments the cataract. D: The fragments are then removed with aspiration.

The initial implementations suffered from a lack of holding ability when the shock wave reached the cataract fragments positioned in front of the opening. The evolution of lasers, and in particular the q-switch that determines the time (nanoseconds) required to reach peak laser power output, has resulted in a greater holding ability and a greater photofragmentation capacity [6]. Currently, this technique has the potential of lowering the amount of energy required for the photolysis process [7], reducing/eliminating corneal thermal damage related to phacoemulsification[8,9,] and reducing potential corneal endothelial cell loss [8,9].

Aim of the Study

This study aimed to compare intraoperative effectiveness and postoperative tissue trauma after using the nanosecond laser technique with the results obtained with conventional manual phacoemulsification cataract surgery.

Materials and Methods

A prospective randomized double-masked interventional trial was performed between March 2014 and March 2015. Recruitment and all surgical procedures were performed at the Department of Ophthalmology at the Charlottenklinik in Stuttgart, Germany. This study conformed to the tenets of the Declaration of Helsinki and was approved by the Landesärztekammer Baden-Württemberg Koerperschaft des Offentlichen Rechts Ethikkommission (Aktenzeichen: F - 2013 - 094) (Germany). Informed written consent was obtained from all patients before enrollment.

Sample size was calculated on the primary outcome measurement, corneal endothelial cell loss, based on detecting a 1.4% difference between groups with a with-in group standard deviation of 140% of the between-group difference. Using a two-tailed hypothesis with $\alpha = 0.05$ and $\beta = 0.20$, 29 patients were required in each group. Considering an estimated dropout rate of 15%, the sample size was set to 34 eyes per group.

Sixty-eight consecutive eyes of 35 cataract patients that met the inclusion and exclusion criteria were enrolled and randomized in two groups. One group received cataract surgery using NL and the other US.

Patients with bilateral visually significant cataracts and a minimum best corrected visual acuity of 20/100 were eligible for inclusion. Exclusion criteria included age younger than 50 years, patients with preexisting low endothelial cell counts (ECC) (< 1800/mm), or clinically detectable pathological alterations of the anterior segment (such as corneal opacities, keratoconus, chronic uveitis, zonular dialysis, pseudoexfoliation syndrome, glaucoma, and diabetes), previous intraocular inflammation or trauma, other ocular pathologies impairing visual function and previous anterior or posterior segment surgery. All surgical procedures were performed by the same experienced surgeon (GS).

Examinations

Preoperatively and 1, 7, 28, and 84 days post-operatively, all patients had a complete eye examination comprising uncorrected distance visual acuity, corrected distance visual acuity, intraocular pressure (IOP) measurement, slit-lamp examination of the anterior and posterior segment with undilated and dilated pupils, respectively. In addition, data were preoperatively collected on axial length (AL), anterior chamber depth (ACD), and biometry measured using partial coherence interferometry (IOLMaster 500 Carl Zeiss Meditec AG). The pre- and post-evaluations were performed in consensus by two experienced ophthalmologists who were blinded to grouping.

Other evaluations included the endothelial cell count (ECC), measured using noncontact specular microscopy (EM-3000, Tomey Corp.) and central corneal thickness (CT), measured with a Scheimpflug imaging system (Pachycam, Oculus Optikgeräte GmbH). Endothelial cell density was calculated by counting the number of cells within an area of interest of 250 x 250 µm. Cell densities are reported as the number of cells per square millimeter (cell/mm^2).

The Lens Opacities Classification System III (LOCS III) was used to classify the cataracts the nuclear opacity (NO) as a measurement of nucleus hardness.

Surgical technique

The surgical protocol for both groups was based on the standard small-incision clear corneal technique. The study eye was dilated, and topical anesthesia was administered repeatedly before the start of the operation. All surgical procedures were performed using standard surgical equipment. The basic steps for both techniques included capsulorhexis, hydrodissection, hydrodelineation, cataract removal, cortical cleanup, and IOL implantation.

Three clear corneal incisions tunnel were created (2.40 mm main incision and two side ports) with the main incision on the steepest corneal meridian. The capsulorhexis was created using the continuous curvilinear capsulorhexis (CCC) technique, followed by hydrodissection and hydrodelineation. In all cases, the residual cortex was removed using bimanual irrigation/aspiration. A Venturi-based vacuum system with maximal intraoperative aspiration set between 250 and 300 mmHg was used. After bimanual cortical cleanup, the capsular bag was inflated with sodium hyaluronate 1.0% (Provisc), and a hydrophobic acrylic IOL (Alcon Surgical) was placed in the capsular bag using an IOL injector. The viscoelastic substance was carefully removed from the anterior chamber and the capsular bag. After the anterior chamber was filled with balanced salt solution, the paracenteses were secured by stromal hydration, no suture was used.

Postoperatively, patients were prescribed topical Moxifloxacin hydrochloride 5.45 mg six times daily for one week as well as dexamethasone 1.0 mg six times daily for four weeks.

Intra-operative parameters included fluidics, EPT, and the total energy released in the eye.

Cataract removal

In the control group, phacoemulsification was performed using a divide-and-conquer approach or phaco-chop technique (phaco system: Pentasys 2, Ruck Company, Aachen, Germany) depending on the lens hardness.

In the NL group an updated laser system (Cetus, A.R.C. Laser GmbH) was used for the cataract extraction. The Cetus nanosecond laser system has Conformité Européenne (CE) approval for clinical use within the European Union and 510K approval from the U.S. Food and Drug Administration (FDA) for clinical use in the United States. This system consists of a base that contains a 1064 nm wavelength Q-switched Nd:YAG laser and an optic fiber that transmits the laser impulse to a handpiece. The generated laser pulses are routed via a flexible 320 µm quartz fiber through the laser handpiece with a pulse energy of 5.5 mJ/pulse and a pulse duration of 7 nanoseconds in a frequency up to 10 Hz. The pulsing photon energy is focused on a titanium plate positioned at a 45-degree angle within the probe tip opening and induces an optical breakdown and plasma formation. This creates a shockwave that emanates from the tip in a cone-like fashion and leads to a fragmentation of the cataract substance. The disrupted particles of the cataract are continuously aspirated out of the eye through the aspiration port located on the same tip using the vacuum of the phaco irrigation/aspiration unit.

Outcome measures

On the day of surgery, the primary endpoint was the effective phacoemulsification/ photofragmentation time (EPT), which was the time required to emulsify and extract the cataractous lens via the phacoemulsification or photofragmentation probe, respectively. Secondary endpoints included the mean phacoemulsification/photofragmentation energy and volume of balanced saline solution used within the eye during the surgery process. After the completion of the cataract removal and intraocular lens (IOL) implantation, all patients were evaluated for the following postoperative parameters at 1 day, 7 days, 30 days and 84 days: corneal endothelial cell count, central corneal thickness, and uncorrected and distance corrected visual acuity (UDVA and CDVA, respectively). However, central corneal thickness was measured only three times after cataract surgery (1 day, 30 days and 84 days postoperative).

Statistical analysis

Statistical analyses were performed using SPSS software (version 21, International Business Machines Corp.). MedCalc Statistical Software version 16 (MedCalc Software Ltd, Ostend, Belgium) was used to determine sample size and to calculate the comparison of standard deviation (F-test). For comparison of clinical characteristics between groups, categorical data were analyzed using the Wilcoxon-Mann-Whitney U test and continuous data using paired or independent sample two-tailed t-test, as appropriate. Patients with missing follow-up visits were excluded from the analysis. Differences were accepted as significant when the p value was less than 0.05.

Results

The study comprised 68 eyes of 35 patients. As seen in the CONSORT Flow Diagram (Figure 2), two patients were lost to follow-up in the NL group and five in the US group. The two groups did not present statistically significant differences in demographic characteristics and clinical characteristics (Table 1), and for cataract grading (Pearson Chi-Squared, p = 0.259). All surgical procedures were completed successfully and none of the patients presented intra- or post-operative complications.

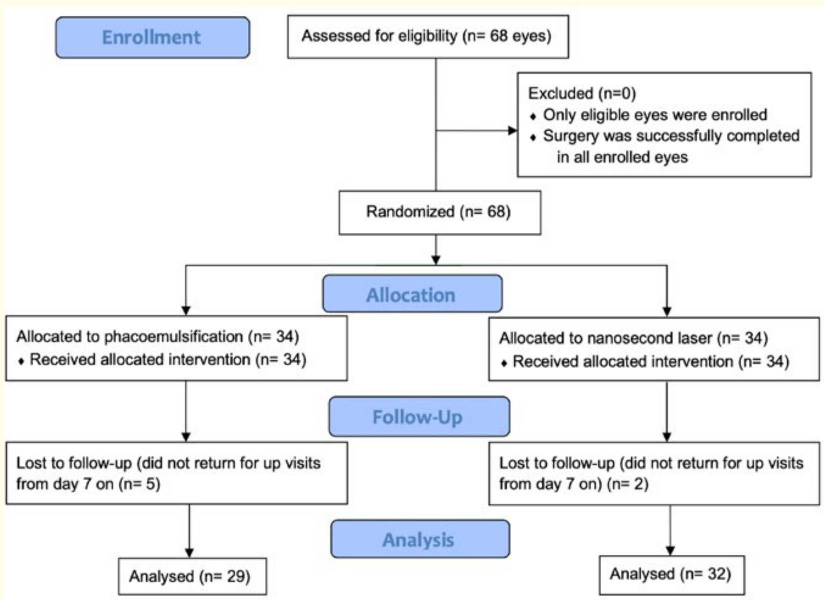

Figure 2: *CONSORT flow diagram.*

	NL	US	p
M/F	15/17	16/13	0.611
Age	62.4 ± 6.4	62.7 ± 7.8	0.349
OD/OS	16/16	13/16	0.442
Pre-operative			
UCVA pre	0.27 ± 0.15	0.24 ± .15	0.406
BCVA pre	0.51 ± 0.15	0.50 ± .12	0.945
IOP (mm Hg pre)	17.7 ± 3.1	17.1 ± 3.6	0.504
One day after surgery			
UCVA 1	0.54 ± 0.21	0.58 ± .26	0.471
BCVA 1	0.76 ± 0.16	0.78 ± .24	0.513
IOP (mm Hg at 1 day)	18.8 ± 5.0	18.4 ± 5.46	0.882

Table 1: *Demographic characteristics and pre- and post-operative clinical characteristics.*

Intraoperative surgical parameters

The between-group difference in fluidics (54.9 ± 30.6 ml for NL and 33.1 ± 37.2 ml for US) was statistically significant ($p = 0.015$) (Figure 3A). The mean EPT was significantly longer for NL (138.7 ± 68.8 sec) than for US (59.7 ± 57.0 sec) ($p < 0.001$) (Figure 3B). Despite this difference, the operating time was less than 14 minutes in all cases. The required energy differed significantly among the two groups ($p < 0.001$) (Figure 3C). NL required on average 213 pulses of 5.5 mJ per pulse (total energy of 1.2 ± 0.7J) and mean energy consumption for US was 41.8 ± 30.9J).

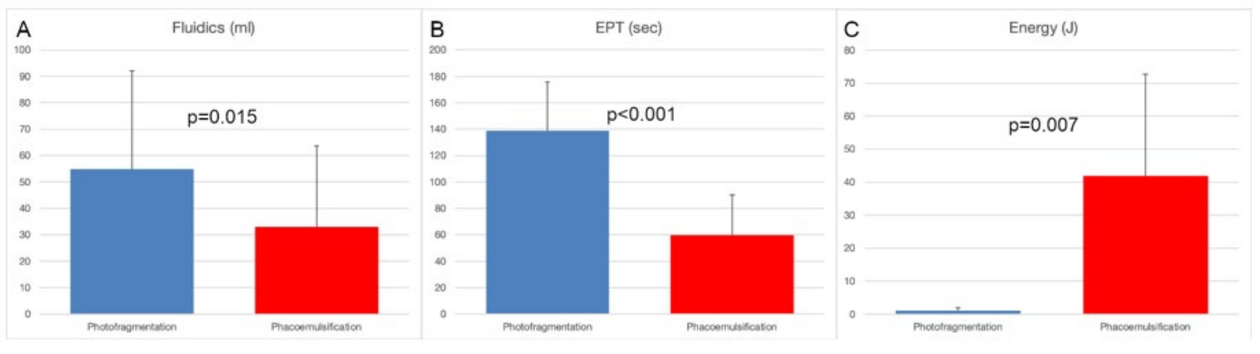

Figure 3: *Intra-operative parameters.*

A: Fluidics B: Effect photofragmentation/phacoemulsification time. C: Energy emitted in the eye during cataract removal. (p values: independent sample two-tailed t-test).

Outcomes in endothelial cell count and central corneal thickness

Preoperatively the two groups did not present statistically significant differences for corneal endothelial cell count and central corneal thickness at the center of the cornea (Figure 4). Postoperatively, the two groups presented significantly significant differences in the endothelial cell count at 7 and 84 days (Figure 4A). The NL group showed statistically ECC at 1, 28, and 84 days compared to pre-operative values and the US group at all time points (Figure 4A). The difference in ECC between the two groups was statistically significant at 27 and 84 days, with the NL group presenting a higher mean (Figure 4A). The percentage loss in ECC at 84 days was lower for the NL group (3.48% ± 10.15) compared to the US group (7.25% ± 15.13). While this difference is not statistically significant, a comparison of the standard deviations (F-test) of the two groups indicated a statistically significant higher variability in the US group.

The two groups did not show statistically significant differences in central corneal thickness at all time points (Figure 4B). Both groups had significantly thicker corneas at 7 days after surgery (Figure 4B).

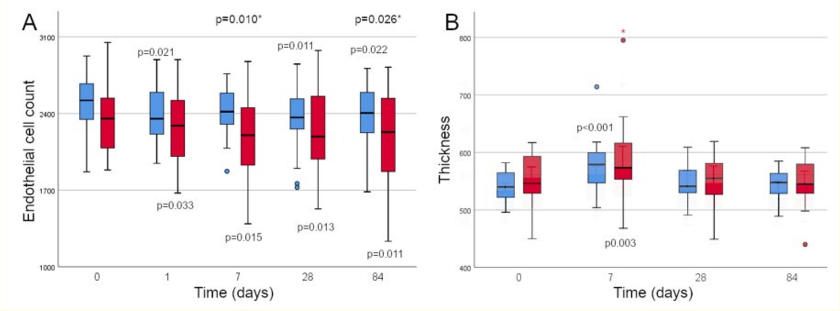

Figure 4: *Post-operative follow-up.*

*A: Endothelial cell counts. B: Central corneal thickness in microns. (p values: two-tailed paired t-test to pre-surgery values. p values with *: Independent sample two-tailed t-test).*

Discussion

In the present prospective, randomized, double masked, clinical interventional study, the postoperative corneal tissue trauma and effectiveness of cataract removal using the NL photofragmentation compared to the well-established US phacoemulsification was evaluated. While the mean fluidics and EPT were significantly lower when using US, NL required a statistically significant lower amount of energy. The corneal thickness reached a maximum after one day and returned to pre-surgery values after 84 days. The maximum endothelial cell loss was observed after one day with NL and after 28 days with US. The overall percentage loss of ECC at 84 days was 108% higher in the US group compared to NL. The former group also showed significantly higher variability in this parameter implicating a lower predictability in outcomes when using US phacoemulsification.

Over the last 50 years, phacoemulsification has evolved becoming the standard of care for patients undergoing cataract extraction in many parts of the industrialized world. The laser photofragmentation technique has also experienced significant evolution since its introduction 30 years ago. Currently, this technique offers a technically new procedure for cataract extraction that in this study yielded a lower efficacy but better safe compared to phacoemulsification.

Laser energy has attracted interest as a means for cataract fragmentation because the design of the tip permits the surgeon to effectively aim the energy where needed, avoiding healthy tissue (endothelial layer of the cornea, iris, etc.) [6]. Also, the risk of exposing the corneal tunnel to increased temperature, even under low or no flow of irrigating solution, is limited since the optic fiber presents a zero loss of energy over its length. Ultrasound, on the other hand, emulsifies the crystalline lens through the direct action of the vibrating phaco needle, via a jackhammer effect sometimes associated with rotational movements. The indirect effects of the cavitation microbubbles induced by these rapid movements produce heat and pressure variations that are important factors in phacoemulsification-induced endothelial cell damage [10]. They also produce hydroxyl free radicals that have a deleterious effect on corneal endothelial cells [10].

Another advantage and contributing factor to the safety of the nanolaser technology is the reduction of intraocular energy necessary for cataract removal. Direct and indirect effects of high energy levels during the fragmentation impair the pump function of endothelial cells thus resulting in corneal swelling. If endothelial cell damage is sufficiently severe, corneal decompensation can occur. In this trial, the mean energy used for cataract extraction performed by nanolaser was 1.2J, while the mean energy required for lens removal with phacoemulsification is 36 times greater than that of photofragmentation with the nanolaser.

The most significant factor for endothelial cell damage and postoperative corneal edema is phacoemulsification/photofragmentati on time. Kannellopoulos., *et al*. reported that the nanolaser system was safe and effective for the removal of cataracts up to grade 3 [7]. Softer nuclei of NO 1 were removed by the photofragmentation technique in a timeframe comparable to that of phacoemulsification. The surgical time for dense nuclei with this new technology was longer so that further improvements in technical-related and surgical-related parameters will be required.

In conclusion, the nanosecond laser cataract surgery has several potential advantages, including a significant reduction in energy and heat release within the eye in comparison to phacoemulsification. But the technique still requires improvement since the photofragmentation time was significantly longer and the consumption of irrigating solution higher than during phacoemulsification.

Considering the 50 years period during which the phacoemulsification technique has been refined, the laser photofragmentation technology already achieves the equivalent or partly better results, despite a much shorter period of development. While the possible future improvements in phacoemulsification will probably be limited, improvements in laser technology are still progressing at a rapid pace. This, alongside the refinement of the handpiece design in terms of the geometric controlled orientation of the energy dispersion and size of the opening, could lead to further improvements in cataract surgery with an increase in patient comfort and reduced recovery time.

Conclusion

Cataract surgery with a nanosecond laser is not generally recognized and unknown among many ophthalmic surgeons. However, it may provide an alternative cataract removal technology in case it can prove to be beneficial in outcomes and safe. Our results of a study comparing traditional ultrasound cataract surgery and nanosecond laser treatment show, that outcomes in visual acuity and central corneal thickness after surgery were comparable, but differences occurred in post op endothelial cell count, which was favorable to the nanosecond laser treatment and treatment time, which was favorable to ultrasound use. We could show that nanosecond laser treatment can be an alternative to ultrasound use, with benefits preserving the endothelium.

In conclusion, while photofragmentation requires a significantly longer EPT and more fluidics to complete, it also requires significantly less energy, resulting in a minor loss of corneal endothelial cells.

Conflict of Interest

The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors. There are no competing interests declared.

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