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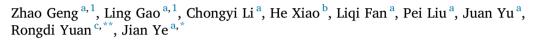


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Full Length Article

The necessity of pretreatment with 0.1% pranoprofen for femtosecond-assisted cataract surgery: A single-center, randomized controlled trial



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ABSTRACT

Purpose: To explore the effect of the variation of pupil diameter (PD) and intraocular pressure (IOP) induced by femtosecond laser treatment on the subsequent phacoemulsfication and intraocular lens implantation. And whether the application of 0.1% pranoprofen could significantly reduce the miosis and increased IOP caused by femtosecond laser treatment in femtosecond laser-assisted cataract surgery (FLACS).

Methods: In this study, patients were pretreated with (trial group) or without (control group) topical 0.1% pranoprofen. The PD and IOP were measured at different time points within 30 min after the completion of the femtosecond laser treatment.

Results: The comparisons of the two groups showed the PD of patients pretreated with 0.1% pranoprofen was significantly larger than that of the control only at 15 min after FLACS (P = 0.046), and there was no significant difference in IOP at any time point (P > 0.05). Neither the ratio of significant miosis (PD ≤ 5 mm) nor intraocular hypertension (IOP ≥ 30 mmHg) was significantly different between the control group (1.72%, 6.67%) and the trial group (1%, 4.17%) (P > 0.05).

Conclusions: The PD and IOP of patients undergoing FLACS showed fluctuations within a small range. The rates of significant miosis and intraocular hypertension are very low, it is safe for surgeons to complete the follow-up procedures within 30 min after femtosecond laser treatment. Pretreatment with 0.1% pranoprofen exerted a slight, albeit significant prophylactic effect preventing pupil miosis. However, it provided only a limited benefit in patients undergoing FLACS without other complications.

1. Introduction

Femtosecond laser technology has been used in cataract surgery since 2009.¹ FLACS has shown several advantages over conventional phacoemulsification, in terms of its high precision in capsulorhexis, better intraocular lens (IOL) centration, shorter phacoemulsification time, better energy efficiency and so on.^{2,3} However, the disadvantages of femtosecond laser technology include increased IOP, miosis, release of the suction ring, subconjunctival hemorrhage, etc.^{4,5} Due to technological advancements and surgical expertise, the release rate of the suction ring and subconjunctive hemorrhage has observably declined. But pupillary constriction and an IOP increase were still accompanied by femtosecond laser treatment.

Although the exact mechanisms of femto-induced miosis and IOP increase are unknown, increasing levels of inflammatory factors such as prostaglandins and interleukins have been reported as independent factors of miosis in femtosecond laser-treated patients.⁶ Pretreatment of topical nonsteroidal anti-inflammatory drugs (NSAIDs) was widely recommended to reduce the risk of intraoperative miosis during FLACS.^{6–8} However, the sole use of NSAIDs does not completely negate

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femtosecond-induced miosis. Previous studies have focused on bromfenac sodium, indomethacin. But, little is known about 0.1% pranoprofen, which is widely used in China.

Significant increase in IOP can cause vascular or rhegmatogenous events.⁹ Previous studies have focused on the variation in IOP during femtosecond laser treatment and concluded that IOP increases significantly during treatment.^{10,11} Possible causes of increased IOP include the application of vacuum suction in femtosecond laser treatment, the increased inflammatory factors and crystallin in the aqueous humor, which may block trabecular meshwork and cause IOP elevation.

Recent studies have focused on miosis and increases in IOP during femtosecond laser treatment,^{11,12} but little is known about the variation of PD and IOP 30 min post-femtosecond laser treatment, which is very important for the subsequent surgery (phacoemulsification). Therefore, the purpose of this study was to observe the variation of PD and IOP in patients pretreated with or without 0.1% pranoprofen within 30 min after femtosecond laser treatment, explore whether the application of 0.1% pranoprofen could significantly reduce the degree of miosis and IOP increase caused by femtosecond laser treatment.

2. Material and methods

2.1. Patients

A prospective single-center randomized controlled study was performed between January 2018 and February 2019. The Clinical registration number is ChiCTR1900021312 (www.chictr.org.cn). Patients who received FLACS at Daping Hospital were recruited. The study conformed to the tenets of the Declaration of Helsinki, and ethics approval was obtained from the Ethics Committee of the Institute of Field Surgery, the Third Affiliated Hospital (Daping Hospital) of the Army Medical University. Informed consent was obtained from all patients.

The inclusion criterion was as follows: aged-related cataract who plan to undergo FLACS, nuclear grade II to IV based on the Lens Opacity Classification System III. The exclusion criteria were as follows: corneal scarring, any previous ocular surgery or trauma, active intraocular inflammation, ocular or systemic use of steroids within 3 months before the preoperative visit, exfoliation syndrome, age-related macular degeneration, uveitis and mechanical intraoperative iris instrument touching or, rupture of posterior capsule damage. Moreover, patients with diabetes mellitus, a history of glaucoma or ocular hypertension were excluded. One eye per patient was included.

Patients who were included in the study underwent a complete ophthalmic evaluation prior to surgery, including slit-lamp biomicroscopy, IOP by handheld applanation tonometry (iCare, TA01i, Finland), uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA), axial length, corneal endothelial count, Bscan ultrasound, macular examination by optical coherence tomography (OCT), and the measurement of IOL power with IOL-Master500.

The patients were randomly divided into two groups: the trial group received 0.1% pranoprofen four times one day prior to surgery, whereas the control group did not receive 0.1% pranoprofen pretreatment. All patients in both groups received 0.4%-levofloxacin (Santen, Japan) four times a day three days prior to surgery and 3 drops of tropicamide 0.5%-phenylephrine (Santen, Japan) 1 h prior to femtosecond laser pretreatment.

2.2. Randomization

Pregenerate a random sequence of numbers from the random number table. Each eligible participant was numbered in order of their study entry, and correspond participant number to the random number generated in advance. If the corresponding random number is odd, the participant will enter the trial group; if it is even, the participant will enter the control group. Retain random allocation scheme data.

2.3. Surgical technique

All surgeries were performed by the same experienced surgeon (JY), and all data were collected by the same experienced surgeon (LQF). The femtosecond laser procedure was performed with LENSAR (LensDoctor Application Version: 10.14.2 (Build 8) with a SoftFit interface (Alcon Laboratories, Inc.). Eyes were anesthetized 30 min before femtosecond laser treatment with 0.25% oxybuprocaine hydrochloride (Santen, Japan). The liquid interface was applied to the planned treatment eye with the patient in the supine position. The interface was then filled with a balanced salt solution (BSS, Alcon Laboratories, Inc.). The imageguidance system then determined the location and dimension of ocular structures. Treatment consisted of anterior capsulotomy and lens fragmentation. Laser adjustments were standardized across all procedures: capsulotomy size 5.5 mm with a pulse energy of 7 μ J, 20 μ m line spacing and 5 µm shot spacing; and lens fragmentation patterned into 3 crosssections with a chop diameter of 4.0 mm with a pulse energy of 10 μ J, 25 µm thick spacing, 20 µm line spacing and 10 µm shot spacing. Phacoemulsification was employed for all patients using a Centurion machine (Alcon Laboratories, Inc.). All IOLs were implanted in the capsular bag. The number of docking attempts, suction time and complications during the procedure were recorded.

2.4. PD and IOP measurements

PD and IOP measurements were recorded at four different time points: before vacuum application in cases with sufficient mydriasis (PD I, IOP I), immediately after the completion of femtosecond laser treatment (PD III, IOP II), 15 min (PD IV, IOP III) and 30 min after the completion of femtosecond laser treatment (PD V, IOP IV). In addition, the PD (PD II) during the femtosecond laser treatment was recorded from the femtosecond laser instrument. Images were provided by a corneal topographer (Cassini, i-Optics BV, Netherlands). The maximum horizontal pupil diameter was measured with the same procedure and ambient brightness (Fig. 1). If the readings differed by more than 0.5 mm, the measurements were repeated. The PD was defined as the mean of at least 2 measurements. The IOP was measured by handheld applanation tonometry (iCare, TA01i, Finland) without a speculum. If the readings differed by more than 2 mmHg, the measurements were repeated. The IOP was defined as the mean of at least two consecutive measurements.

2.5. Statistical analysis

Statistical analysis was performed using Excel 2016 software

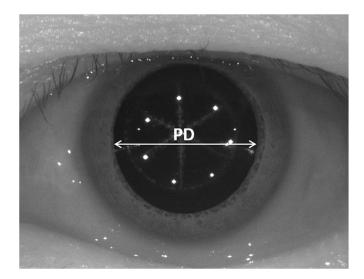


Fig. 1. The maximum horizontal pupil diameter (PD) measured by Cassini.

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(Microsoft Corp) and PASW statistics software 21 (version 21.0.0, SPSS, Inc). Continuous data were expressed as the mean \pm SD and analyzed with repeated measures analysis of variance and independent *t*-test. Categorical data were expressed as ratios and were analyzed with the chi-square test. Differences were considered significant when the *P* value was less than 0.05.

3. Results

3.1. Baseline demographics

This study was based on the test results of 288 eyes (149 right, 139 left) from 288 patients among the 375 patients recruited (Fig. 2). 178 patients were female (61.81%) and 110 were male (38.19%) with an overall mean age of 61 years (range 44–88 years). Table 1 summarizes the patients' baseline demographics. Petechial and subconjunctival hemorrhage was infrequent, and no intraoperative cataract complications were noted.

3.2. Pupil diameter

The PD in both the control group and the trial group showed a tendency to fluctuate instead of exhibiting a continual decrease (Fig. 3). Compared with PD I, the PD during the femtosecond laser treatment (PD II) decreased significantly in both groups (P < 0.05) and then increased slightly at the end of femtosecond laser treatment (PD III) (P > 0.05). The recorded PD of 15mins (PD IV) and 30mins (PD V) after femtosecond

Table 1Demographics of patients (N = 288).

Demographics of patients (iv = 200).					
Parameter	Control	Trial	P Value		
Age (years)	57.98 ± 13.27	59.53 ± 13.05	0.344		
Sex					
Male	41	69	0.710		
Female	71	107			
Eye					
Right	60	89	0.631		
Left	52	87			
Suction time (s)	115.15 ± 30.73	117.26 ± 44.04	0.668		
Ocular hypertension	17	28	1.000		

Continuous data (age, suction time) were analyzed with the independent *t*-test; categorical data (sex, eye, ocular hypertension) were analyzed with Pearson's chi-square test.

laser treatment decreased in the two groups. Compared with PD I (8.16 \pm 0.56 mm), the differences of PD IV (7.59 \pm 1.08 mm) and PD V (7.71 \pm 1.07 mm) were significant in the control group (*P* < 0.05), while there was no significance in the trial group (*P* > 0.05) (Table 2). The comparisons of the two groups demonstrated that PD IV was significantly different between the control group (7.59 \pm 1.08 mm) and the trial group (7.88 \pm 0.85 mm), there were no significant differences between the two groups at any other time points (Table 2).

The differences of pupil diameter less than 5 mm between the two groups were not significant (P = 0.650), 2(1.72%) in the control group and 1(1.00%) in the trial group.

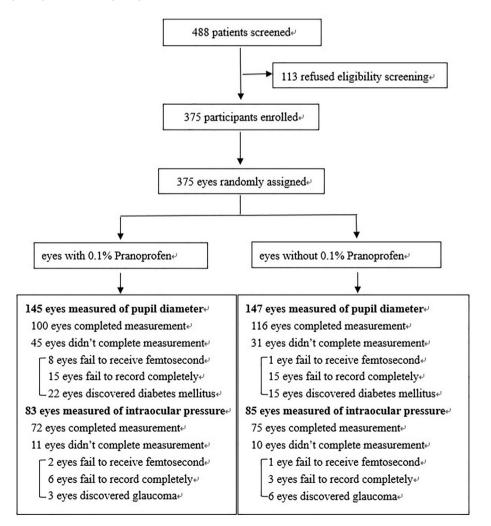


Fig. 2. Study profile.

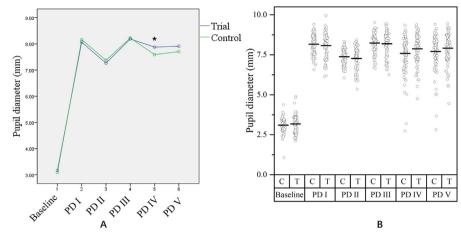


Fig. 3. Variation of PD at different time points. (A) Variation of PD; (B) Scatter diagram of PD. The PD in both the control group and the trial group showed a small tendency of fluctuation instead of a continual decrease. Only PD IV was significantly different between the two groups. (* indicates $P \le 0.05$).

Table 2PD at different time points.

$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$		-				
PD I 8.16 ± 0.56 8.07 ± 0.73 0.306 PD II 7.37 ± 0.48 0.000^* 7.26 ± 0.62 0.000^* 0.178 PD III 8.23 ± 0.58 0.933 8.19 ± 0.71 0.613 0.658 PD IV 7.59 ± 1.08 0.000^* 7.88 ± 0.85 0.241 0.046^*		• •				
	PD I PD II PD III PD III PD IV	$\begin{array}{c} 8.16 \pm 0.56 \\ 7.37 \pm 0.48 \\ 8.23 \pm 0.58 \\ 7.59 \pm 1.08 \end{array}$	0.933 0.000 *	$\begin{array}{c} 8.07 \pm 0.73 \\ 7.26 \pm 0.62 \\ 8.19 \pm 0.71 \\ 7.88 \pm 0.85 \end{array}$	0.613 0.241	0.306 0.178 0.658 0.046 *

Values are expressed as the mean \pm standard deviation. Data were analyzed with the one-way ANOVA F test. P1 value represents the P value compared with PD I, P2 value represents the P value compared with the two groups. (* indicates $P \leq 0.05$).

3.3. Intraocular pressure

The IOP in both groups tended to show fluctuating increases instead of a continual increase (Fig. 4). In the control group, all the IOP after femtosecond laser treatment (IOP II-IV) increase significantly when compared with IOP I (P < 0.05). In the trial group, the IOP II and IOP IV were significantly higher than IOP I (Table 3).

The comparisons of IOP showed that the differences of the two groups were not statistically significant at any time point (Table 3).

Table 3	
IOP at different time points.	

Time	Control IOP (mm	<i>P1</i>	Trial IOP (mm	<i>P1</i>	<i>P2</i>
point	Hg) (n = 75)	Value	Hg) (n = 72)	Value	Value
Baseline IOP I IOP II IOP III IOP IV	$\begin{array}{c} 15.18 \pm 2.30 \\ 16.00 \pm 3.16 \\ 20.82 \pm 5.05 \\ 18.88 \pm 5.26 \\ 22.26 \pm 6.60 \end{array}$	0.000* 0.002* 0.000*	$\begin{array}{c} 15.53 \pm 1.94 \\ 17.07 \pm 3.62 \\ 21.16 \pm 4.60 \\ 18.84 \pm 4.69 \\ 20.64 \pm 5.42 \end{array}$	0.000 * 0.054 0.000 *	0.352 0.070 0.645 0.960 0.092

Values are expressed as the mean \pm standard deviation. Data were analyzed with the one-way ANOVA F test. P1 value represents the P value compared with IOP I, P2 value represents the P value compared with the two groups. (* indicates $P \le 0.05$).

The difference of IOP higher than 30 mmHg between the two groups was not significant (5 (6.67%) in the control group and 3 (4.17%) in the trial group).

4. Discussion

In this study, we evaluated PD and IOP variations in patients pretreated with or without 0.1% pranoprofen prior to FLACS. We collected the PD in 216 eyes and the IOP in 147 eyes. The results of the repeated measures analysis of variance for PD and IOP showed that both the time

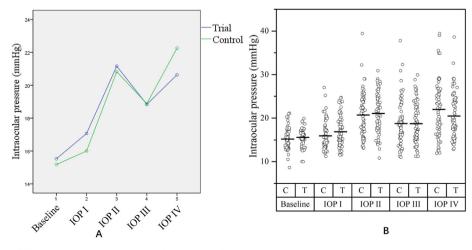


Fig. 4. Variation in IOP at different time points for the trial group and the control group. (A) Variation in IOP; (B) Scatter diagram of IOP. The IOPs in both groups show fluctuating increase instead of a continual increase. The difference of the two groups was not statistically significant at any time point. (* indicates $P \le 0.05$).

and the interaction of time and treatment exerted a statistically significant effect on PD and IOP variations, but treatment with 0.1% pranoprofen did not.

In the study we have found that there was an initial increase in PD and IOP at the end of femtosecond treatment, followed by a decrease at 15 min and a subsequent increase at 30 min after femtosecond treatment. This variation in PD was consistent with the results reported by Natalia.⁷ The trend of variation in PD and IOP was consistent, and the preoperative use of topical 0.1% pranoprofen did not completely negate miosis and elevation of IOP, indicating that other common factors must be involved in the changes in PD and IOP caused by femtosecond laser treatment.

The reported prevalence of pupil constriction induced by the femtosecond laser is 1.26–32%,¹³ which may be explained by differences in equipments and parameters; for example, the liquid immersion interface we used offers advantages over corneal contact applanation. Although many studies have shown that the suction on the eye and the release of inflammatory mediators are significantly associated with intraoperative miosis during FLACS,¹⁴ the use of topical non-steroidal anti-inflammatory drugs (NSAIDs) preoperatively has been shown to help reduce the risk of intraoperative miosis during FLACS.⁸ But we were surprised to find that PD decreased during femtosecond laser treatment, but the decrease was not persistent within the 30 min after femtosecond laser pretreatment. Instead, it increased slightly at the end of femtosecond laser pretreatment, which may be related to release of suction on eye and expansion of the capsular bag caused by the formation of gas during the application of the laser energy to the lens. Then, with the continuous release of inflammatory mediators and spillover of crystallin, the PD decreased at 15 min.

Compared with the control group, pretreatment with 0.1% pranoprofen showed significant alleviation of miosis at 15 min after femtosecond laser treatment, indicating the important role of inflammatory mediators in the miosis caused by femtosecond laser. A further increase in PD was observed at 30 min after femtosecond laser treatment. As time passes, the inflammatory factors produced by laser-tissue interactions are gradually metabolized, and the crystallin of the humor increases because of the destruction of the capsular bag by the femtosecond laser. The slight increase in PD may indicate that the role of inflammatory factors is more important than that of crystallin in miosis during this period, but this notion requires further exploration.¹⁵

According to literatures, preoperative pupil size and suction time^{16,17} were also significantly associated with intraoperative miosis during FLACS. In our study, the differences in the preoperative pupil size and suction time of the two groups were not statistically significant. It has also been reported that the time of topical NSAIDs application before FLACS was related to intraoperative pupil diameter. Eyes, which received NSAIDs within 2 h prior to start of FLACS, were more likely to show sustained mydriasis during surgery.¹³ However the optimal timing of NSAIDs application needs further exploration.

Pupil size was found to be negatively related to the risk of complications, namely, iris trauma, uveitis, anterior capsule tears, zonular dehiscence, posterior capsule rupture and vitreous loss during cataract surgery. A small pupil size has been linked to an increased risk of complications during phacoemulsification. When PD was less than 5 mm, the risk of surgery increases, necessitating the use of intracameral phenylephrine prior to phacoemulsification. In our study, the number of cases with the pupil diameter smaller than 5 mm was 2 (1.72%) in the control group and 1 (1.00%) in treated group. This finding also suggests that the incidence of significant pupil constriction (PD less than 5 mm) is very low whether the preoperative use of 0.1% pranoprofen or not.

Elevation of IOP is another important side-effect of femtosecond laser treatment. Once the IOP higher than the ocular perfusion pressure, ocular blood flow may become impaired, and patients may experience temporary amaurosis. In our study, no patients complained of temporary amaurosis.

Similarly, the IOP did not persistently increase within the 30 min after femtosecond laser treatment. It increased at the end of femtosecond laser pretreatment, decreased in the following 15 min and increased again 30 min after femtosecond laser pretreatment. The range of this fluctuation is very small. Although there was no significant difference between the two groups, 30 min after femtosecond laser treatment, the IOP of eyes pre-treated with 0.1% pranoprofen were lower. This may indicate that inflamatory factors are also involved in the increase of IOP after femtosecond laser treatment.

Increased IOP depends not only on a patient's age and ocular trauma history and the presence of glaucoma but also on the starting pressure at baseline.¹⁸ We excluded patients with ocular trauma and glaucoma, and no significant differences of baseline IOP (base and IOP I) were observed between the two groups. According to literatures, the possible reasons for the elevated IOP at the end of femtosecond (IOP II) are as follows: first, fixation of the eye during surgery may change the corneal curvature, leading to variable decreases in the volume of the anterior chamber¹⁹; second, ocular rigidity may change due to vacuum suction²⁰; third, gas may form during the application of the laser energy to the lens.¹⁶ With the release of vacuum suction, the IOP decreased gradually (IOP III) but did not recover to IOP I and increased again (IOP IV). Based on literature review, we analyze the possible reasons for fluctuations: the continuous release of inflammatory cytokines in the humor, the immune reaction of crystallin²¹ may affect aqueous circulation, blockage of the trabecular mesh, fragments of lens particles or swollen macrophages in the humor may also contribute to the increases of IOP. In addition, since the patients didn't have any sedation during the surgery, excessive anxiety may result in valsalva maneuvers during the procedure, which may increase the IOP.

However, this study has some limitations. Only one type of NSAID (0.1% pranoprofen) was used, and the pretreatment time of 0.1% pranoprofen was one day before surgery. It is not known whether the use of other types of NSAIDs or the prolonged use of 0.1% pranoprofen would elicit different effects on PD and IOP variation. It is even possible that the same effect could be achieved by several hours use of NSAIDs preoperation according to drug pharmacokinetics, which may have less impact on the ocular surface.

5. Conclusions

In conclusion, within 30 min after femtosecond laser treatment, phacoemulsification was hardly affected by miosis and the elevated IOP caused by femtosecond laser pretreatment. Pretreatment with 0.1% pranoprofen has a slight and limited benefit for miosis and no significant effect in preventing IOP elevation within 30 min after femtosecond treatment in patients undergoing FLACS.

Study approval

The authors confirm that any aspect of the work covered in this manuscript that involved human patients or animals was conducted with the ethical approval of all relevant bodies and the study was performed in accordance with the Declaration of Helsinki.

Author contributions

All authors have been informed and agreed to contribute.

LF, Juan Y, PL: Data curation; ZG, LG, CL, HX: Formal analysis. Jian Y, RY, ZG, LG: Methodology.

Jian Y, RY: Conceptualization; Investigation; Funding acquisition; Project administration; Resources; Supervision; Validation.

ZG, LG, CL, LF, Juan Y, PL: Visualization.

ZG, LG: Writing - original draft; Jian Y, RY, ZG, LG: Writing - review and editing.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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