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Surgically induced astigmatism using femtosecond laser clear corneal incision for cataract surgery compared to conventional phacoemulsification

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Abstract-
The objectif of this study is to investigate the early changes in the amount of surgically induced astigmatism (SIA) and the visual outcome following Femtosecond laser clear corneal incision for cataract surgery compared to the traditional manual sutureless 2.2mm superior clear corneal incision at 12-o'clock. A prospective, comparative analysis was performed in case series. A total of 48 eyes of 41 patients had undergone cataract surgery, with 20 eyes underwent Femtosecond laser-assisted cataract surgery and 28 eyes underwent manual cataract surgery. The main outcomes were the surgically induced astigmatism (SIA) and the distance visual acuity (unaided and best corrected) at one 1 and 3 months postoperatively. This study included 48 eyes of 41 patients with a mean age of 65.2 ± 12 years old (range 38 to 89 years). 20 eyes received femtosecond laser–assisted CCIs (Group 1) and 28 eyes received manual CCIs (Group 2). The mean preoperative corneal astigmatism was 0.81 ± 0.43 D and 0.82 ± 0.52 D for Group 1 and Group 2, respectively, whereas, at1 month and 3 months after cataract surgery, it was 0.91 ± 0.81 D; 0.85±0.55 D and 0.89 ± 0.73 D; 1.03±0.64 D, respectively. There was no statistically significant difference between the 2 groups for preoperative astigmatism and postoperative astigmatism (*P*> .05). The mean SIA in laser and the manual group at 1 month was 0.57±0.75 D and 0.61±0.73 D, respectively. The mean SIA of the manual group was unchanged 0.60±0.73D, whereas, the mean SIA of laser group decreased to 0.37±0.92 D at 3 months, although was not statistically significant between the two groups (*P* =0.318). The preoperative uncorrected distance visual acuity (UCDVA) were 0.28 ± 0.20 for laser group and 0.31 ± 0.20 for manual group, there was no statiscally significant (*P* = 0.860). The preoperative best corrected visual acuity (BCDVA) were 0.33 ± 0.26 for the laser group and 0.36 ± 0.23 for the manual group, there was no statistically significant (*P* = 0.789). The uncorrected distance visual acuity for femtosecond laser group at one month and three months postoperatively were 0.74 ± 0.24 and 0.85 ± 0.19, respectively, higher than the manual group 0.64 ± 0.27 and 0.76 ± 0.30, but were not statistically significant (*P*> .05). The best corrected distance visual acuity (BCDVA) at one month and three months postoperatively were 0.88 ± 0.24 and 0.97 ± 0.07 for the laser group, respectively and 0.86 ± 0.23 and 0.92 ± 0.19 for the manual group, respectively, there were no statistically significant between groups (P> .05). Surgically induced astigmatism and the visual outcome do not vary significantly in early postoperative period between femtosecond laser-assisted clear corneal incision and the manual clear corneal incision for cataract surgery. Nevertheless, a decrease in surgically induced astigmatism has been found at three months postoperatively for the femtosecond laser group; however, it remains unchanged for the manual group. Conduct of further studies with a larger series of patients and clear corneal incision placement regard of the patient's own corneal cylinder and axis and longer follow-up is warranted in order ensure the long-term refractive outcomes.

Key words: cataract surgery, Femtosecond laser, phacoemulsification, surgically induced astigmatism

1 INTRODUCTION

Cataract surgery using conventional phacoemulsification is the current method of choice in performing routine cataract surgery [1].
However, the evolution of refractive cataract surgery and refractive lens exchange (RLE) has resulted in decreased tolerance for postoperative astigmatism, with patients often expecting spectacle independence after surgery [2].
Recent cataract surgery procedures allow rapid visual recovery but surgically induced astigmatism (SIA) remains a common issue to achieving an excellent postoperative uncorrected visual acuity [3].

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Femtosecond laser-assisted cataract surgery, which is a relatively new technique that uses commercial femtosecond laser platforms to perform capsulorrhexis, cataract fragmentation, clear corneal incision (CCI) [4, 5] and limbal relaxation incision with the goal of reducing the intraoperative complication rate, postoperative astigmatism and improve the postoperative visual outcome.

Recent studies have found the femtosecond laser to be more accurate than manual Capsulotomy [6, 7].This improved accuracy translates into the more stable intraocular lens (IOL) position and more predictability in the IOL power calculation [8], which may influence the visual outcome.
The purpose of this current study is to investigate the early amounts of changes in surgically induced astigmatism (SIA) and the visual outcome following femtosecond laser clear corneal incision (FS-CCI) for cataract surgery compared to the traditional manual superior 2.2mm clear corneal incision with intraocular lens implantation.

2 MATERIALS AND METHODS

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This study is a prospective randomized comparative case series of patient, comparing femtosecond laser-assisted cataract surgery (FLACS) to conventional phacoemulsification surgery. A consecutive case series of 48 eyes (29 Right and 19 left) from forty-one patients (24 male and 17female) with senile cataracts divided in two groups. The first group included twenty (n=20) eyes that underwent Femtosecond laser-assisted cataract surgery followed by implantation of a hydrophobic acrylic foldable intraocular lens through the 2.2mm superior laser clear corneal incision. The second group included twenty-eight (n=28) eyes that underwent the conventional phacoemulsification cataract surgery with implantation of a hydrophobic acrylic foldable intraocular lens. A single experienced surgeon performed all the surgical procedures in the period between 2014 and 2015.

Included in this study, all the patients without a history of previous ocular surgery or diseases that would affect the corneal refraction and excluded all patients who did not meet the criteria of femtosecond laser stipulated by the manufacturer were applied. All the patients underwent a complete ophthalmological examination pre-operatively and post-operatively at 1 month and 3 months, including a manifest refraction using a refractometer, ophthalmoscopy, tonometry and the visual acuity using snellen projector chart. Astigmatism was measured from the keratometry readings. Data on Age, gender, uncorrected or unaided distance visual acuity (UCDVA), best corrected distance visual acuity (BCDVA), corneal refraction, intraocular pressure (IOP) and automatic keratometry using ARK-510A, NIDEK were collected.

The surgeon sat in the superior position for the conventional group. A side port incision at 9- o'clock was made with 15-degree disposable blade. Injecting sodium hyaluronate (IVIZ®). Triplanar, clear corneal incisions were made with a 2.2 mm disposable blade. Superior clear corneal incision at 12-o'clock was used in both right and left eyes. The depth of the first cut was approximately one-third of the corneal thickness; the tunnel length was ranged from 1.50 mm to 1.60 mm. Capsulorrhexis (approximately 5.5 mm in diameter), and hydro dissection were performed. After sodium viscolastic (DISCOVISE) injection; phacoemulsification, nuclear and the cortex removal and injecting sodium hyaluronate (IVIZ®). A 1-piece foldable acrylic intraocular lens (Restor 1-Piece intraocular lens or others), was then inserted. Then the stromal hydration to seal the wound, which induces corneal edema.

FLACS was performed using the LenSx Laser (Alcon, Texas, USA) for the initial incision (primary computed at 2.2mm with triplanar and secondary at 1.5mm of size), Capsulorrhexis computed at 5.3mm of diameter, cataract fragmentation. The patient was then moved from the laser room to the operating room for the rest of the procedure. Opening of the clear corneal incisions using iris forceps. Then, sodium viscolastic (DISCOVISE) was injected. Capsulorrhexis was carried out using a capsulorhexis forceps. Hydrodissection was performed. The nuclear and the cortex were removed using phaco hand piece. Sodium hyaluronate (IVIZ®) was injected. A1-piece foldable acrylic intraocular lens (Restor 1-Piece intraocular lens or others), was then inserted. Then the stromal hydration to seal the wound, which induces corneal edema. The LenSx Laser system is an all-solid-state laser source that acts by producing a kHz pulse train of Femtosecond pulses nm [9]. It acts by focusing a beam of low-energy infrared light pulses into the eye. These pulses create photo disruption of a microvolume of tissue at the focal point of the beam. Upon scanning, the beam puts the individual photo disruption sites in a consecutive pattern to create continuous incisions [9]. An optical coherence tomography (OCT) imaging device and a video camera microscope are utilized to view the patient's eye and locate specific target locations. The intended uses of the LenSx system for cataract surgery include anterior capsulotomy, phaco fragmentation and creation of single plane and multi-plane arc cuts/incisions in the cornea [9]. Capsulorrhexis was carried out with a Capsulorhexis forceps.

The descriptive statistic and independent samples t-test were used for continuous variables to compare laser and the manual group. Values are expressed as n (%) or mean± standard deviation (SD). The analysis was conducted using SPSS for windows software (Version 19.0, SPSS, inc.). A $P< .05$ was considered as statistically significant.

Surgically induced astigmatism was calculated by vector analysis using the Holladay-Carvy-Koch formula [10].

3 RESULTS

3.1 Baseline Characteristic of subjects in the study

The study presents 48 eyes of 41 patients with senile cataract, who had undergone cataract surgery by Femtosecond laser-assisted cataract surgery (laser group n=20 eyes) and conventional keratometric astigmatism manual phacoemulsification cataract surgery (manual group n= 28); in the period between 2014 and 2015.

Table 1 summarizes the patient's baseline characteristics. The mean age of the patients was 65.2 ±12 years old (range 38-89). There were no statistically significant differences in age, gender, preoperative uncorrected visual acuity; preoperative best-corrected distance visual acuity ($P > 0.05$).

3.2 Uncorrected distance visual acuity

The uncorrected distance visual acuity (UCDVA) was measured on a Snellen visual acuity chart.

The UCDVA by surgical group is shown in table 2. The uncorrected distance visual acuity of both, laser and the manual at 1 and 3 months were higher than those before surgery with 0.74±0.24, 0.85±0.19, respectively, for the laser group and

0.64±0.27, 0.76±0.30, respectively for the manual group, but there were not statistically different between groups (*P* > .05).

3.3 Best-corrected distance visual acuity

The best-corrected distance visual acuity (BCDVA) was measured on a Snellen visual acuity chart.
The BCDVA by surgical group is shown in table 1and 2. Both groups achieved better-corrected distance visual acuity at 1 and 3 three months postoperatively with 0.88±0.24, 0.97±0.07, respectively, for the laser group and 0.86±0.23, 0.92±0.19, respectively, for the manual group (Table 2)and they were higher than those before surgery 0.33±0.26 for laser and 0.36±0.23 for manual (Table 1). There were not statistically significant different between the two groups in Best-corrected distance visual acuity postoperatively (*P* > .05).

3.4 Keratometric astigmatism and corneal meridian

The preoperative keratometric astigmatism and corneal meridian were 0.81±0.43 D, 139±23 degree for the laser group and 0.82±0.59 D, 134±31 degree; there was no statistically significant between groups (*p*= 0.913and 0.455, respectively) Table 1. The postoperative keratometric astigmatism is displayed in the table 2. The femtosecond group has less keratometric astigmatism than the manual group. The mean keratometric astigmatism and corneal meridian at 1 month for laser group was 0.91±0.81 D, 140±29.0 degree and 0.89±0.73 D, 145±33.0 degree for the manual group, There was no statistically significant between the two groups (*P* = 0.930 and 0.548, respectively). The average keratometric astigmatism and corneal meridian in the femtosecond group was 0.85±0.55D, 140±37.0 degree compared to manual group 1.03 ±0.64 D , 137±35.0 degree at 3 months postoperatively, there was not statistically significant difference (*P* =0.332 and 0.743 , respectively) Table 2.

3.5 Surgically induced astigmatism

The magnitude of surgically induced corneal astigmatism (SIA) was calculated from pre- and post-operative keratometry readings using the Holladay-Carvy-Koch formula. [10] de
The surgically induced astigmatism is displayed in the table 2 and figure 1. The mean SIA in laser and the manual group at 1 month was 0.57±0.75D and 0.61±0.73D, respectively. The SIA of the manual group was unchanged 0.60±0.73 D, whereas, the SIA of laser group decreased to 0.37±0.92 D at 3 months, although was not statistically significant between the two groups (*P* =0.318). No statistically significant was detected in the axis of SIA at one month and three months postoperatively between the groups, laser group 75.2±64.2 and 76.7±64.0 degree, manual group 94.5±69.7 and 92.5±68.5 degree, respectively (p=0.355 and 0.447, respectively).

3.6 Intraocular pressure

Preoperative IOP was 17.7 ± 3.20 mmHg for the laser group and 16.9 ± 3mmHg for the manual group, there was no statistically significant between groups. The postoperative IOP at one month and three months were 14.2±2.60 mmHg and 14.1±0.86 mmHg for the laser group, respectively and 13.3±1.90 mmHg and 13.1±1.64 mmHg for the manual group, respectively, there were no statistically significant between groups (P> .05).

Table 1 Baseline Characteristic of subjects in the study n (%), mean±SD

Variables	All subjects (N=41)	Femtosecond laser-assisted cataract (N=20)	conventional manual (N=21)	p[b] (Manual vs FS laser)
Age (a)	65.2 ±12	64.8±10.6	65.6 ±13.5	0.924
Range	(38-89)			-
Gender (%)				
Male	24 (58.5%)	14 (70%)	10 (47.6%)	0.814
Female	17 (41.5%)	6 (30%)	11 (52.4%)	0.785
Laterality (%)				
Right	29 (60.4%)	12 (60%)	17 (60.7%)	0.815
Left	19 (39.6%)	8 (40%)	11 (39.3%)	0.916
Preop UCDVA[a]	0.30±0.19	0.28±0.20	0.31±0.20	0.860
Preop BCDVA[a]	0.35±0.24	0.33±0.26	0.36±0.23	0.789
Preop Astigmatism (D)	0.82±0.52	0.81±0.43	0.82±0.59	0.913
Range (D)	(0.25-2.31)	(0.25-2.00)	(0.25-2.31)	-
Steep axis (degree)	-	139±23	134±31	0.455
Preop IOP (mmHg)	17.2±3.10	17.7±3.20	16.9±3.10	0.993

UCDVA: Uncorrected distance visual acuity, BCDVA: Best corrected distance visual acuity, IOP: intraocular pressure, D: diopter, [a]According to Snellen chart, [b]Independent Student's *t*-test

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Table 2 comparison of UCDVA, BCDVA, Astigmatism, SIA and IOP between groups over time mean±SD

Variables	Groups: Femtosecond laser-assisted cataract Group (N=20)	Groups: Conventional manual Group (N=21)	P
UCDVA*			
Postop 1 month	0.74±0.24	0.64±0.27	0.256
Postop 3 months	0.85±0.19	0.76±0.30	0.218
BCDVA*			
Postop 1 month	0.88±0.24	0.86±0.23	0.753
Postop 3 months	0.97±0.07	0.92±0.19	0.365
Astigmatism (Diopter)			
Postop 1 month	0.91±0.81	0.89±0.73	0.930
Steep axis (degree)	140±29.0	145±33.0	0.548
Postop 3 months	0.85±0.55	1.03±0.64	0.332
Steep axis (degree)	140±37.0	137±35.0	0.743
SIA (Diopter)			
Postop 1 month	0.57±0.75	0.61±0.73	0.853
Axis (degree)	75.2±64.2	94.5±69.7	0.355
Postop 3 months	0.37±0.92	0.60±0.68	0.318
Axis (degree)	76.7±64.0	92.5±68.5	0.447
IOP (mmHg)			
Postop 1 month	14.2±2.60	13.3±1.90	0.113
Postop 3 months	14.1±0.86	13.1±1.64	0.113

UDVA: Uncorrected distance visual acuity, BCDVA: Best corrected distance visual acuity, SIA: Surgically induced astigmatism, IOP: intraocular pressure, *According to Snellen chart

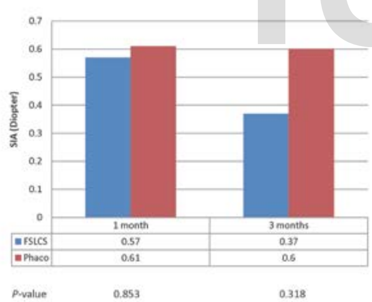

Fig . Inter-group comparison of surgically induced astigmatism (SIA) at 1 and 3 months postoperatively.

FSLCS: Femtosecond laser assisted cataract surgery, Phaco: Phacoemulsification

4 DISCUSSIONS

Recent findings demonstrate that laser-assisted cataract surgery has been shown to be associated with an initial learning curve [11]. The use of femtosecond laser in cataract surgery increase more accuracy and precise anterior capsulotomy, improve intraocular lens centration and reduce intraocular lens tilt issues [12]

In addition, others authors demonstrated a reduced intraoperative ultrasound energy use (equivalent phacoemulsification time) [13-15] and anterior chamber cells and flare postoperatively [16] Potentially lessened surgically induced endothelial cell damage [17] as compared to conventional phacoemulsification cataract surgery. In terms of the surgically induce astigmatism and the visual outcome, many of recent studies showed no significant difference with femtosecond laser-assisted cataract surgery versus conventional cataract surgery. [18- 22] However, few studies have been shown to be at least as good as those of conventional phacoemulsification are [23-25].

Analysis of the two groups by age, gender, corneal astigmatism, intraocular pressure, uncorrected and best-corrected distance visual acuity prior to surgery found them to be statistically identical ($P > .05$) Table 1.

In this study, all the patients underwent triplanar clear corneal incision, as planned preoperatively. The size and the location of the primary and secondary incision were standardized in both, laser and the conventional phacoemulsification groups, with 2.2mm for the size and 12- o'clock for the location. The clear corneal incision is related to the surgically induced astigmatism that influences the visual outcome after cataract surgery, especially when planning to implant a Toric or Multifocal lens [26]. The surgically induced astigmatism depends of several factors including, incision size, incision location, incision distortion, healing and preoperative astigmatism [27]

Nagy ZZ et al, a group from Europe performed a prospective, randomized study of the effects on surgically induced astigmatism of a laser wound creation vs manual one since induced astigmatism could affect postoperative vision; they found no significant difference in surgically induced astigmatism ($P > .05$) [22].

Another study conducted by Kavitha R. Sivaraman et al.[28], also compared the amount of surgically induced astigmatism after cataract surgery with femtosecond laser-assisted wound construction versus manual wound construction in 109 eyes and they documented that the Surgically induced astigmatism did not vary statistically significant between femtosecond laser-assisted wound creation and manual wound creation.

Similarly, we also found in our study any statistically significant difference in surgically induced astigmatism between groups at one month and three months postoperatively, respectively (*P*> 0.853) and (*P* > 0.318). Nevertheless, there was a decrease in surgically induced astigmatism in the laser group at three months postoperatively; however, it remains unchanged in the manual group.

Although most studies agree that femtosecond lasers increase the accuracy and reproducibility of the visual outcomes compared with standard surgery [29-32], but the question remains whether its superiority over standard surgery.

The findings from this study show that the uncorrected and the best-corrected distance visual acuity at one month and three months postoperatively appeared no statistically significant between both groups, laser and conventional.

Our findings are related to Miháltz K, Knorz MC, Alió Jl. [29] et al, who suggested that the corrected and uncorrected distance visual acuity were statistically equivalent for the laser and control groups; manual phacoemulsification.

In addition, Nagy ZZ, Ecsedy M, Kovacs I, et al. [33] studied the Macular morphology assessed by optical coherence tomography image segmentation after femtosecond laser-assisted and standard cataract surgery also found no statistically significant in the best-corrected visual acuity.

However, Loretta T. Ng et al. [23] found a statistically significant better visual outcome in the laser group than the conventional group at six-week post-operative.

Our study had some limitations. It was a small study with 41 patients and 48 eyes investigated. We could not obtain more data from patients because some of them had obtained improved visual acuity after surgery was lost to follow-up. All the patients have been standardized.

5 CONCLUSIONS

Surgically induced astigmatism and visual outcomes do not vary significantly in early postoperative period between femtosecond laser-assisted clear corneal incision and the manual clear corneal incision for cataract surgery at superior twelve o clock position. Nevertheless, there was a decrease in surgically induced astigmatism in laser group at three months postoperatively; however, it remains unchanged in the manual group. Conduct of further studies with a larger series and clear corneal incision placement regard of the patient's own corneal cylinder and axis and longer follow-up is warranted in order to ensure the long-term refractive outcomes.

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