RESEARCH ARTICLE

Incisional correction of corneal astigmatism during phacoemulsification – a randomized trial [version 1; peer review: 1 approved with reservations, 1 not approved]

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Abstract

Background: Phacoemulsification is regarded as a type of refractive surgery by which it is possible to reduce pre-existing corneal stigmatism. This study aimed to evaluate the efficacy and safety of on-axis corneal incision with or without opposite clear corneal incisions (OCCI) to correct preoperative corneal astigmatism during uncomplicated phacoemulsification surgeries.

Methods: A randomized, prospective, parallel two-arm interventional study, which included a total 40 eyes from 40 patients, was conducted. Patients were divided into two groups: 20 patients as controls underwent phacoemulsification with on-axis incision (CCI group), and 20 patients underwent phacoemulsification with OCCI (OCCI group).

Results: Mean astigmatic correction was significantly higher in the OCCI group (0.665 vs 0.265 diopters, p-value <0.001), compared to the CCI group. Most of the parameters (surgical induced astigmatism, magnitude of error, and correction index) were significantly higher in the OCCI group compared to the CCI group (p-value <0.01). There were no incision-related complications.

Conclusions: Both incisional methods are useful methods for correction of preoperative corneal astigmatism but OCCIs correct a higher amount of astigmatism than the on-axis clear corneal incision.

Registration: ClinicalTrials.gov [NCT04418986](https://clinicaltrials.gov/ct2/show/study/NCT04418986) (05/06/2020).

Keywords

Phacoemulsification, Corneal astigmatism, Clear corneal incision, Opposite clear corneal incision, Vector analysis.

Open Peer Review

Approval Status ? X

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Any reports and responses or comments on the article can be found at the end of the article.

This article is included in the **Eye Health** gateway.

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Introduction

Currently cataract surgery is considered to be a refractive surgery, with the main therapeutic goal of achieving emmetropia; as a result, correction of corneal astigmatism becomes essential for such an operation.^{1,2} The prevalence of corneal astigmatism of more than 1 diopter is as high as 45% of those who undergo cataract surgery.³

It is possible to reduce pre-existing corneal astigmatism by creating a clear corneal incision at the steep meridian of the cornea; however, astigmatism correction is limited to a maximum of 1 diopter (D) when corrected by a small incision. A possible limitation is the difficulty in performing the operation which is caused by the location of the steep meridian, such as the difficulty of creating superonasal or inferonasal incisions at the left eye. This approach is usually sufficient for correcting astigmatism less than 1 D in most eyes.^{1,4} An opposite side clear corneal incision (OCCI) could enhance the flattening effect on the cornea.⁵

The current work aims to evaluate the efficacy and safety of on-axis corneal incision with or without OCCIs to correct preoperative corneal astigmatism during uncomplicated phacoemulsification surgeries. The current work is based on the fact that the cornea is not a perfect sphere and many patients present with corneal astigmatism in addition to cataracts. In one procedure, phacoemulsification, cataracts and corneal astigmatism can be corrected based on the principle of releasing incision.

Methods

Ethical statement

Written informed consent was obtained from each participant for participation and publication of clinical information. The study was approved by the institutional regulation board committee of Faculty of Medicine – Baghdad University (Ref#0122-2019). The study followed the Declaration of Helsinki 2008 for research on human subjects.

This trial was registered with [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04418986) (NCT04418986) on 5th June 2020. The trial was registered retrospectively, since mandatory clinical trial registration was only recently introduced to research policies in Iraq so after the study, we registered the trial to ensure transparency of the study.

Trial design

This study was a randomized, parallel two-arm interventional study. The study included 40 eyes with visually significant cataract and preoperative corneal regular astigmatism between 0.75 and 2 D undergoing phacoemulsification surgery.

Patients were divided into two groups in a 1:1 ratio: 20 patients as controls underwent phacoemulsification with on-axis incision (CCI group), and 20 patients underwent phacoemulsification with OCCIs (OCCI group).

Study setting

The study was carried out in the ophthalmology clinic in Ghazi al-Hariri Surgical Specialties Hospital. The recruitment period was three months, from July 2019 until September 2019. All procedures took place in the ophthalmology clinic in Ghazi al-Hariri Surgical Specialties Hospital, and all the procedures were carried out by NKM.

Participants

The participants were approached by the investigators during their visit to the ophthalmology clinic of Ghazi al-Hariri Surgical Specialties Hospital. The primary investigator, Dr. Najah K. Mohammad, examined each participant at admission to the center and conducted an initial interview to check the adherence of the patients to the inclusion and exclusion criteria, specifically age, previous ocular surgeries, and systemic diseases, and if the cataract intervention met their requirements. After obtaining their informed consent and confirming adherence of the participants to the inclusion and exclusion criteria they entered the study. Since this was a pilot study, the sample size was not determined by formal power analysis.

Randomization

Computer-based randomization was used in which the patients were randomly divided into two groups. After the initial interview, the patients were numbered consequently, then randomized into two groups using the online software [Research Randomizer](#).

Inclusion criteria

Negative history of ocular surgery, clear cornea, and central corneal thickness (CCT) less than 640.

Exclusion criteria

Patients with lenticular astigmatism, corneal opacities or pathology like Fuch's endothelial dystrophy, previous ocular surgeries like glaucoma surgery or PKP or pterygium excision, posterior segment diseases and pathology, and complicated phacoemulsification were excluded from this study.

Baseline assessment

All the patients had their complete history taken and underwent ophthalmic examination that included: manifest refraction; uncorrected distance visual acuity (UCDVA); best corrected distance visual acuity (BCDVA); intraocular pressure (IOP) measurement by non-contact air puff tonometry; detailed examination of the anterior segment using slit lamp biomicroscopy; posterior segment detailed examination using indirect ophthalmoscopy; corneal topography, mesopic pupil size and corneal pachymetry were done using Sirius Topographer (CSO, Italy); and ocular biometry to measure axial length, anterior chamber depth, and horizontal white to white (WTW) distance were done using partial coherence interferometry (PCI), the ZEISS IOLMaster® 500 (Carl Zeiss Meditec AG, Germany).

Ophthalmological procedure

The procedure is similar to our previous study by Eliwa *et al.*,⁶ in which the steep meridian of the corneal topography was marked using a Whitehouse Gravity Axis Marker. This was done before local anesthesia was administered. Peribulbar anesthesia (lidocaine 2% [5 ml], bupivacaine 0.5% [5ml], and hyaluronidase 1,500 IU/mL [2 ml], all given via the peribulbar route) associated with mild sedation with midazolam was used in all cases.

Coaxial small incision cataract surgery was performed for all cases of both groups using a 2.8 mm keratome placed at steep meridian and 1-mm paracentesis was made 90 degrees apart with a 20-gauge microvitrectomy blade (Alcon Laboratories, Inc., Fort Worth, TX). Surgery was performed with a 30-degree, 0.9-caliper phacoemulsification tip (microtip) with the divide-and-conquer technique using the INFINTI vision system (ALCON laboratories INC).

The AcrySof SN60WF (Alcon Laboratories, Inc.) intraocular lens (IOL) was loaded in cartridge C and then inserted using a Royale injector (ASISCO LLC, Westmont, IL). The tip of the cartridge was introduced into the external part of the incision, after which the IOL was injected into the capsular bag.

In the OCCI group, a single penetrating incision was created with a 2.8 mm keratome in clear cornea, 1.5 mm anterior to limbal blood vessels, centered over the steep meridian and opposite the phacoemulsification incision.

Postoperative topical therapy included a combination of topical antibiotics (moxifloxacin drops 2% [1 – 2 drops every six hours for a two-week duration]), and steroid eye drops (prednisolone acetate 1% [1 – 2 drops every six hours for a two week duration, than tapered to twice daily for two weeks] and eye lubricants (Systane Ultra drops, 1 – 2 drops every six hours for four weeks).

Outcomes

Primary outcomes

Change in surgically induced astigmatism (SIA) one month after the phacoemulsification. Corneal astigmatism was examined by corneal topography, preoperatively and four weeks after the surgery, by the same technician, and changes in astigmatism were assessed by Alpíns vector analysis comparing the SIA pre- and postoperatively.

Secondary outcomes

To investigate the differences between CCI and OCCI regarding the changes in corneal astigmatism assessed by corneal topography and SIA.

Statistical analysis

The Anderson-Darling test was used to assess the adherence of variables to normality, the paired t-test (or Wilcoxon median rank test if data did not follow normal distribution) was used to analyze the difference between preoperative and postoperative outcomes and the independent t-test (or Mann–Whitney U test if data did not follow normal distribution) was used to analyze the difference between two independent variables. The p-value was considered to be significant if <0.05 and all analysis was carried out using SPSS version 20.0.1 (IBM Corp, Armonk, NY).

Results

The study included 40 eyes (Figure 1). The mean age of participants was 57.9 ± 13.25 , and 52.5% were males (21/40).¹⁶ These cases were divided into two groups: CCI and OCCI groups. There was no statistically significant difference between the two groups regarding patient demographic data, as illustrated in Table 1.

Mean corneal power significantly reduced after one month postoperatively in the OCCI group, while the CCI group showed a slight reduction in mean corneal power postoperatively. The UCVA significantly improved in both groups after the procedure, from 0.114 ± 0.048 and 0.146 ± 0.102 preoperatively in CCI and OCCI groups, respectively (approximately 6/60, 1 LogMAR), to 0.35 (approximately 6/18, 0.48 LogMAR) in the CCI group and 0.45 (approximately 6/12, 0.3 LogMAR) in the OCCI group postoperatively. Mean BCVA significantly increased from 0.283 ± 0.097 (approximately 6/24, 0.60 LogMAR) preoperatively to 0.438 ± 0.146 (approximately 6/12, 0.3 LogMAR) postoperatively in the CCI group, and the OCCI group showed a statistically significant increase in BCVA from 0.375 ± 0.150 (approximately 6/18, 0.48 LogMAR) preoperatively to 0.564 ± 0.125 (approximately 6/9, 0.18 LogMAR) postoperatively, as illustrated in Table 2.

The mean change in topographic astigmatism was statistically significantly higher in the OCCI group (0.665 ± 0.268 D) than the CCI group (0.265 ± 0.142 D) (p -value < 0.001 ; Figure 2A), while there was no statistically significant difference between the two groups regarding the change in mean corneal power (see Figure 2B).

Mean magnitude of target induced astigmatism vector (TIA) of both groups was 1.37 D, which was similar to preoperative topographic astigmatism. Most of the parameters (surgical induced astigmatism, magnitude of error, and correction index) were significantly higher in OCCI group compared to the CCI group (p -value < 0.01), as illustrated in Table 3.

Discussion

Cataract surgery is considered to be a refractive procedure aiming for postoperative emmetropia, which required correction of spherical and astigmatic errors.² Corneal astigmatism of more than 1 D has been reported in up to

Figure 1. Flow chart of the trial. CCI, clear corneal incision; OCCI, opposite clear corneal incision.

Table 1. Demographic and preoperative ocular data.

Variables	CCI arm	OCCI arm	p-value
Number	20	20	-
Age (years)			0.065
Mean $\pm$ SD	61.75 $\pm$ 12.36	54.05 $\pm$ 13.28	
Range	41 – 85	31 – 78	
Gender, n (%)			0.342
Female	12 (60%)	9 (45%)	
Male	8 (40%)	11 (55%)	
Eye, n (%)			0.206
Right	12 (60%)	8 (40%)	
Left	8 (40%)	12 (60%)	
UCVA, mean $\pm$ SD	0.114 $\pm$ 0.048	0.146 $\pm$ 0.102	0.203
BCVA, mean $\pm$ SD	0.238 $\pm$ 0.097	0.375 $\pm$ 0.150	0.028
Topographic astigmatism, mean $\pm$ SD	1.370 $\pm$ 0.384	1.370 $\pm$ 0.505	1.000
Topographic axis, mean $\pm$ SD	103.210 $\pm$ 33.662	101.150 $\pm$ 35.487	0.850
Mean corneal power, mean $\pm$ SD	43.56 $\pm$ 1.48	43.53 $\pm$ 1.59	0.950

UCVA, uncorrected visual acuity; BCVA, best-corrected visual acuity; SD, standard deviation; CCI, clear corneal incision; OCCI, opposite clear corneal incision.

Table 2. Topographic astigmatism and corneal power in both groups.

Variables	CCI arm			OCCI arm		
	Preoperative	Postoperative	p-value	Preoperative	Postoperative	p-value
Topographic astigmatism	1.370 $\pm$ 0.384	1.105 $\pm$ 0.416	<0.001	1.370 $\pm$ 0.505	0.705 $\pm$ 0.408	<0.001
Mean corneal power	43.56 $\pm$ 1.48	43.34 $\pm$ 1.61	0.057	43.53 $\pm$ 1.59	43.29 $\pm$ 1.43	0.016
UCVA	0.114 $\pm$ 0.048	0.345 $\pm$ 0.130	<0.001	0.146 $\pm$ 0.102	0.446 $\pm$ 0.167	<0.001
BCVA	0.283 $\pm$ 0.097	0.438 $\pm$ 0.146	<0.001	0.375 $\pm$ 0.150	0.564 $\pm$ 0.125	<0.001

Data presented as mean $\pm$ SD. UCVA, uncorrected visual acuity; BCVA, best-corrected visual acuity; SD, standard deviation; CCI, clear corneal incision; OCCI, opposite clear corneal incision.

Figure 2. Assessment of mean change from baseline for, A) topographic astigmatism, B) mean corneal power in both groups. CCI, clear corneal incision; OCCI, opposite clear corneal incision.

45% of cataract surgery candidates,³ while 11.6% of eyes undergoing cataract surgery have more than 2 D of corneal astigmatism.⁷

Since the astigmatic effect of CCIs on the steep meridian is well documented, it is reasoned that adding an CCI opposite to the first incision (OCCI) would enhance the flattening effect, providing a good method to manage the preexisting

Table 3. Vector analysis of postoperative astigmatism for both arms.

Variables	CCI arm	OCCI arm	p-value
TIA	1.37 ± 0.384	1.37 ± 0.505	0.999
SIA	0.403 ± 0.183	0.849 ± 0.519	0.001
ME	-0.986 ± 0.390	-0.522 ± 0.553	0.004
CI	0.323 ± 0.218	0.636 ± 0.335	0.001

TIA, target induced astigmatism vector (the astigmatism changes [by magnitude and axis] the surgery intended to induce); SIA, surgical induced astigmatism vector (the amount and axis of astigmatism change induced by the surgery); ME, magnitude of error (the arithmetic difference between the magnitudes of the SIA and TIA [ME is positive for overcorrection and negative for under-correction]); CI, correction index (calculated by determining the ratio SIA/TIA [in overcorrection CI is >1 and <1 for under-correction]); CCI, clear corneal incision; OCCI, opposite clear corneal incision.

corneal astigmatism during cataract surgery. OCCIs are simple to perform, do not require additional skills or instruments, and since the additional incision is self-sealing, particularly when it is not used to introduce instruments, the added risk to the surgery is negligible compared to its benefit of astigmatism reduction.^{5,8}

The topographic corneal astigmatism in the CCI group decreased by 0.265 ± 0.142 diopters, while OCCI reduced the topographic corneal astigmatism by 0.665 ± 0.268 diopters, which was in agreement with Bhalla's study, which reported a reduction of 0.28 and 0.7 D in topographic astigmatism in CCI and OCCI groups, respectively,⁹ but these results were different to other studies.

In 2000, Lever and Dahn performed cataract surgery on 33 eyes of 26 patients with an OCCI ranging from 2.8 to 3.5 mm in length and they reported a mean corneal astigmatism correction of 2.06 D with this technique.⁵ Qammar and Mullaney in 2005 reported a mean astigmatic correction of 1.23 ± 0.49 D.¹⁰ In 2006, Khokhar and colleagues¹¹ reported that a 3.2 mm CCI reduced topographic astigmatism by 0.59 ± 0.43 D at three months follow-up, which is more than our CCI group, which showed a 0.265 ± 0.142 D reduction in topographic astigmatism. The OCCI group of Khokhar's study showed a reduction in preoperative corneal astigmatism of 1.60 ± 0.45 D versus 0.665 ± 0.268 D in our study.

On the other hand, our results were higher than Tadros' study, which reported a 0.5 ± 0.73 D reduction in preoperative corneal astigmatism.¹² They were also higher than Bazzazi's study, which reported the mean topographic astigmatism change to be 0.003 D and 0.036 D in superior and temporal CCI groups, respectively, which was less than our CCI group (0.265 D), while in the OCCI groups topographic astigmatism was reduced by 0.505 D and 0.557 D in superior and temporal groups, respectively, versus 0.665 D in our study.¹³ In addition, Nemeth's study found a 0.13 D reduction in topographic astigmatism in their CCI group, which was less than our CCI group (0.265 D), while Nemeth's OCCI group showed a reduction in topographic astigmatism of 0.2 D versus 0.665 D in our study.¹⁴

Using vector analysis,¹⁵ we also evaluated the predictability of the astigmatic correction. The topographic data were analyzed. The mean magnitude of TIA was 1.370 ± 0.384 D in the CCI group and 1.370 ± 0.505 D in the OCCI group that was similar to preoperative topographic astigmatism. The mean magnitude of SIA was 0.403 ± 0.183 D in our CCI group, which was less than Khokhar's study (0.85 ± 0.75 D)¹¹ and Nemeth's study (0.61 ± 0.43 D)¹⁴ but more than Bazzazi's study (0.036 ± 0.51 D)¹³ and Bhalla's study (0.33 ± 0.22 D).⁹ Regarding the OCCI group of our study, the mean magnitude of SIA was 0.849 ± 0.519 D, which was less than that of Lever and Dahn's study (2.25 D),⁵ Tedros' study (1.57 D),¹² Qammar and Mullaney's study (2.10 D),¹⁰ Nemeth's study (0.99 D)¹⁴ and Khokhar's study (1.66 D).¹¹ On contrary, the mean SIA of our OCCI was higher than that of Bazzazi's study (0.505 D), and Bhalla's study (0.76 D).⁹

All the above differences in the resulted mean change in astigmatism and SIA could be the result of using 2.8 mm incisions in our study compared to 3.2 mm incisions used in most of the studies that corrected a higher astigmatism than we did, or may be due to different sample sizes, postoperative topographic astigmatism (1.37 D in our study versus 3.6 D in other studies), and follow up period (one month versus 2-3 months in others).

Conclusion

Both incisional methods are useful methods for correction of preoperative corneal astigmatism but OCCIs correct a higher amount of astigmatism than the on-axis CCIs. In addition, using a 3.2 mm incision in both ways may correct a higher amount of astigmatism than using a 2.8 mm incision.

Data availability

Underlying data

Zenodo: Corneal Astigmatism - excel. <https://doi.org/10.5281/zenodo.4907691>.¹⁶

This project contains the study data in XLSX format.

Extended data

Zenodo: Incisional Correction Of Corneal Astigmatism During Phacoemulsification-proposal. <https://doi.org/10.5281/zenodo.4907717>.¹⁷

This project contains a copy of the study protocol in DOCX format.

Reporting guidelines

Zenodo: CONSORT checklist for “Incisional correction of corneal astigmatism during phacoemulsification – a randomized trial”. <http://doi.org/10.5281/zenodo.5028589>.¹⁸

Data are available under the terms of the [Creative Commons Attribution 4.0 International license](https://creativecommons.org/licenses/by/4.0/) (CC-BY 4.0).

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Open Peer Review

Current Peer Review Status: ? ✖

Version 1

Reviewer Report 24 January 2022

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The authors aimed to assess the efficacy and safety of on-axis cornea incision with or without opposite clear incisions to correct preoperative cornea astigmatism. Despite that this is an interesting topic, the current study had significant flaws in terms of protocol compliance, data analysis, and processing. I have listed a few comments for the authors' reference:

1. The efficacy of on-axis corneal incision with or without OCCI to correct preoperative corneal astigmatism has been studied before, What are the innovation and necessity of this research?
2. the Method section of Abstract: has not been clarified clearly, such as the inclusion criteria, the range, and type of astigmatism, the follow-up time, and examination items. Besides, the methods of statistical analysis were not mentioned.
3. the Result section of Abstract: The data reported in the MS should strictly follow the protocol registered. The secondary outcome displayed in clinicaltrials.gov was the change in visual acuity, instead of the differences regarding the changes in cornea astigmatism between the two groups.
4. Abstract: a spelling mistake: pre-existing corneal astigmatism; grammar mistakes, a total of 40 eyes of 40 patients.
5. Introduction: "however, astigmatism correction is limited toat the left eye". Please list the references you have referred to here.
6. Introduction: "The current work is based on.....releasing incision" is unnecessary. The author should explain the necessity of this study compared to previous research.
7. the Ethical statement in Method: Clinical trials are defined by the WHO as "any research study that prospectively assigns human participants or groups of humans to one or more

health-related interventions to evaluate the effects on health outcomes." Registration should be with an appropriate registry and should take place before the enrolment of the first participant. Regardless of any national policies that may exist, trials registered after the date of the first enrolment are considered to be retrospective.

8. the Participants in Method: The sample size was not determined by formal power analysis, and even lack a post-hoc power analysis, thus it was questionable whether such a small sample size was sufficient to evaluate this question.
9. the Exclusion criteria in Method: Why did you exclude patients with lenticular astigmatism?
10. Results: The baseline BCVA was better in the OCCI group, instead of the authors' claim that there was no statistical difference between the two groups at baseline.
11. Results: The change in astigmatism is a vector, should be analyzed with the consideration of both magnitude and meridian. Thus, the mean vector or centroid is the proper value to use. The double-angle plots of the differences in corneal astigmatism measurements should be displayed.
12. Discussion: The first paragraph should summarize the main finding of the study, rather than repeat the Introduction.

Is the work clearly and accurately presented and does it cite the current literature?

Partly

Is the study design appropriate and is the work technically sound?

Partly

Are sufficient details of methods and analysis provided to allow replication by others?

Yes

If applicable, is the statistical analysis and its interpretation appropriate?

Partly

Are all the source data underlying the results available to ensure full reproducibility?

Yes

Are the conclusions drawn adequately supported by the results?

Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: cataract

I confirm that I have read this submission and believe that I have an appropriate level of expertise to state that I do not consider it to be of an acceptable scientific standard, for reasons outlined above.

Reviewer Report 24 September 2021

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Hesam Hashemian

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The study is designed to compare two techniques of corneal incisional surgery to correct corneal astigmatism during cataract surgery.

Incisional surgeries have been used for refractive correction on the cornea in LRI, AK, and RK surgeries. In all these surgeries a nearly full thickness incisions cut continuous collagen layers which are extended from limbus to limbus and violate the integrity of the cornea. As we see in all cases of incisional surgery inability of result prediction and regression or overcorrection in long run are drawbacks of this technique. Violation in biomechanical stability of cornea is the other concern that is due to near full thickness cutting of collagen strands.

A decrease in corneal sensation caused by cutting nerve endings and secondary dry eye is another concern in these patients.

So it was better to have a longer follow-up to address refractive stability; biomechanical changes and checking corneal sensation.

Irregular astigmatism of any kind can not be predictably corrected by incisional surgery. And due to biomechanical deterioration, any kind of corneal ectasia should be considered as an exclusion. So the authors should mention these two conditions as an exclusion to study.

Is the work clearly and accurately presented and does it cite the current literature?

Yes

Is the study design appropriate and is the work technically sound?

Partly

Are sufficient details of methods and analysis provided to allow replication by others?

Yes

If applicable, is the statistical analysis and its interpretation appropriate?

Yes

Are all the source data underlying the results available to ensure full reproducibility?

Yes

Are the conclusions drawn adequately supported by the results?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Cornea, Keratoconus, ICRS, refractive surgery

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

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