·Clinical Research·

# A comparable study of clinical and optical outcomes after 1.8, 2.0 mm microcoaxial and 3.0 mm coaxial cataract surgery

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## Abstract

**• AIM: To evaluate the clinical and optical outcomes after clear corneal incision cataract surgery (CICS) with three different incision sizes (1.8, 2.0 and 3.0 mm).**

**• METHODS: Eyes of 150 patients with age-related cataract scheduled for coaxial cataract surgery were randomized to three groups: 1.8, 2.0, or 3.0 mm CICS. Intraoperative data and postoperative outcomes including surgically induced astigmatism (SIA), the corneal incision thickness, wavefront aberrations and modulation transfer function (MTF) of cornea were obtained.**

**• RESULTS: There were no significant differences among the three groups in demographic characteristics and intraoperative outcome. The 1.8 and 2.0 mm microincisions showed more satisfactory clinical outcomes than the 3.0 mm incision. The 1.8 mm incision showed significantly less SIA than the 2.0 mm incision until postoperative 1mo ($P$<0.05), but the difference was only 0.14-0.18 D. Combined with less increased incision thickness only at postoperative 1d ($P$=0.013), the 1.8 mm incision presented better uncorrected distance visual acuity (UCDVA) than the 2.0 mm incision only at 1d postoperatively ($P$=0.008). For higher-order aberrations and other Zernike coefficients, there were no significant differences between the 1.8 mm group and 2.0 mm group ($P$ >0.05).**

**• CONCLUSION: Converting from 3.0 mm CICS to 1.8 or 2.0 mm CICS result in better clinical and optical outcomes. However, when incision is 1.8 mm, the benefits from further reduction in size compared with 2.0 mm are limited. The necessity to reduce the incision size is to be deliberated.**

• **KEYWORDS:** microsurgery; phacoemulsification; treatment outcome
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## INTRODUCTION

Microincision cataract surgery (MICS) has become popular in recent years. Compared with standard incision cataract surgery (SICS), MICS causes less surgical injury, which results in less surgically induced astigmatism (SIA), better postoperative corneal optical quality, rapid wound healing and fewer intraoperative complications [1]. However, recent studies showed almost the opposite, reporting that an additional reduction in incision sizes (*e.g.* 1.8 mm) did not further improve SIA or result in better uncorrected distance visual acuity (UCDVA) or better wound integrity than a 2.2 mm or, even, a 3.0 mm incision [2-3]. The surgeons' familiarity with the phacoemulsification systems may has affected their conclusions. And the incision enlargement may indicate an inappropriate method for intraocular lens (IOL) implantation.

Therefore, to perform a more objective assessment, the present study investigated clinical and optical outcomes after clear corneal incision cataract surgery (CICS) with three different incision sizes using the same phacoemulsification system and evaluated the relation between the incision size and surgically induced incision oedema, SIA and corneal optical quality. Two MICS groups were tested in this study to investigate whether a smaller incision is better and to evaluate the necessity and benefits of developing new systems and supplies for smaller incisions.

## SUBJECTS AND METHODS

This was a prospective, randomized, double-masked clinical trial (Registration Number-ChiCTR-TRC-12002565). It was approved by the Institutional Review Board of the Second

Affiliated Hospital of Zhejiang University School of Medicine, Hangzhou, China, and performed in accordance with the tenets of the Declaration of Helsinki stated in 2002[4]. Informed consent was obtained from all the patients before enrollment.

This study comprised age-related cataract patients in the Eye Center, the Second Affiliated Hospital of Zhejiang University School of Medicine, Hangzhou, Zhejiang Province, China. Inclusion criteria were ages between 50 and 80y, with no medication history or other eye disease. Patients with diabetes or other diseases which may influence the biomechanical properties of the cornea were also excluded. Patients were randomly assigned to one of three groups the day before surgery. Group I was to undergo 1.8 mm clear corneal incision surgery with an Akreos MI 60 IOL (Bausch &Lomb, USA) implantation. Group II was to undergo 2.0 mm clear corneal incision surgery with a NY-60 IOL (Hoya, Japan) implantation. Group III was to undergo conventional coaxial phacoemulsification through a clear corneal incision of 3.0 mm with a PY-60 IOL implantation (Hoya, Japan). Only one eye of each patient was involved in the trial. All patients were followed up at 1d, 1wk, 1 and 2mo after surgery.

All surgeries were performed by the same experienced surgeon (Yao K) using the Bausch&Lomb Stellaris system (Bausch &Lomb, USA). First, to minimize the differences in incision among the three groups and facilitate the postoperative examination of incision, a one-step stab incision of 1.8, 2.0, or 3.0 mm width was made at the 12 o'clock meridian with a stainless steel keratome. Another 0.6 mm side incision was created in the clear cornea, 90 degrees from the main incision. Continuous curvilinear capsulorhexis measuring approximately 5.5 mm in diameter was done with a microforceps. After hydrodissection, phacoemulsification of the nucleus was performed using the stop-and-chop technique. After aspiration of residual cortex, an Akreos MI 60 IOL was implanted with wound-assisted technique for Group I, and a foldable IOL (Hoya NY-60 IOL for Group II, Hoya PY-60 IOL for Group III) was implanted with an injector through the main incision. The methods for IOL implantation were strictly consistent with product manuals. Then the wound widths were measured using the F-gauge by the same surgeon (Yao K). All surgeries were uneventful. Intraoperative outcome measures, including average ultrasound power (AVE), effective phacoemulsification time (EPT), and ultrasound time (UST), were recorded at the end of the surgeries.

The postoperative follow-up was performed by the same independent examiner (Yu YB), who did not perform any of the surgeries. Uncorrected and best spectacle-corrected decimal visual acuity was recorded at all examination visits postoperatively. The keratometric cylinder was measured using a Corneal Topography System (Orbscan IIZ™, Bausch & Lomb, Germany) at each visit. The data on keratometric cylinder and axes of each cornea were used for calculation of the surgically induced astigmatism by the vector analysis described by Jaffe and Clayman [5]. The corneal endothelial cell density (cells per square millimeter) was measured using a specular microscope (EM-3000, Tomey, Japan); 100 cells per cornea were counted at the preoperative and 2mo postoperative examinations. Corneal incision thickness at the 12 o'clock meridian was measured with anterior segment optical coherence tomography (Visante OCT, Zeiss Meditec, USA) at all visits. Wavefront aberrations and modulation transfer function (MTF) were measured using the OPD-Scan (ARK-10000, NIDEK Co. Ltd., Japan). In this study, corneal wavefront aberrations up to the sixth order through a 5 mm optical zone of the cornea and the spatial frequencies at 0.5 MTF of the cornea were analyzed at each visit.

**Statistical Analysis** Statistical analysis was performed using SPSS for Windows software (version 13.0, SPSS, Inc.). Data were expressed as mean±standard deviation. The amount of SIA, age, AVE, EPT, UST, nucleus sclerosis, visual acuity, endothelial cell count and increase in corneal incision thickness, other variables in corneal aberrations, and 0.5 MTF values among the three groups were compared using ANOVA test. The Chi-square test was used to compare sex. Any differences showing a $P$ value less than 0.05 were considered statistically significant.

## RESULTS

One hundred and fifty patients (150 eyes) were enrolled in the study and divided into three groups ($n$=50 in each). The distribution of sex, age, preoperative UCDVA and mean nucleus sclerosis was comparable among the three groups. No significant differences were observed in the intraoperative outcome among the three groups. At postoperative 2mo, the mean endothelial cells among the groups were similar. The mean proportional enlargement in the wound size in Group II was greater than that in Group I and Group III (8.5% *vs* 1.11% and 1.33%, respectively) (Table 1).

The SIA decreased in each group with an increase in the time since the surgery. The mean SIA tended to be greater in Group III than in Groups I and II in all follow-up visits. At postoperative 1d, 1wk and 1mo, the SIA was significantly lower in Group I than in Group II ($P$=0.006, 0.011, 0.021), although the difference was only 0.14-0.18 D (Figure 1A). At postoperative 1d, 1wk, and 1mo, there was significant difference in SIA among the 3 groups ($P$=0.001, 0.002, 0.013). At 2mo after surgery, the SIA in Group III was significantly greater than that in Group I and Group II ($P$=0.011, 0.021), but there was no significant difference between Group I and Group II ($P$=0.251).

**Table 1 Patient characteristics and surgical data** $\bar{x} \pm s$

| Parameters | Group I | Group II | Group III | *P* |
|---|---|---|---|---|
| Eyes/patients (*n*) | 50/50 | 50/50 | 50/50 | - |
| Male/female (*n*) | 11/39 | 13/37 | 13/37 | 0.866 |
| Mean age (a) | 70.30±6.67 | 70.68±6.98 | 70.34±7.23 | 0.937 |
| Preop UCDVA | 0.88±0.44 | 0.73±0.39 | 0.81±0.44 | 0.623 |
| Mean nuclear sclerosis | 1.84±0.78 | 1.77±0.72 | 1.85±0.81 | 0.779 |
| Corneal endothelial cell density (cells/mm$^2$) | | | | |
| Pre-op | 2638.8±291.2 | 2700.0±295.7 | 2656.2±286.4 | 0.501 |
| Post-op 2mo | 2465.5±269.7[a] | 2463.4±241.7[a] | 2423.7±175.3[a] | 0.732 |
| EPT (s) | 6.35±4.84 | 6.18±4.37 | 5.50±4.49 | 0.573 |
| AVE (%) | 13.16±3.81 | 13.32±4.11 | 14.02±4.31 | 0.508 |
| UST (s) | 38.68±16.29 | 38.76±12.61 | 36.51±18.52 | 0.702 |
| Implanted IOL | Bausch&Lomb MI60 | Hoya NY-60 | Hoya PY-60 | - |
| Incision width before IOL implantation (mm) | 1.8 | 2.0 | 3.0 | - |
| Final main incision width (mm) | 1.82±0.04 | 2.17±0.05 | 3.04±0.05 | - |
| Change (%) | 1.11 | 8.50 | 1.33 | - |

UCDVA: Uncorrected distance visual acuity; EPT: Effective phacoemulsification time; AVE: Average ultrasound power; UST: Ultrasound time. [a]$P$<0.05 *vs* preoperative value in the same group.

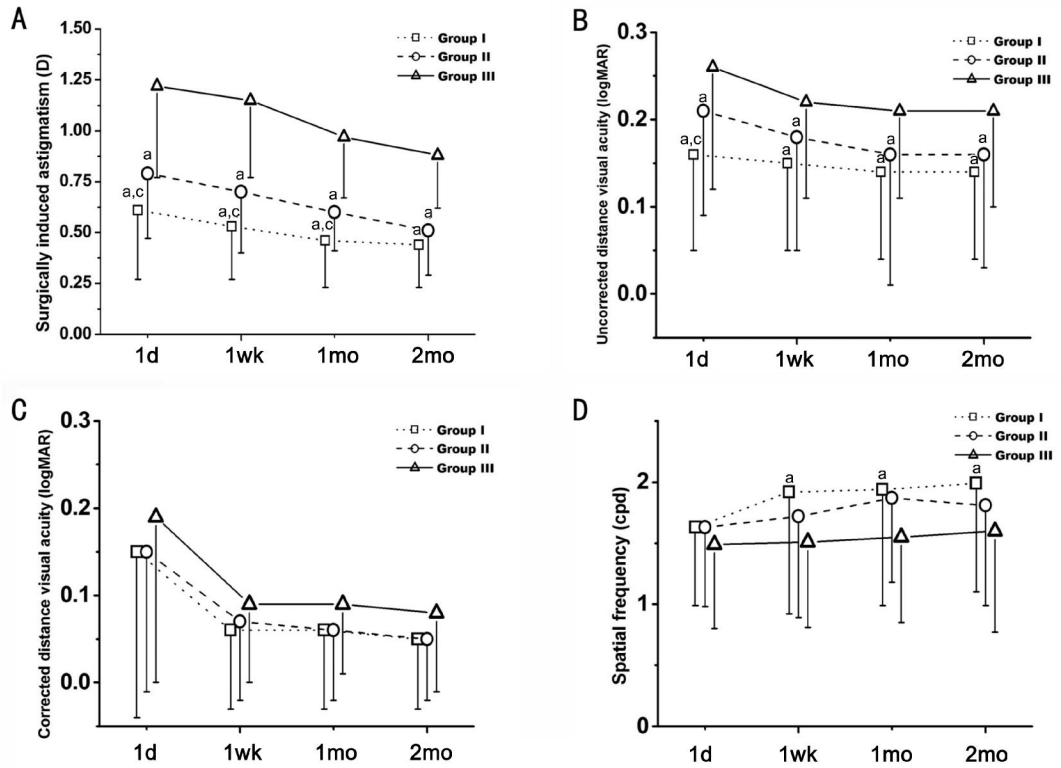


**Figure 1 The clinical and optical outcomes in each group** A: Comparison of SIA in the three groups at 1d, 1wk, 1, and 2mo after surgery; B, C: Comparison of UCDVA and CDVA among the three groups at 1d, 1wk, 1, and 2mo after surgery; D: Spatial frequency (cpd) of 0.5 MTF in the three groups at preoperative and postoperative 1d, 1wk, 1, and 2mo. Group I: 1.8 mm incision; Group II: 2.0 mm incision; Group III: 3.0 mm incision. [a]$P$<0.05 *vs* Group III; [c]$P$<0.05 *vs* Group II.

There was also a statistically significant difference in the mean UCDVA of Group I (approximately 20/30) and Group II (approximately 20/32) on postoperative day 1 ($P$=0.037). The UCDVA was better in both Group I and Group II than in Group III at all follow-up times (postoperative day 1: $P$=0.001 for Group I *vs* Group III, $P$=0.012 for Group II *vs* Group III; postoperative week 1: $P$=0.003 for Group I *vs* Group III, $P$=0.018 for Group II *vs* Group III; postoperative month 1: $P$=0.008 for Group I *vs* Group III, $P$=0.021 for Group II *vs* Group III; postoperative month 2: $P$=0.009 for Group I *vs* Group III, $P$=0.030 for Group II *vs* Group III) (Figure 1B). At postoperative 1d, mean UCDVA in Group I

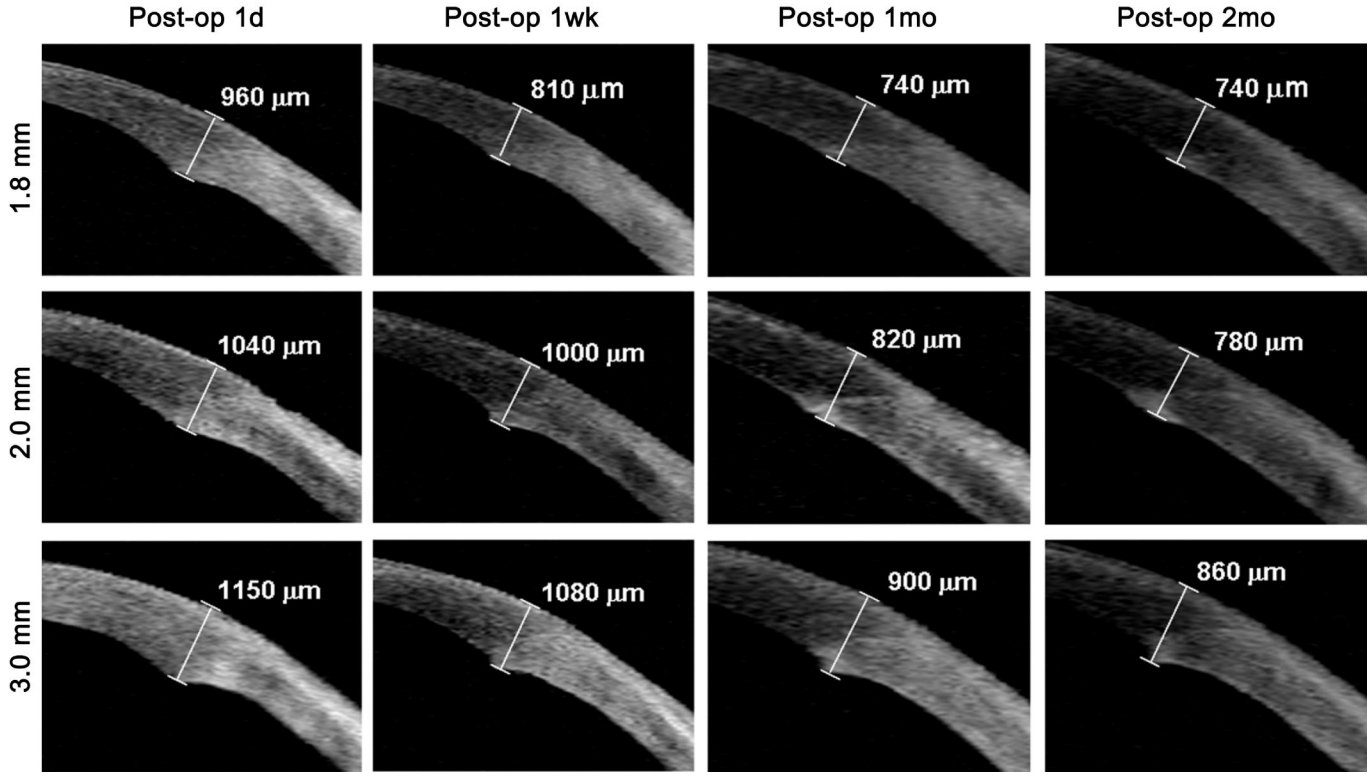


**Figure 2 Anterior segment OCT images of clear corneal incision thickness observed at all visits after surgery** Images of 1.8, 2.0 and 3.0 mm showing the evolution of corneal incision thickness at postoperative 1d, 1wk, 1 and 2mo.

was significantly higher than that in Group II ($P$=0.033). There was no significant difference in mean UCDVA between Group I and Group II at postoperative 1wk, 1 and 2mo ($P$= 0.078, 0.121, 0.283).

There was no statistically significant difference in the mean corrected distance visual acuity (CDVA) among the three groups at any postoperative visit (Figure 1C). One week, 1 and 2mo postoperatively, the mean 0.5 MTF in Group I was significantly higher than those in Group III ($P$=0.002, 0.005, 0.023) (Figure 1D). There were no significant differences among the three groups in 0.5 MTF before surgery ($P$=0.658).

The pachymetric values of the corneal incision thickness are shown in Table 2. The corneal thickness in the incision was significantly less increased in Group I than in Group III on 1d and 1wk postoperatively ($P$=0.017, 0.009). There was also a significant difference in increased corneal thickness between Groups I and II ($P$=0.036) but only on 1d postoperatively. Figure 2 shows the evolution in clear corneal incision thickness after the surgery.

As shown in Table 3, in Group III, the mean values for higher-order aberrations (HOAs) and total trefoils were significantly different between the preoperative and 1wk postoperative periods ($P$=0.029 for HOAs, $P$=0.037 for total frefoils) but not between the preoperative and 1 or 2mo postoperative periods. In Group I and Group II, these values were increased only in postoperative week 1, but the difference was not significant.

**Table 2 Increased corneal incision thickness in the three groups**

μm; $\bar{x} \pm s$

| Follow-up time | Group I | Group II | Group III |
|---|---|---|---|
| Post-op 1d | 304.9±67.6[a, c] | 337.7±59.5[a] | 382.4±73.7 |
| Post-op 1wk | 234.7±64.7[a] | 260.5±64.4 | 303.5±51.9 |
| Post-op 1mo | 96.6±34.7 | 98.5±36.8 | 110.9±41.8 |
| Post-op 2mo | 51.5±28.2 | 57.6±30.1 | 63.5±31.5 |

[a]$P$<0.05 *vs* Group III; [c]$P$<0.05 *vs* Group II.

## DISCUSSION

This study compared the clinical and optical outcomes of phacoemulsification in three incision sizes: 1.8, 2.0 and 3.0 mm. The aim was to determine whether the smaller incisions sizes (1.8 and 2.0 mm) conferred more advantages than the larger incision size (3.0 mm) and whether the 1.8 mm incision had obvious advantages over the 2.0 mm incision. To limit bias, the patients were assigned to three groups with similar preoperative characteristics. There were no intraoperative complications, cases of wound burn or Descemet membrane damage in our study. In agreement with the finding of other studies [6] of MICS and SICS, we did not find any statistically significant differences in the phacoemulsification time, ultrasound energy, and corneal endothelial cell loss among the three groups. These findings indicate that the three different incision sizes, which were made with the Venturi pump system, are equally efficient and safe, suggesting that converting from SICS to MICS will not

**Table 3 Preoperative and postoperative root mean square (RMS) values of the corneal wave aberrations for the three groups** $\bar{x} \pm s$

| Parameters | Pre-op | Post-op 1wk | Post-op 1mo | Post-op 2mo |
|---|---|---|---|---|
| HOAs | | | | |
| Group I | 1.40±0.36 | 1.53±0.33[a] | 1.45±0.33 | 1.44±0.23 |
| Group II | 1.45±0.39 | 1.60±0.45 | 1.50±0.30 | 1.46±0.25 |
| Group III | 1.37±0.37 | 1.72±0.40[c] | 1.57±0.38 | 1.54±0.26 |
| Total spherical aberration | | | | |
| Group I | 0.18±0.18 | 0.18±0.18 | 0.18±0.17 | 0.17±0.15 |
| Group II | 0.18±0.15 | 0.19±0.17 | 0.18±0.14 | 0.16±0.10 |
| Group III | 0.19±0.13 | 0.21±0.19 | 0.21±0.16 | 0.18±0.13 |
| Total coma | | | | |
| Group I | 0.36±0.26 | 0.37±0.29 | 0.36±0.24 | 0.35±0.22 |
| Group II | 0.37±0.26 | 0.38±0.29 | 0.37±0.33 | 0.34±0.25 |
| Group III | 0.37±0.31 | 0.39±0.38 | 0.36±0.29 | 0.33±0.27 |
| Total trefoils | | | | |
| Group I | 0.76±0.56 | 0.82±0.55[a] | 0.78±0.50 | 0.82±0.52 |
| Group II | 0.77±0.67 | 0.92±0.67 | 0.82±0.42 | 0.85±0.80 |
| Group III | 0.77±0.50 | 1.08±0.84[c] | 0.92±0.58 | 0.88±0.55 |
| Total tetrafoils | | | | |
| Group I | 0.36±0.32 | 0.40±0.43 | 0.36±0.30 | 0.36±0.22 |
| Group II | 0.42±0.31 | 0.43±0.39 | 0.38±0.25 | 0.40±0.25 |
| Group III | 0.39±0.28 | 0.53±0.49 | 0.42±0.30 | 0.39±0.32 |

[a]$P<0.05$ *vs* Group III; [c]$P<0.05$ *vs* preoperative value in the same group.

lengthen the duration of the surgery or reduce the efficiency of the surgery in nuclear sclerosis cases under Grade III.

It is generally recognized that wound healing is faster and that the recovery time is shorter when a smaller incision size is used[7]. Raise the question of whether an incision size with a mean of 1.8 mm would result in better wound healing than a 3.0 mm incision or, even, a 2.0 mm incision. Luo *et al*[2] showed that this was not the case, reporting a significantly greater mean maximal incision thickness and greater enlargement of incision size with 1.8 mm incisions than 2.2 and 3.0 mm incisions postoperatively. Vasavada *et al*[3] also showed a greater incision enlargement in a 1.8 mm group compared to a 2.2 mm group. However, in these studies, the surgeons used different phacoemulsification systems between groups, and each of the surgeons made a big incision enlargement in 1.8 mm group. Our clinical observations yielded different results from their studies. We found that the mean increase in the corneal incision thickness in Group I was significantly less than that in Group III on both day 1 and week 1 postoperatively and that the thickness was even less than that in Group II on postoperative day 1. Moreover, similar to that reported by Can *et al*[8] and Alió *et al*[9], the size of the incision in Group I after IOL implantation was 1.82±0.04 mm. The change in the size of the incision was only 1.11% in Group I, significantly less than that in Luo *et al*'s[2] study (11.41%) and Vasavada *et al*'s[3] study (13.89%). The increase in the thickness and size of the corneal incision is attributed to many intraoperative manipulations, such as phacoemulsification, cortical aspiration, IOL implantation and the water tightness of the incision. In our study, phacoemulsification and I/A did not result in any incision enlargement, whereas Luo *et al*[2] and Vasavada *et al*[3] reported a significant enlargement in the incision before IOL implantation (5.69% *vs* 9.44%). As a result of the different phacoemulsification systems they used, we thought their familiarity with the respective phacoemulsification systems may have affected their results. We also noticed that the size of the incision increased substantially during the IOL implantation (5.39% in Luo *et al*'s[2] study *vs* 4.06% in Vasavada *et al*'s[3] study). We thought that the enlargement in the size of the incision may have been caused by an inappropriate IOL implantation method. We used the wound-assisted technique to implant MI60 IOL, and this resulted in only a 1.11% enlargement in the incision. The insertion of an IOL injector into the incision would have increased the size of the incision. Based on our results, we propose that a smaller incision results in less damage and less likelihood of oedema. The use of a smaller sized incision by an experienced surgeon will not result in an increase in incision size.

The size of the incision is the main factor governing the amount of SIA after phacoemulsification. However, SIA is a complex problem, which is influenced by various other factors, such as the location, shape and healing of the

incision[10-11]. In Luo *et al*'s[2] and Vasavada *et al*'s[3] studies, the between-group difference in SIA and UCDVA was not statistically significant. However, the magnitude of SIA in the 1.8 mm group was greater than that in the 2.2 and 3.0 mm groups on postoperative day 1 (Luo *et al*'s [2] study) and greater than that in the 2.2 mm group 3mo postoperatively (Vasavada *et al*'s[3] study). Moreover, the UCDVA in the 1.8 mm group was worse than that in the 2.2 mm group on postoperative day 1 [3]. While, in our study, SIA was significantly reduced in Group I at all follow-up periods compared to that in Group II and Group III. In Group I, UCDVA was best on postoperative day 1, which is in agreement with that of other studies [12-13]. Interestingly, although there was a significant difference in SIA between Group I and Group II until postoperative 1mo, the difference was only 0.14-0.18 D, which had little effect on the UCDVA. These results suggested that SIA was obviously reduced by moving from a 3.0 mm incision to a 2.0 mm incision, but moving from a 2.0 mm incision to an even smaller 1.8 mm incision offered limited benefit in reducing SIA and improving visual acuity.

Many studies have reported that cataract surgery with IOL implantation induces and increases HOAs, which are not effectively corrected with spectacles, limiting the performance of the eye. Although aspherical IOL are applied to reduce the aberrations of the whole eyeball, corneal incisions can alter the cornea's optical power, generating SIA and postoperative changes in aberration [14]. In this study, we found a significant increase in HOAs and total trefoils of the cornea between the preoperative and 1wk postoperative periods in Group III. The HOAs and total trefoils of the cornea were significantly greater in Group III compared to those in Group I only 1wk postoperatively, which is in agreement with other studies [15]. After analysis of the effects of surgically induced changes in corneal aberrations on the image quality using MTF, the 0.5 MTF value was higher in Group I than in Group III at every postoperative visit, which confirmed our previous data [16]. However, with the 1.8 and 2.0 mm incisions, there were consistently no differences in the HOAs or in the 0.5 MTF value. Our data indicate that successful MICS gives better visual quality compared with SICS and leads to better patient satisfaction, especially in the early postoperative period. However, there appear to be little difference in the aforementioned parameters with 2.0 mm or even smaller (1.8 mm) incisions.

In conclusion, our results indicate that switching from conventional SICS to MICS will result in less SIA, faster visual rehabilitation, better incision integrity and better vision quality, without any reduction in efficiency and safety. In addition, the microcoaxial phacoemulsification technique does not require an additional learning curve when converting from a standard coaxial technique in the same phacoemulsification system and offers comparable outcomes with 1.8 and 2.0 mm incisions. Comparing the 1.8 and 2.0 mm incisions, the corneal optical quality is almost the same, and the 1.8 mm incision results in less SIA, less increase in the thickness of the corneal incision and better UCDVA than the 2.0 mm incision in the early postoperative period. However, the difference between the two groups is small and has little effect on the clinical outcomes. Thus, when the incision is reduced to 1.8 mm, compared with 2.0 mm, the benefits of the smaller incision on clinical outcomes seem negligible. The development of a phacoemulsification system for the smallest incision needs to be deliberated.

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