Aberration-correcting effect of ThinOptX IOL

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CLINICAL STUDY

Abstract

Purpose To evaluate spherical aberration and visual function after microincision cataract surgery using the ThinOptX rollable intraocular lens.

Design Prospective, comparative, and interventional case series.

Methods: Setting Single-centre institutional practice. This prospective study evaluated 58 patients with cataracts who underwent bimanual microphaco cataract surgery in both eyes. A ThinOptX lens was introduced into one eye and an Alcon Acrysof lens, as a control, into the other. One month after cataract surgery, the corneal, whole-eye, and internal spherical aberration, and contrast sensitivity in both eyes were measured. We also measured the spherical aberration in artificial model eyes bearing Acrysof and ThinOptX lenses. Two-sided paired *t*-test was used for assessing all data.

Results The root mean square (RMS) for both whole-eye and internal spherical aberrations was smaller in eyes bearing ThinOptX ($P=0.03$ and $P=0.07$, respectively). Although there was no statistically significant difference in the RMS for internal spherical aberration between ThinOptX- and Acrysof-bearing eyes, according to the Zernike polynomial expansion, all human and model eyes bearing ThinOptX registered negative internal spherical aberration in Z(4,0) and Z(6,0). On the other hand, all human and model eyes bearing Acrysof registered positive internal spherical aberration in Z(4,0) and Z(6,0). The ThinOptX lens yielded slightly higher contrast sensitivity in all cycles.

Conclusion As the ThinOptX lens is designed for negative spherical aberration, we encountered smaller whole spherical aberrations and higher contrast sensitivity than with the Acrysof lens. The implantation of ThinOptX IOL after microincision cataract surgery yielded good visual function.

Eye (2009) 23, 703–707; doi:10.1038/sj.eye.6703068; published online 21 December 2007

Keywords: microincision cataract surgery; ThinOptX; acrysof; IOL; aberration; contrast sensitivity

Introduction

Sleeveless bimanual microincision cataract surgery (MICS), as reported by Alio,^{1,2} Agarwal,^{3,4} or Tsuneoka,^{5,6} employs an irrigation chopper, a sleeveless tip, and the bimanual phaco technique, which is supposed to be safer and less invasive than the conventional coaxial phaco method. A 2004 survey by the American Society of Cataract and Refractive Surgery indicated that 40% of eye surgeons in the United States planned to use the bimanual microincision phaco technique. To implant intraocular lenses (IOL), the phaco incision must be 2.2–3.0 mm. In 2003, Dogru⁷ reported performing MICS with the ThinOptX rollable IOL (ThinOptX Inc., Abingdon, VA, USA) and discussed the feasibility of IOL implantation via a 1.6-mm incision. They found that ThinOptX IOL implantation resulted in the best-corrected visual acuity and postoperative corneal endothelium density when compared to those seen in the AcrySof (Alcon Inc., Fort Worth, Texas, USA) implantation. Thus, we examined visual function after MICS with ThinOptX rollable IOL implantation. Aberrometry has been applied recently to evaluate visual quality after cataract or refractive surgery.^{8–11} Most reports related to high-order aberrations of an IOL-implanted eye measure whole-eye aberration, and yet measurements are affected by front corneal aberration, which may disrupt on-target evaluation of the IOL. We measured, compared, and evaluated whole-eye, corneal, and internal spherical aberrations of ThinOptX IOL- and Acrysof IOL-implanted eyes. We also measured

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Received: 23 September 2007

Accepted in revised form: 19 November 2007
Published online: 21 December 2007

spherical aberrations of ThinOptX IOL- and Acrysof IOL-bearing model eyes. Contrast sensitivity was also measured.

Surgical technique

After making two 1.1-mm clear corneal incisions with an MVR knife (Visitec Inc., Franklin Lakes, NJ, USA), sodium hyaluronate is injected, and a continuous curvilinear capsulorhexis is created with a 26-gauge needle. Bimanual phaco surgery is then performed as described by Tsuneoka.⁵ Briefly stated, after hydrodissection with a balanced salt solution, a sleeveless, 20-gauge ultrasound tip and irrigating chopper are inserted through the two 1.1-mm corneal incisions and phacoemulsification is performed. The cortex is then removed by irrigation/aspiration and the capsular bag is filled with sodium hyaluronate. For ThinOptX IOL implantation, the 10 o'clock incision is

enlarged to 1.6 mm with a slit knife (Mani Inc., Utsunomiya, Tochigi, Japan), and the ThinOptX IOL, rolled into a cylindrical shape in the injector, is inserted into the posterior chamber through the 1.6-mm corneal incision (Figure 1a,b). For Acrysof IOL implantation, a 3.0-mm clear corneal incision is made at the temporal site and an unfolded IOL is inserted by the usual procedure using an injector.

Patients and methods

The study population consisted of 58 patients (116 eyes) who underwent bilateral lensectomy for corticonuclear cataract using the bimanual microphaco procedure. High myopia of more than 5 dioptre or high astigmatism of more than 2 dioptres was excluded. The study did not include patients having concurrent surgery, those with poor mydriasis, those with superficial anterior chamber or corneal disorder, glaucoma, or other retinal diseases. The mean age of the patients was 66.9 years (ranged 52–78 years). A prospective, randomized open study was conducted in parallel at a single study centre between March 2005 and March 2006. All operations were performed by the same surgeon and second operations were performed within 2 weeks of the first. After obtaining informed consent from all patients and approval from the Ethical Board Committee of Kyoto Prefectural University Hospital, they were consecutively assigned to receive a ThinOptX IOL in either the right or left eye, according to a randomization list (ThinOptX group). The fellow eye received the Acrysof MA30-BA IOL (Alcon Inc.) as a control (Acrysof group). To avoid the influence of proliferation of lens epithelial cells on the posterior capsule, all patients were examined 1 month after surgery. We measured whole-eye, corneal, and internal spherical aberrations, as well as contrast sensitivity, refractive status, uncorrected and best-corrected distance visual acuity, and corneal endothelium cell density.

Spherical aberrations with a pharmacologically induced, fully dilated pupil were measured using a scanning slit aberrometer OPD-Scan (Nidek Inc., Gamagori, Aichi, Japan). Zernike coefficients (up to and including the sixth order) were calculated for each image for a 4.0-mm pupil. We also measured the spherical aberration in ThinOptX- and Acrysof-bearing model eyes without a cornea¹² for more information about the optical characteristics of each IOL. The OPD-Scan is a combination unit that measures wave front aberrations, corneal topography, auto-refraction, and keratometry and can compute internal aberrations by subtracting corneal wave aberrations from total wave aberrations.^{13,14} Therefore, internal aberrations comprise aberrations of the IOL and posterior corneal surface aberrations.

Figure 1 (a, b) ThinOptX IOL implantation. A ThinOptX IOL was injected through a 1.6-mm clear corneal incision using the ThinRoller™ injector system (a), and unrolled to plate form in the capsule (b).

It should be noted, however, that the amount of posterior corneal surface aberrations have been shown to be negligible compared with IOL aberrations in normal and pseudophakic eyes.⁴ Contrast sensitivity in the right and left eye was measured using the CSV-1000 (Vector Vision Inc.) under photopic (85 cd/m²) conditions with best-correcting spectacles. The contrast sensitivity thresholds were determined to be the inverse of the contrast value of the lowest contrast patch, which the patient identified correctly for target spatial frequency values of 3, 6, 12, and 18 cycles per degree.

Statistical analysis

Differences in all data were assessed using a two-sided paired *t*-test. A *P*-value less than 0.05 was considered statistically significant.

Results

No intraoperative complication was recorded and the postoperative clinical course was normal in both groups. There was no significant difference between the ThinOptX IOL- and the Acrysof IOL-bearing eyes with respect to mean uncorrected and best-corrected visual acuity, refractive status, and corneal endothelial cell density (Table 1).

Table 2 shows the root mean square (RMS) for spherical-like aberrations at 1 month after surgery. Both whole-eye and internal spherical aberrations were

smaller in the ThinOptX IOL-bearing eyes than in the Acrysof IOL-bearing eyes (*P* = 0.03 and 0.07, respectively). Although there was no statistically significant difference in the RMS for internal spherical aberration between ThinOptX IOL- and Acrysof IOL-bearing eyes, according to the Zernike polynomial expansion, all eyes bearing the ThinOptX lens registered negative spherical aberration in Z(4.0) and Z(6.0). Conversely, all eyes bearing the Acrysof lens had positive spherical aberration in Z(4.0) and Z(6.0) (Table 3). In all eyes, the corneal topography exhibited positive spherical aberration, with no significant differences of the Zernike polynomial of spherical aberration between the two groups (Table 4). The ThinOptX IOL-bearing model eye also had negative spherical aberration outside the 3.0-mm optical zone and slightly positive spherical aberration inside the 3.0-mm zone, and the Acrysof lens had positive spherical aberration throughout the whole range (Figure 2).

The ThinOptX lens yielded higher contrast sensitivity in all cycles, although the difference between it and the Acrysof lens was not statistically significant (Figure 3).

Discussion

Cataract surgery using phacoemulsification and foldable IOLs introduced via a 3.0-mm incision has now become routine. But recently, the removal of cataracts via incisions as small as 1.3 mm, or smaller, has been reported. These new and advanced techniques, known as bimanual MICS,^{1,2,5,9,10} phakonit,^{3,4} and photolysis,^{15,16} utilize ultrasound or a laser with a sleeveless tip and an irrigation chopper. Although there is interest in this new technology, it has not been widely implemented, because the IOLs suitable for introduction via microincision have been approved only in Europe. The ThinOptX IOL is made of hydrophilic acryl and is ultrathin, allowing it to

Table 1 Postoperative examination

<i>Spherical equivalent refractive error (undiluted pupils) (dioptre)</i>	
<i>Acrysof</i>	<i>ThinOptX</i>
-0.59 ± 0.68	-0.53 ± 0.58 (<i>P</i> = 0.88)
<i>Uncorrected distance visual acuity (logMAR)</i>	
<i>Acrysof</i>	<i>ThinOptX</i>
0.008 ± 0.072	-0.017 ± 0.048 (<i>P</i> = 0.47)
<i>Best-corrected distance visual acuity (logMAR)</i>	
<i>Acrysof</i>	<i>ThinOptX</i>
-0.157 ± 0.088	-0.119 ± 0.063 (<i>P</i> = 0.64)
<i>Change in endothelial cell density (%)</i>	
<i>Acrysof</i>	<i>ThinOptX</i>
3.7 ± 3.1	4.8 ± 2.6 (<i>P</i> = 0.29)

Table 2 Postoperative spherical-like aberrations (S4 + S6)

	<i>Acrysof RMS (μm)</i>	<i>ThinOptX RMS (μm)</i>
Whole eye	$-0.234 \pm 0.108 >$	0.192 ± 0.086 (<i>P</i> = 0.03)
Internal	$-0.122 \pm 0.091 >$	0.097 ± 0.027 (<i>P</i> = 0.07)

Table 3 Postoperative Zernike polynomial of internal spherical aberrations

	<i>Acrysof</i>	<i>ThinOptX</i>
Z(4.0)	$0.040 \pm 0.030 >$	-0.053 ± 0.089 (<i>P</i> < 0.001)
Z(6.0)	$0.009 \pm 0.008 >$	-0.045 ± 0.106 (<i>P</i> = 0.001)

Table 4 Postoperative Zernike polynomial of corneal spherical aberrations

	<i>Acrysof</i>	<i>ThinOptX</i>
Z(4.0)	0.078 ± 0.061	0.058 ± 0.068 (<i>P</i> = 0.32)
Z(6.0)	0.004 ± 0.009	0.019 ± 0.133 (<i>P</i> = 0.49)

Figure 2 Spherical aberrations of ThinOptX- and Acrysof-bearing model eyes. In the ThinOptX-bearing model eye, spherical aberration is negative outside the 3.0-mm central area and slightly positive inside the 3.0-mm zone (concave lines in the lower graph indicate negative aberration, whereas convex lines indicate positive aberration) (left). On the other hand, in the Acrysof-bearing eye, spherical aberration is positive in all areas (right).

Figure 3 Contrast sensitivity at 1 month postoperation. Although the difference from the Acrysof-bearing eyes was not statistically significant, the ThinOptX-bearing eyes registered higher contrast sensitivity in all cycles at 1 month.

be rolled and injected through a microincision.^{7,17} However, exhaustive functional studies on this IOL are yet to be performed. Multiple investigations have demonstrated that contrast sensitivity is a strong indicator of vision quality^{18,19} and high order, eg spherical and coma aberrations affect contrast sensitivity and vision quality.^{20–23} Mester²⁴ evaluated a newly designed aspheric IOL based on these parameters.

We assessed visual function after MICS using the ThinOptX IOL to determine whether the ultrathin nature, and unique surface design of this lens results in better visual function than the widely used foldable acrylic IOL.

Postoperative comparative analysis of uncorrected and best-corrected distance visual acuity revealed no significant differences between the two lens types. Further, we saw no remarkable differences between the ThinOptX IOL- and Acrysof IOL-bearing eyes with respect to anterior chamber inflammation. However, on the basis of their subjective assessment recorded in the questionnaires, our patients rated the eye bearing the ThinOptX lens as providing better visual quality (data not shown). Although the results were unequivocal, the patients were informed which eye bears the new type of lens for ethical reasons, and the influence of bias cannot be excluded. However, contrast sensitivity was also higher in the ThinOptX IOL-bearing eyes, and this objective data might support and help explain the results of the questionnaire.

According to this study, the ThinOptX lens indicated better visual function, and it may be attributable to the lower whole-eye spherical aberration. Human corneas have positive spherical aberration, whereas crystalline lenses generally have negative spherical aberration, thus cancelling each other out. However, in the case of lens-extracted eyes, corneal-positive spherical aberration has a direct effect on whole-eye spherical aberration, and implanted spherical IOLs accelerate positive aberration. On the other hand, there was no significant difference in the mean corneal spherical aberration between the groups (Table 4), suggesting that any difference in whole-eye spherical aberration was attributable to the IOL. To date, several new IOLs have been designed to decrease spherical aberration. Most of these new designs, known

as aspherical IOLs, have a curvature gradient from the central area to the periphery. The ThinOptX IOL is a very thin plate haptic IOL with approximately 300 μm thickness in optic and 50 μm thickness in haptic. This thinness itself results in smaller spherical aberration, but also its curvature becomes larger from the 3.0-mm optical zone to the periphery at every 50 μm step and yields negative spherical aberration. Even though there is positive spherical aberration within the 3.0-mm central zone, it is relatively small because of the thinness of the lens. This is the reason why ThinOptX IOL-bearing eyes have smaller spherical aberration, especially outside the 3.0-mm optical zone.

Although further studies are required to assess possible posterior capsule opacification and the long-term stability of the ThinOptX IOL, we consider it a promising new candidate for cataract surgery.

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