·Clinical Research·

Clinical study of customized aspherical intraocular lens implants

Lie-Xi Jia, Zhao-Hui Li

Department of Ophthalmology, Chinese PLA General Hospital, Beijing 100853, China

Co-first authors: Lie-Xi Jia and Zhao-Hui Li

Correspondence to: Zhao-Hui Li. Fuxing Road 28, Department of Ophthalmology, Chinese PLA General Hospital, 100853, Beijing, China. lizhaohui301@126.com

Received: 2014-03-20 Accepted: 2014-07-14

Abstract

• AIM: To compare if there is an improvement in visual functions with age-related cataracts between patients receiving a aspherical intraocular lens (IOL) based on corneal wavefront aberration and patients randomly assigned lenses.

• METHODS: A total of 124 eyes of 124 patients with age-related cataracts were placed in experimental group and a group receiving randomly assigned (RA) lenses. The experimental group was undergone Pentacam corneal spherical aberration measurement before surgery; the targeted range for residual total spherical aberration after surgery was set to 0-0.3 μm. Patients with a corneal spherical aberration <0.3 μm were implanted with a zero-spherical aberration advanced optics (AO) aspherical IOL and patients with an aberration ≥0.3 μm received a Tecnis Z9003 aspherical lens in experimental group. RA patients were randomly implanted with an AO lens or a Tecnis Z9003 lens. Three months after surgery total spherical aberration, photopic/mesopic contrast sensitivities, photopic/mesopic with glare contrast sensitivities, and logMAR vision were measured.

• RESULTS: Statistical analysis on logMAR vision showed no significant difference between two groups (*P*=0.413). The post-surgical total spherical aberration was 0.126±0.097 μm and 0.152±0.151 μm in the experimental and RA groups, respectively (*P*=0.12). The mesopic contrast sensitivities at spatial frequencies of 6, 12 and 18 c/d in the experimental group were significantly higher than of the RA group (*P*=0.00; *P*=0.04; *P*=0.02). The mesopic with glare contrast sensitivity in the experimental group at a spatial frequency of 18 c/d was also significantly higher *vs* the RA group (*P*=0.01).

• CONCLUSION: Pre-surgical corneal spherical aberration measurement in cataract patients followed by customized selection of aspherical IOL implants improved mesopic contrast sensitivities at high spatial frequencies, and thus is a superior strategy compared to the random selection of aspherical intraocular lens implants.

• KEYWORDS: intraocular lens; cataract extraction; corneal wavefront aberration; mesopic vision; night vision

DOI:10.3980/j.issn.2222-3959.2014.05.14

Jia LX, Li ZH. Clinical study of customized aspherical intraocular lens implants. *Int J Ophthalmol* 2014;7(5):816-821

INTRODUCTION

Cataract phacoemulsification and intraocular lens (IOL) implantation are common techniques for treating cataracts. Ophthalmologists often seek to decrease the post-operative aberration of the whole eye and improve the quality of the patient's vision. Aspherical intraocular lenses are widely used in intraocular lens implantation. Here, the goal is to cancel the aberration in the human cornea, thus reducing the total aberration of the whole eye after surgery and improving visual acuity. Recent clinical studies have shown that aspherical intraocular lenses significantly improve post-operative vision in cataract patients compared with traditional intraocular lenses [1,2]. A wide range of aspherical intraocular lenses is currently available for clinical application, although the value added from the asphericity differs between them. Two questions emerge: 1) Can a random choice of different types of aspherical intraocular lenses used for implantation benefit all cataract patients, and 2) can customized implantation of corresponding aspherical intraocular lenses, which have a negative spherical aberration based on the pre-surgical corneal spherical aberration, improve visual quality. We report the results of a prospective, controlled study conducted to address these questions.

SUBJECTS AND METHODS

Subjects One hundred and twenty-four (124 eyes) with age-related cataracts were included in this study [67 males and 55 females, aged 51-84 (mean 69±7y)]. The selection criteria were as follows: ≥50 and ≤85 years old and diagnosed with only age-related cataracts; pre-surgical axial range: 22-26 mm; normal cognition; normal tear film; the ability to attend follow-ups as scheduled. The exclusion criteria were as follows: previous history of impaired visual recovery after surgery, including pre-surgical eye trauma, retinal diseases, glaucoma and corneal disease; history of corneal refractive surgery; post-surgical complications, including increased intraocular pressure and endophthalmitis. Informed and written consent was obtained from all individuals, and the study was approved by the local ethical review boards in accordance with the Declaration of Helsinki.

Clinical Observations 1) Slit lamp microscopy: Before and 1d, 1wk, and 3mo after surgery, the degree of corneal edema, wound healing status, and anterior chamber reactions were examined and recorded. 2) Patients were measured before and 3mo after surgery, using the Pentacam anterior segment measurement and analysis system (Oculus, Germany). Measurements were performed by the same person, and the test results, which were repeatable and with complete tear film, were averaged and recorded. 3) Five meter distance vision was measured according to the international standard vision chart and the logMAR vision was recorded. Using an Allegretto Wave Analyzer total spherical aberration meter (Wavelight AG, Germany), the aberration of the whole eye was measured with the 6 mm pupil diameter. In each case, the highest-quality images were used to establish the parameters and calculate the average. Contrast and glare sensitivities were determined using contrast sensitivity examination equipment (OPTEC-6500, Stereo Optical, USA). At the three-month follow-up, the best corrected distance visual acuity, whole-eye aberration, and the contrast sensitivities measured under the following conditions, photopic (light intensity: 85 cd/m^2), photopic with glare (glare intensity: 135 Lx), mesopic (light intensity: 3 cd/m^2), and mesopic with glare (glare intensity: 28 Lx). The recorded contrast sensitivity values were transformed into log values.

Criteria for Receiving a Aspherical IOL Based on Corneal Wavefront Aberration and Patient Grouping Wang and Koch [3] provided a detailed review of whole-eye aberration values. With a defocus of 0.00 or -0.50 D, most eyes achieved the best image quality at an ocular SA of -0.10 to 0.00 μm and 0.15 to 0.30 μm, respectively. Therefore, the post-surgical whole-eye refractive status was maintained between 0 and -0.5 D. The refraction of the IOL was calculated according to an IOL Master Measurement. The goal of a customized selected aspherical IOL implant is to achieve a targeted total spherical aberration between 0 and 0.3 μm after surgery. The patients were divided into two groups based on the sequence of admission. An experimental group included patients receiving aspherical intraocular lenses based on their pre-surgical corneal spherical aberration. The selection method was as follows: When the corneal spherical aberration was <0.3 μm, the patient received an Akreos AO IOL implant (Bausch & Lomb, Inc, San Dimas, California, USA.); when the corneal spherical aberration was ≥0.3 μm, the patient received a Tecnis Z9003 IOL implant (Advanced Medical Optics, Inc, Santa Anna, California, USA). In the random assignment group (RA), patients received an Akreos AO or Tecnis Z9003 IOL implant based on the result of a coin toss. Because the Acrysof IQ blue-blocking IOL with a -0.2 μm aberration might affect contrast sensitivity, it was not included in the study.

Surgical Methods Surgery was performed following ocular anesthesia and employed a transparent corneal incision. The main incision was made at the 10 o'clock position with a 3.0 mm disposable microkeratome, and an auxiliary incision was made on the corneal edge at the 2 o'clock position using a 15° corneal puncture knife. After injection of a viscoelastic agent into the anterior chamber, a continuous 5.5 mm diameter circular capsulorhexis was performed. Ultrasonic emulsification was applied to the lens and the residual cortex aspirated, after which the IOL was implanted in the lens capsule and the viscoelastic agent removed.

Statistical Analysis The data was analyzed using SPSS17.0 statistical software (SPSS Inc.); all data are expressed as the mean and standard deviation. The data were tested with the Shapiro-Wilk test to determine if it was normally distributed, and if this test failed then non-parametric statistical tests were used. Statistical analyses were performed using Mann-Whitney U test and Spearman's correlation test, and the χ^2-test. P values ≤0.05 were considered to indicate a statistically significant difference.

RESULTS

General Conditions There was no statistical significance (P>0.05) between the number of eyes in the experimental and RA groups, the gender or age of the patients, the axial length, or the refraction of the implanted IOL (Table 1). The intraocular lenses in all of the patients were positioned normally at follow-up. No significant opacity was observed in the posterior capsule of the lens, and post-operative complications were not found.

Pre- and Post-surgical Corneal Spherical Aberration and Post-surgical Total Spherical Aberration Before surgery, there was no statistically significant difference (P=0.569) in the total corneal spherical aberration (including anterior and posterior corneal surfaces, SA) of the experimental (0.297±0.149 μm) *vs* the RA group (0.303±0.124 μm), nor was there a significant post-operative difference at three months (0.281±0.129 μm *vs* 0.299±0.110 μm, respectively; P=0.362). In addition, the 6 mm pupil diameter total spherical aberration measured three months after surgery was also not shown significantly different between the experimental and RA patients (0.126±0.097 μm *vs* 0.152±0.151 μm, respectively; P=0.12. The total spherical aberration in the targeted 0-0.3 μm range was achieved in 85.5% of the experimental patients (53/62)

Table 1 Cataract patients in the control and experimental groups $\bar{x} \pm s$

Parameters	Total number of eyes (n)	Gender M	Gender F	Age (a)	Axial length (mm)	Intraocular lens (D)	AO[1] (n)	Tecnis[2] (n)
Experimental	62	32	30	70 ± 10.25	23.77 ± 0.91	21.66 ± 1.76	27	35
Random	62	35	27	68 ± 8.77	23.86 ± 1.13	21.35 ± 2.14	33	29
t		0.475[a]		0.824	-0.937	0.886	1.663[a]	
P		0.491		0.436	0.376	0.373	0.181	

[a]The χ^2 value; [1]Akreos AO intraocular lens implant (Bausch & Lomb,Inc.); [2]Tecnis Z9003 intraocular lens implant (Advanced Medical Optics, Inc.)

(Figure 1A), but only 59.7% of the RA patients (37/62) (Figure 1B).

Post –surgical LogMAR Vision Three months after surgery, the corrected distance vision was 0.032± 0.055 in the experimental group and 0.035± 0.053 in the RA group, which was not statistically significant (P=0.304).

Contrast and Glare Sensitivities Three Months After Surgery Three months after surgery, comparison between the two groups showed similar enhancement of contrast sensitivities under photopic and photopic with glare conditions (Table 2).

However, in the experimental group the mesopic contrast sensitivities were 1.891±0.197, 1.147±0.207 and 0.742±0.200, when tested at the respective spatial frequencies of 6, 12 and 18 c/d. These values were significantly higher than the values seen in the RA group under the same conditions (1.691±0.151; 1.048±0.172; 0.635±0.224) (Figure 2A). The mesopic with glare contrast sensitivity in the experimental group was 0.672 ±0.234 at a spatial frequency of 18 c/d, and was significantly higher compared with that of the RA group (0.565±0.278) (Figure 2B).

Correlation of the Predicted and Measured Values of Post –Surgical Aberration The total spherical aberration was predicted according to the simplified formula SA_{eye} = $SA_{individual\ cornea}$ + SA_{lens} [4]. The $SA_{individual\ cornea}$ was the 6 mm pupil diameter corneal aberration measured 1d before the surgery. The SA_{lens} of the Akreos AO IOL was 0 μm, and that of the Tecnis Z9003 IOL was -0.27 μm. The predicted values of the total spherical aberration were positively correlated with the values measured after the surgery (R^2=0.66, P<0.01; Figure 3). The difference between the predicted and measured postoperative SA for the entire investigated population showed that the mean absolute error was 0.043± 0.064 μm.

DISCUSSION

Aspherical intraocular lenses are widely used in IOL implantation. Studies have shown [5-8] that aspherical intraocular lenses, including the Acrysof SN60WF, Tecnis and Akreos AO, reduced post-surgical whole-eye aberration and improved the quality of vision in patients, compared to the spherical intraocular lenses of their countertypes (Acrysof SN60AT, Sensar AR40e and Akreos Fit). The added value, as well as the design ideas, differs for the various aspherical intraocular lenses. The Tecnis lens series has an added value of -0.27 μm and was designed for an average corneal spherical aberration in patients. The aim here was to reduce the whole-eye aberration to zero. The Akreos AO lens is an aspherical IOL with a zero-aberration design and the goal was to provide a certain depth of focus and maintain better image regulation ability without increasing the positive spherical aberration [9]. However, the variation in spherical aberration of the human cornea is relatively large. Wang *et al*[10] observed the distribution of high-level imaging from the anterior corneal surface in a given population (134 cases, 228 eyes; aged 20-79y). Their results showed that the spherical

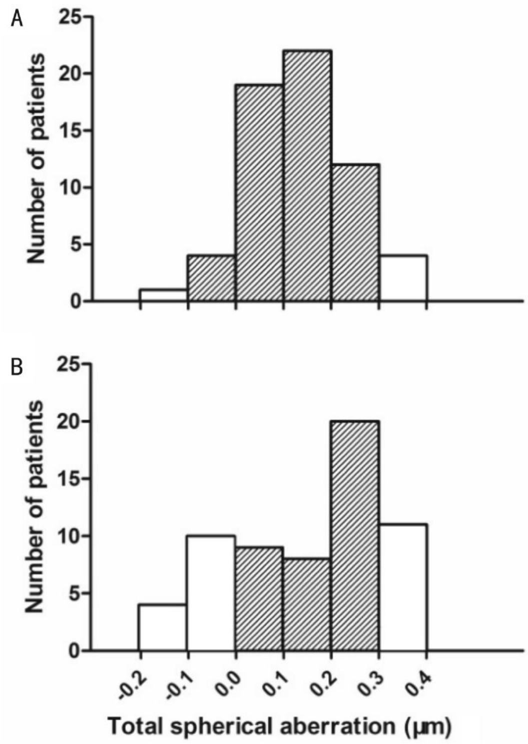

Figure 1 Distribution of patient total spherical aberration three months after the surgery A: Experimental group. The shaded area shows the number of patients that fell within the targeted range of 0.0 to 0.3 μm and represents 85.5% of the patients (53/62); B: Random assignment group. The shaded area represents only 59.7% of the patients (37/62).

Table 2 Contrast sensitivity (log values) under photopic, photopic with glare, mesopic, and mesopic with glare conditions

Cycles per degree	Experimental	RA	*P*
Photopic contrast			
1.5	1.77±0.18	1.78±0.16	0.69
3	1.91±0.31	1.90±0.29	0.98
6	1.92±0.21	1.89±0.22	0.49
12	1.22±0.23	1.23±0.21	0.67
18	0.95±0.66	0.82±.33	0.19
Photopic contrast with glare			
1.5	1.70±0.20	1.73±0.19	0.61
3	1.76±0.23	1.75±0.20	0.88
6	1.86±0.21	1.82±0.16	0.22
12	1.16±0.22	1.10±0.19	0.15
18	0.83±0.25	0.77±0.25	0.08
Mesopic contrast			
1.5	1.69±0.20	1.71±0.21	0.60
3	1.77±0.19	1.75±0.20	0.64
6	1.89±0.20	1.69±0.15	0.00[b]
12	1.15±0.21	1.05±0.17	0.04[a]
18	0.74±0.20	0.64±0.23	0.02[a]
Mesopic contrast with glare			
1.5	1.62±0.15	1.60±0.16	0.64
3	1.73±0.18	1.66±0.19	0.06
6	1.76±0.22	1.71±0.18	0.08
12	1.04±0.2	1.00±0.16	0.23
18	0.67±0.23	0.57±0.28	0.01[b]

[a]Significantly different at 0.05 level; [b]Significantly different at 0.01 level.

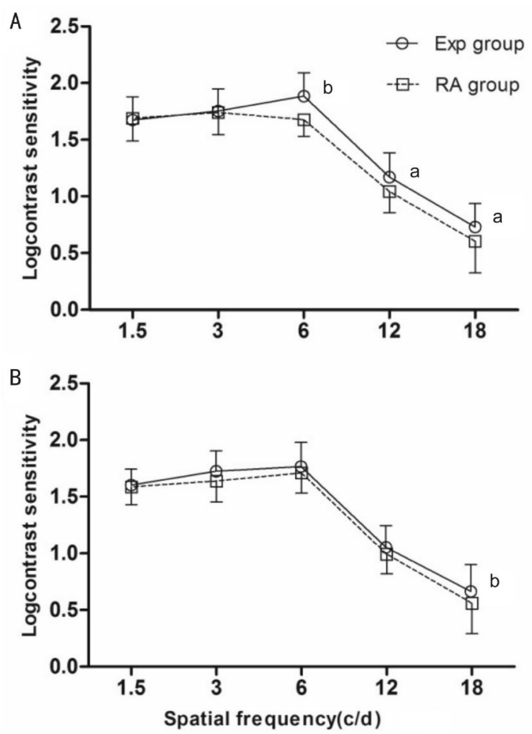

Figure 2 Contrast sensitivities at different spatial frequencies for the experimental (Exp) and randomly assigned (RA) groups three months after surgery A: Mesopic conditions; B: Comparison of mesopic with glare. Significant comparisons between Exp *vs* RA are indicated ([a]$P\leqslant 0.05$, [b]$P\leqslant 0.01$).

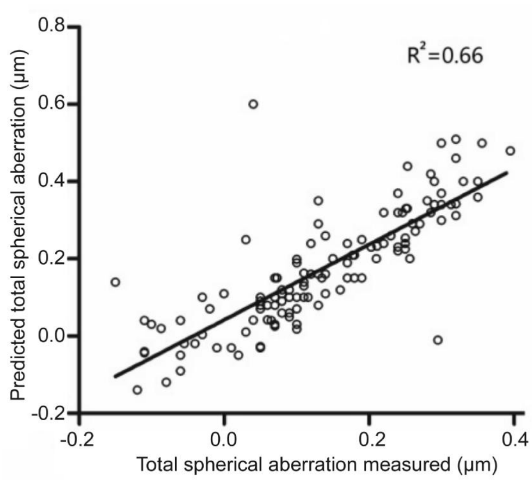

Figure 3 Correlation between predicted and measured values of the total ocular aberration three months after the surgery.

aberration from the anterior corneal surface varied between individuals, and that the values were all positive and averaged 0.280± 0.086 μm. He *et al* [11] studied the anterior corneal surface aberration of both eyes in 45 young people and found that the average spherical aberration coefficient was 0.30 ± 0.08 μm. Tong *et al* [12] measured the 6 mm anterior corneal spherical aberration in 144 cases (188 eyes) of age-related cataract patients and reported a mean of 0.231±0.092 μm (range: -0.096 to 0.469 μm). In agreement with the precious finding, we found the total corneal spherical aberrations (including anterior and posterior corneal SA) before surgery of the experimental and RA groups were 0.297±0.149 μm and 0.303±0.124 μm respectively (total range for all patients: 0.03 to 0.639 μm). Thus, if corneal spherical aberration is not measured before IOL implantation and the aspherical IOL is selected randomly, the optimum expected post-surgical total spherical aberration might not be achieved for all patients.

The purpose of customized selected aspherical IOL implantation based on corneal aberration is to reduce a patient's aberration and keep this within a target range. We set the targeted residual total spherical aberration after surgery between 0-0.3 μm and achieved a post-surgical total spherical aberration of 0.120±0.097 μm in the experimental group. Although the total spherical aberration was not significantly different between the experimental and RA patients three months after surgery, a higher proportion of experimental patients fell within the targeted range compared to RA patients. Nochez *et al* [13] performed a customized selected aspherical IOL implantation in order to produce a residual ocular SA close to +0.10 μm and achieved a final ocular SA of 0.085± 0.084 μm after surgery. Packer *et al*[14] selected an aspheric IOL for implantation based on preoperative corneal spherical aberration and the labeled IOL (AO, AcrySof IQ and Tecnis Z9002) spherical aberration, such that the arithmetic sum of these two values was closest to zero. The result showed that total postoperative ocular spherical aberration for the entire population measured -0.013 ± 0.072 μm. However, this study [14] lacked a random implant group for evaluation of visual function. Although they suggested that customized selected aspherical IOL implants improved the post-surgical total spherical aberration to close to zero, no evidence was provided as to whether visual quality was further improved.

The ultimate goal in reducing a patient's aberration to the targeted range is to provide a better visual outcome after the surgery. Customized selected aspherical IOL implantation would be meaningless if it only achieved the targeted aberration without improving visual function. Therefore, contrast sensitivity was examined after the surgery in both groups. The results showed that contrast sensitivity in the mesopic and mesopic with glare conditions at middle and high spatial frequencies was better in the experimental *vs* the RA group. This finding is in agreement with a similar recent study by Nochez *et al* [13] in which patients were implanted with zero-aberration Acri.Smart 46LC lenses (the reference group) or Acri.Smart36A lenses (experimental group) based on pre-surgical corneal spherical aberration. These authors showed that under mesopic conditions at high spatial frequencies, the contrast sensitivity was significantly better in the experimental group. The final target ocular spherical aberration between 0.07 μm and 0.10 μm should be considered to be the best compromise between subjective depth of focus and objective contrast sensitivity [15]. Beiko[16] performed a similar clinical trial, in which patients were divided into two groups, one with a corneal spherical aberration greater than +0.33 μm, and a group for which corneal spherical aberration was not measured. Patients in both groups received a Tecnis IOL (aberration: -0.27 μm) implant. The results indicated that the visual contrast sensitivity in the customized implant group (*i.e.* those based on pre-surgical measurements) was higher than that of the control group. These results underscore the necessity of customizing aspherical IOL implantation, especially for patients with a higher requirement for mesopic or night vision (*e.g.* taxi drivers).

Our study showed that the pre-operative predicted values of the total spherical aberration were positively correlated with the values measured after the surgery (r=0.811, P<0.01). However, we found a mean absolute predictive error of 0.043± 0.064 μm for postoperative SA in agreement with Nochez *et al*[13] (0.040± 0.047 μm) and very similar to that of Packer *et al* [14] (0.058± 0.056 μm) who tested three different IOLs (AO, AcrySofIQ and Tecnis). Minor variations in predictive value were explained as a result of the postoperative aperture size being limited by the capsulorhexis and by variations in pupil dilatation [14]. In our study, one should be aware that there were minor variations in the corneal spherical aberration before and after surgery between the two groups (pre: 0.297±0.149 μm and 0.303 ±0.124 μm, post: 0.281±0.129 μm and 0.299±0.110 μm). These variations of corneal spherical aberration may be one of the reasons for the predictive error of postoperative SA.

Further clinical studies are needed on the selective implantation of aspherical IOL based on corneal aberrations. There are relatively few types of aspherical IOL to choose from and the aspherical parameters are not comprehensive, but this might still be a future trend. Following the development of corneal refractive surgery in recent decades, myopic refractive surgery might increase corneal positive spherical aberration, while hyperopic refractive surgery might reduce it, even to negative values [17-20]. For this reason, in addition to accurate calculation of IOL refraction, cataract patients with previous refractive surgery should receive corresponding aspherical IOL based on their corneal spherical aberration.

ACKNOWLEDGEMENTS

The authors wish to thank Dr. T. Fitz Gibbon for comments and suggestions on earlier drafts of the manuscript. Gratitude is also extended to all of the patients for participating in the study.

Conflicts of Interest: Jia LX, None; **Li ZH,** None.

REFERENCES

1 Montés-Micó R, Ferrer-Blasco T, Cerviño A. Analysis of the possible benefits of aspheric intraocular lenses: review of the literature. *J Cataract Refract Surg* 2009;35(1):962-963

2 Belluci R, Morselli S. Optimizing higher-order aberrations with intraocular lens technology. *Curr Opin Ophthalmol* 2007;18(1):67-73

3 Wang L, Koch DD. Custom optimization of intraocular lens asphericity. *J Cataract Refract Surg* 2007;33(10):1713-1720

4 Holladay JT, Piers PA, Koranyi G,van der Mooren M, Norrby NE. A new intraocular lens design to reduce spherical aberration of pseudophakic Eyes. *J Refract Surg* 2002;18(6):683-691

5 Caporossi A, Casprini F, Martone G, Balestrazzi A, Tosi GM, Ciompi L. Contrast sensitivity evaluation of aspheric and spherical intraocular lenses 2 years after implantation. *J Refract Surg* 2009;25(7):578-590

6 Santhiago MR, Netto MV, Barreto J Jr, Gomes BA, Oliveira CD, Kara-Junior N. Optical quality in eyes implanted with aspheric and spherical intraocular lenses assessed by NIDEK OPD-Scan: a randomized, bilateral, clinical trial. *J Refract Surg* 2011;27(4):287-292

7 Ohtani S, Miyata K, Samejima T, Honbou M, Oshika T. Intraindividual comparison of aspherical and spherical intraocular lenses of same material and platform. *Ophthalmology* 2009;116(5):896-901

8 Morales EL, Rocha KM, Chalita MR, Nosé W, Avila MP. Comparison of optical aberrations and contrast sensitivity between aspheric and spherical intraocular lenses. *J Refract Surg* 2011;27(10):723-728

9 Santhiago MR, Netto MV, Barreto J Jr, Gomes BA, Mukai A, Guermandi AP, Kara-Junior N. Wavefront analysis, contrast sensitivity, and depth of focus after cataract surgery with aspherical intraocular lens implantation *Am J Ophthalmol* 2010;149(3):383-389

10 Wang L, Dai E, Koch DD, Nathoo A. Optical aberations of the human anterior cornea. *J Cataract Refract Surg* 2003;29(8):1514-1521

11 He JC, Gwiazda J, Thorn F, Held R. Wave-front aberrations in the anterior corneal surface and the whole eye *J Opt Soc Am A Opt Image Sci Vis* 2003;20(7):1155-1163

12 Tong NX, Zhao YE, Wang QM, Li XY. Distribution of human anterior corneal spherical aberration and its related factors *Zhonghua Yan Ke Za Zhi* 2007;43(8):684-687

13 Nochez Y, Favard A, Majzoub S, Pisella PJ. Measurement of corneal aberrations for customisation of intraocular lens asphericity: impact on quality of vision after micro-incision cataract surgery *Br J Ophthalmol* 2010;94(4):440-444

14 Packer M, Fine IH, Hoffman RS. Aspheric intraocular lens selection based on corneal wavefront *J Refract Surg* 2009;25(1):12-20

15 Nochez Y, Majzoub S, Pisella PJ. Effect of residual ocular spherical aberration on objective and subjective quality of vision in pseudophakic eyes *J Cataract Refract Surg* 2011;37(6):1076-1081

16 Beiko GH. Personalized correction of spherical aberration in cataract surgery *J Cataract Refract Surg* 2007;33(8):1455-1460

17 Muñoz G, Albarrán-Diego C, Ferrer-Blasco T, Garcìa-Lázaro S, Cerviño-Expósito A. Long-term comparison of corneal aberration changes after laser *in suit* keratomileusis: mechanical microkeratome versus femtosecond laser flap creation *J Cataract Refract Surg* 2010;36 (11): 1934-1944

18 Calvo R, McLaren JW, Hodge DO, Bourne WM, Patel SV. Corneal aberrations and visual acuity after laser *in suit* keratomileusis: femtosecond laser versus mechanical microkeratome *Am J Ophthalmol* 2010;149 (5): 785-793

19 Keir NJ, Simpson T, Hutchings N, Jones L, Fonn D. Outcomes of wavefront-guided laser *in suit* keratomileusis for hyperopia *J Cataract Refract Surg* 2011;37(5):886-893

20 Durrie DS, Smith RT, Waring GO 4th, Stahl JE, Schwendeman FJ. Comparing conventional and wavefront-optimized LASIK for the treatment of hyperopia *J Refract Surg* 2010;26(5):356-363