

Clinical Evaluation of Optical Quality and Intraocular Scattering after Posterior Chamber Phakic Intraocular Lens Implantation

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PURPOSE. We assessed the optical quality and intraocular scattering after posterior chamber phakic intraocular lens implantation.

METHODS. We examined prospectively 38 eyes of 19 consecutive patients undergoing implantable contact lens (ICL) implantation (mean age \pm SD 36.3 ± 5.7 years), and 38 age-matched normal eyes of 19 healthy volunteers (mean age 36.4 ± 4.9 years). We assessed quantitatively the values of modulation transfer function (MTF) cutoff frequency, Strehl ratio, objective scattering index (OSI), and the Optical Quality Analysis System (OQAS) values (OVs). We compared these variables in eyes undergoing ICL implantation to those in healthy eyes.

RESULTS. The mean MTF cutoff frequency, Strehl ratio, OSI, OV 100%, OV 20%, and OV 9% were 28.69 ± 8.59 cycles/degree, 0.17 ± 0.04 , 1.06 ± 0.48 , 0.96 ± 0.29 , 0.83 ± 0.31 , and 0.83 ± 0.32 , respectively, 3 months after ICL implantation. We found no significant differences in the MTF cutoff frequency (Mann Whitney *U* test, $P=0.31$), Strehl ratio ($P=0.46$), OSI ($P=0.30$), or OVs at contrasts of 100% ($P=0.51$), 20% ($P=0.46$), and 9% ($P=0.36$), between the ICL and control groups.

CONCLUSIONS. The optical quality parameters, such as the MTF cutoff frequency, Strehl ratio, OSI, or OVs in the ICL group, were not significantly different from those in the control group, suggesting that the optical quality and intraocular scattering of eyes undergoing ICL implantation essentially was equivalent to those of healthy eyes. (*Invest Ophthalmol Vis Sci* 2012;53:3161-3166) DOI:10.1167/iovs.12-9650

The Visian Implantable Collamer Lens (ICL, STAAR Surgical, Nidau, Switzerland), a posterior chamber phakic intraocular lens (IOL), has been reported to be effective for the correction of moderate to high ametropia.¹⁻¹⁰ In addition, this surgical procedure largely is reversible and, unlike laser in situ keratomileusis (LASIK), allows the lens to be exchanged even when unexpected refractive changes occur after surgery.

Recently, toric ICL also has been demonstrated to be effective for the correction of high myopic astigmatism.¹¹⁻¹⁴

The Optical Quality Analysis System (OQAS, Visiometrics, Terrassa, Spain), which is designed on the basis of the asymmetric pattern of the double-pass technique,^{15,16} with different entrance and exit pupil sizes, enabling the detection of both symmetric and asymmetric aberrations, is the only currently available instrument used for objective measurement of optical quality in a clinical setting.¹⁷ In addition to optical quality measurements, the system also provides an objective estimation of intraocular scattering.¹⁸ This system allows direct objective measurement of the effect of optical aberrations and the loss of ocular transparency on the optical quality of the human eye. Since the effectiveness of ICL implantation has been improved in recent years, it has an important role in differentiating refractive outcomes for this surgery in quantitative characterization of the optical quality of the eye. However, to our knowledge, the postoperative visual performance after this surgical technique has been discussed hitherto only in terms of visual acuity, higher order aberrations, or contrast sensitivity. To our knowledge, neither detailed optical quality nor the intraocular scattering, both of which have an important role in the postoperative visual performance after ICL implantation, has been investigated quantitatively to date. The aim of our study was to compare these optical quality variables prospectively, including the intraocular scattering in eyes undergoing ICL implantation with those in age-matched healthy eyes.

MATERIALS AND METHODS

Study Population

A total of 38 eyes of 19 consecutive patients (7 men and 12 women), who underwent implantation of the Visian ICL posterior chamber phakic implantable collamer lens for the correction of moderate to high myopia (manifest spherical equivalent ≤ -4.00 diopters [D]), was included in this prospective interventional study as the study group (ICL group). Since it sometimes is difficult to determine these preoperative optical variables precisely and reproducibly, especially in high myopic eyes, 38 eyes of 19 age-matched healthy volunteers (8 men and 11 women), who had no ophthalmic disease other than myopic refractive errors, also were included in our study as the control group. The sample sizes in our study offered 82% statistical power at the 5% level to detect a 5-cycles/degree difference in modulation transfer function (MTF) cut off frequencies between the two groups, when the SD of the mean difference was 7.5 cycles/degree. They also offered 90% statistical power at the 5% level to detect a 0.03-difference in the Strehl ratio between the two groups, when the SD of the mean difference was 0.04, and offered 82% statistical power at the 5% level to detect a 0.40-difference in the objective scattering index (OSI) between

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two groups, when the SD of the mean difference was 0.60. Mean \pm SD patient ages were 36.3 ± 5.7 years (range 29–45 years) in the ICL group and 36.4 ± 4.9 years (range 29–46 years) in the control group. The manifest spherical equivalents were -7.04 ± 2.02 D (range -4.00 to -12.00 D) preoperatively and -0.02 ± 0.21 D (range 0.50 to -0.50 D) postoperatively in the ICL group, and -0.32 ± 0.79 D (range 0.70 to -2.25 D) in the control group. The manifest refractive cylinders were -0.73 ± 0.49 D (range 0.00 to -1.50 D) preoperatively and -0.26 ± 0.35 D (range 0.00 to -1.00 D) postoperatively in the ICL group, and -0.16 ± 0.20 D (range 0.00 to -0.50 D) in the control group. In the ICL group, we selected non-toric ICL in 32 eyes (84%) with the manifest cylinder of 1.25 D or less, or toric ICL in 6 eyes (16%) with that of 1.5 D or more. Eyes with keratoconus were excluded from the study by using the keratoconus screening test of Placido disk videokeratography (TMS-2; Tomey, Nagoya, Japan). The study was approved by the Institutional Review Board at Kitasato University School of Medicine, and followed the tenets of the Declaration of Helsinki. Informed consent was obtained from all patients.

Implantable Collamer Lens Power Calculation

ICL power calculations were performed by the manufacturer (STAAR Surgical) using a modified vertex formula. Toric ICL power calculation was performed by the manufacturer using the astigmatism decomposition method. The size of the ICL also was chosen by the manufacturer based on the horizontal corneal diameter and anterior chamber depth measured with scanning-slit topography (Orbscan IIz; Bausch & Lomb, Rochester, NY).

Implantable Collamer Lens Surgical Procedure

The patients preoperatively underwent 2 peripheral iridotomies with a neodymium-YAG laser. On the day of surgery, the patients were given dilating and cycloplegic agents. After topical anesthesia, a model V4 ICL was inserted through a 3-mm clear corneal incision with the use of an injector cartridge (STAAR Surgical) after placement of a viscosurgical device (Opegan; Santen, Osaka, Japan) into the anterior chamber. The ICL was placed in the posterior chamber, the remaining viscosurgical device was washed completely out of the anterior chamber with balanced salt solution, and a miotic agent was instilled. For toric ICL implantation, to control for potential cyclotorsion in a supine position, the zero horizontal axis was marked preoperatively using a slit-lamp. A Mendez ring also was used for measuring intraoperatively the required rotation from the horizontal axis. Afterwards, the ICL had then been placed in the posterior chamber and rotated by 22.5 degrees or less using the manipulator. After surgery, steroidal (0.1% betamethasone, Rinderon; Shionogi, Osaka, Japan) and antibiotic (levofloxacin, Cravit; Santen) medications were administered topically 4 times daily for 2 weeks, and the dose was reduced steadily thereafter.

Optical Quality Measurement

We measured the optical quality parameters of the eye, such as the MTF cutoff frequency, Strehl ratio, OSI, and OQAS values (OVs, 100%, 20%, and 9%) 3 months after ICL implantation, using the OQAS for a 4.0-mm pupil. The manifest refractive error of the subjects was corrected fully during these measurements; the spherical error (up to -8.00 D) was corrected automatically by the double-pass system, and the residual spherical error (over -8.00 D) as well as the cylindrical error were corrected with an external lens because the uncorrected refractive error affects directly the optical outcome of the system. The pupil diameter was provided by this device from an image of an additional video camera that allowed pupil alignment. We confirmed that the pupil diameter was more than 4.0 mm in all eyes. The room illumination was kept low (approximately 25 lux) during testing. The value considered is the cutoff point of the MTF curve on the x-axis. The results are given in cycles per degree, representing the highest spatial

frequency at lower contrast. The MTF cutoff in the double-pass system is the frequency at which the MTF reaches a value of 0.01. Because the point spread function (PSF) images recorded by the double-pass instrument can be affected by high-frequency noise, which is inherent in the use of cameras, the frequency for very small MTF values may become unstable, potentially leading to artifacts. To avoid this problem, the device uses an MTF threshold value of 0.01, which corresponds to 1% contrast. Thus, the MTF cutoff frequency in our study refers to the frequency up to which the eye can focus an object on the retina with a significant 1% contrast. The Strehl ratio is an expression of the ratio of the central maximum of the illuminance of the PSF in the aberrated eye to the central maximum that would be found in a corresponding aberration-free system. It is the measure of the fractional drop in the peak of the PSF as a function of the wavefront error. The OSI is an objective evaluation of intraocular scattered light. The index is calculated by evaluating the amount of light outside the double-pass retinal intensity PSF image in relation to the amount of light on the center. In the particular case of the instrument OQAS, the central area selected was a circle of a radius of 1 minute of arc, while the peripheral zone was a ring set between 12 and 20 minutes of arc.¹⁹ The OSI for normal eyes would range around 1, while values over 5 would represent highly scattered systems. The three OVs are normalized values of three spatial frequencies, which correspond to MTF values that describe the optical quality of the eye for three contrast conditions, commonly used in ophthalmic practice: 100% (OV 100%), 20% (OV 20%), and 9% (OV 9%).²⁰ Specifically, the OV 100% is related directly to the MTF cutoff frequency (it is the MTF cutoff frequency divided by 30 cycles/degree) and, therefore, to the patient's visual acuity, although it is not affected by retinal and neural factors. The OV 20% and OV 9% are computed in the same way from smaller frequencies that are linked to 0.05 and 0.1 MTF values, respectively, which maintain the proportion of contrasts of 20% and 9%.

In addition, to assess the repeatability of the measurements for confirming the applicability of the data, the measurements with this device were made in 20 normal eyes at the same time of day on two days. We evaluated the repeatability of the two measurements as described previously using Bland-Altman plots.²¹

Statistical Analysis

All statistical analyses were performed using StatView software version 5.0 (SAS, Cary, NC). The Mann-Whitney *U* test was used to compare the data between the two groups. The Wilcoxon signed-rank test was used to compare the data before and after surgery. The results are expressed as mean \pm SD, and a value of $P < 0.05$ was considered statistically significant.

RESULTS

The demographic data of the study population are shown in Table 1. All surgical procedures were uneventful, and no postoperative complications, such as cataract formation, pigment dispersion syndrome, pupillary block, or axis rotation, were seen throughout the observation period. There was no significant difference in terms of patient age ($P = 0.80$), sex ($P = 0.34$), manifest spherical equivalent ($P = 0.21$), manifest cylinder ($P = 0.37$), or logarithm of the minimal angle of resolution (LogMAR) best spectacle-corrected visual acuity ($P = 0.11$). Figure 1 shows representative examples of the double-pass images of eyes undergoing ICL implantation and healthy eyes. The MTF cutoff frequency, Strehl ratio, and OSI were 28.69 ± 8.59 cycles/degree (range 12.49–46.86 cycles/degree), 0.17 ± 0.04 (range 0.10–0.26), and 1.06 ± 0.48 (range 0.40–2.80), respectively, in the ICL group. The MTF cutoff frequency, Strehl ratio, and OSI were 30.44 ± 9.52 cycles/degree (range 14.46–50.95 cycles/degree), 0.18 ± 0.05 (range 0.09–0.28), and 1.03 ± 0.65 (range 0.40–3.00),

ICL group

Control group

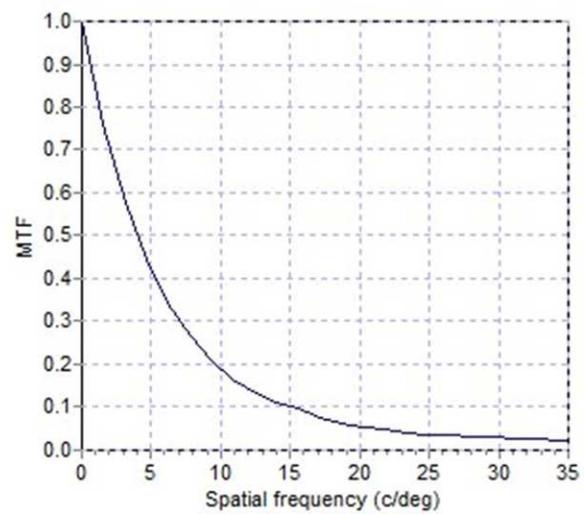
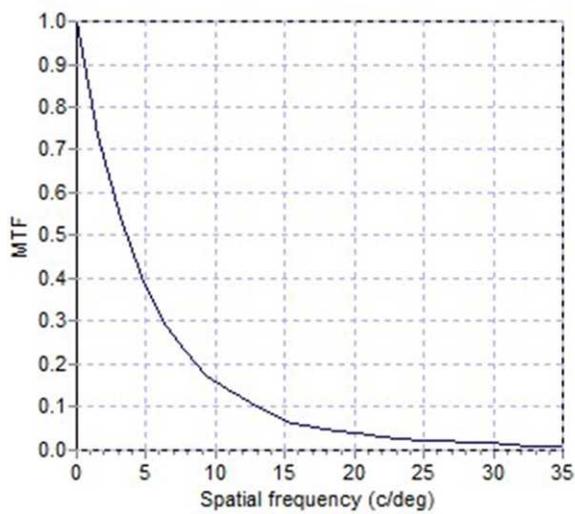
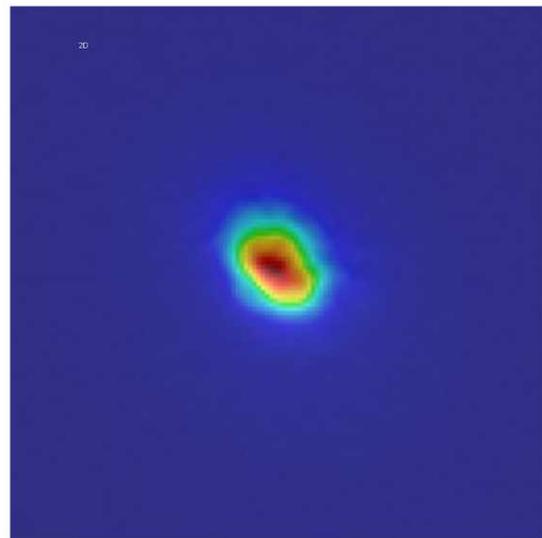
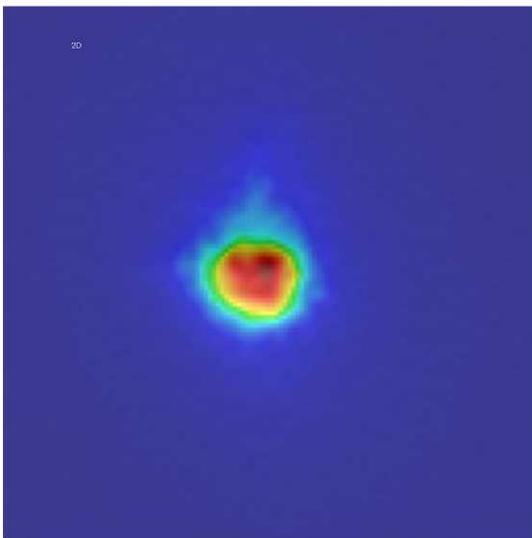
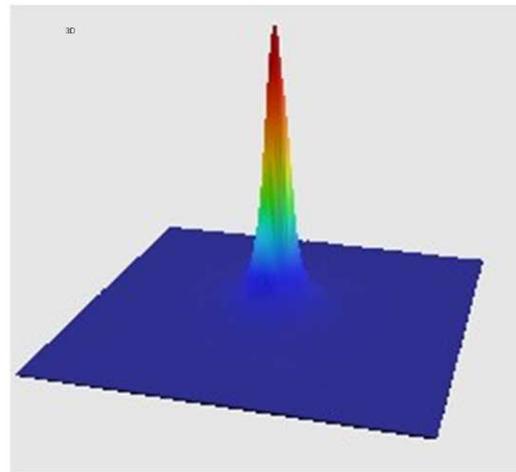
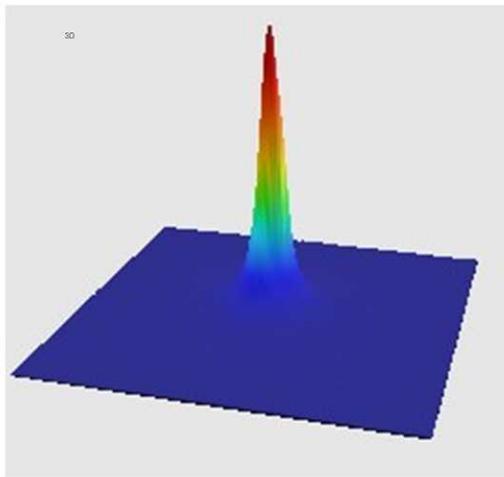


FIGURE 1. The double-pass images of eyes undergoing ICL implantation and healthy eyes.

TABLE 1. Demographics of Eyes Undergoing ICL Implantation and Normal Control Eyes

	ICL Group	Control Group	P Value
Age (years)	36.3 ± 5.7 (range 29–45)	36.4 ± 4.9 (range 29–46)	0.80
Sex (% female)	36.8	42.1	0.34
Manifest spherical equivalent (D)	−0.02 ± 0.21 (range 0.50 to −0.50)	−0.32 ± 0.79 (range 0.70 to −2.25)	0.21
Manifest cylinder (D)	−0.26 ± 0.35 (range 0.00 to −1.00)	−0.16 ± 0.20 (range 0.00 to −0.50)	0.37
LogMAR BSCVA	−0.26 ± 0.06 (range −0.18 to −0.30)	−0.24 ± 0.06 (range −0.18 to −0.30)	0.11

BSCVA, best spectacle-corrected visual acuity.

respectively, in the control group. We found no significant differences in the MTF cutoff frequency (Mann Whitney *U* test, $P=0.31$), Strehl ratio ($P=0.46$), or OSI ($P=0.30$) between the two groups (Table 2). The OV 100%, OV 20%, and OV 9% were 0.96 ± 0.29 (range 0.42–1.56), 0.83 ± 0.31 (range 0.34–1.70), and 0.83 ± 0.32 (range 0.36–1.54), respectively, in the ICL group, and 1.01 ± 0.32 (range 0.48–1.70), 0.85 ± 0.22 (range 0.52–1.35), and 0.85 ± 0.20 (range 0.47–1.32), respectively, in the control group. We found no significant differences in the OV 100% ($P=0.51$), OV 20% ($P=0.46$), or the OV 9% ($P=0.36$) between the two groups (Table 2). We also compared preoperative and postoperative optical parameters in 8 eyes with moderate myopia (lower than −8 D, no astigmatism) that could be compensated only by using the Badal system. The preoperative and postoperative mean MTF cutoff frequencies, Strehl ratios, and OSI, OV 100%, OV 20%, and OV9 % values, were 32.20 ± 8.79 (range 20.73–43.16) and 31.99 ± 9.72 (range 18.09–44.10) cycles/degree; 0.18 ± 0.08 (range 0.10–0.34) and 0.18 ± 0.04 (range 0.13–0.22); 0.96 ± 0.17 (range 0.80–1.30) and 1.04 ± 0.40 (range 0.70–1.60); 1.09 ± 0.32 (range 0.69–1.57) and 1.07 ± 0.32 (range 0.60–1.47); 0.92 ± 0.33 (range 0.46–1.43) and 0.90 ± 0.36 (range 0.42–1.34); and 0.81 ± 0.37 (range 0.25–1.37) and 0.84 ± 0.40 (range 0.43–1.52), respectively. We found no significant differences in the MTF cutoff frequency (Wilcoxon signed-rank test, $P=0.89$), Strehl ratio ($P=1.00$), OSI ($P=0.80$), or OVs at contrasts of 100% ($P=0.89$), 20% ($P=0.78$), and 9% ($P=0.89$) before and 3 months after ICL implantation. Bland-Altman plots indicate that the mean difference between two measurements with this device ($\pm 95\%$ limits of agreement; LoA) was 1.02 ± 3.64 cycles/degree (−6.10–8.15 cycles/degree) for MTF cutoff frequency, 0.00 ± 0.03 (−0.07–0.06) for Strehl ratio, and $−0.02 \pm 0.17$ (−0.35–0.32) for OSI (Fig. 2).

DISCUSSION

In our study, we demonstrated that there were no significant differences in the optical quality parameters, namely the MTF cutoff frequency, Strehl ratio, OSI, or OVs at contrasts of 100%, 20%, and 9%, between the two groups. These results indicate that the optical quality, including the intraocular scattering of eyes undergoing ICL implantation, was essentially equivalent to that of healthy eyes. It is known that the optical quality of the eye decreases with aging.^{22,23} We know that these optical

values in this study were lower than those in previous studies,^{23,24} possibly because of the relatively high patient age. Until now, the postoperative visual performance after ICL implantation has been determined only in terms of visual acuity, higher order aberrations, or contrast sensitivity. Considering that the double pass system will continue to have a vital role in daily clinical practice, it probably will be useful clinically for quantitatively characterizing the optical quality of the eye. To our knowledge, this is the first study to assess the detailed optical quality of the eye, including the intraocular scattering, after posterior chamber phakic IOL implantation. With regard to the iris-supported phakic IOLs, Vilaseca et al. demonstrated that the patients with phakic IOL implants recovered more optical quality than the LASIK patients 1 month after surgery, but that the Verisyse phakic IOL implantation significantly reduced the eye's optical quality 1 day after surgery, mainly due to the larger incision required and the higher number of sutures used.²⁰ However, they did not assess quantitatively the intraocular scattering itself, which is considered to have a large impact on the vision of patients who have undergone refractive surgery. Since the tilt or decentration of the IOL induces some additional scattering in/of the eye after phakic IOL implantation, it is important clinically to assess this scattering quantitatively. We assume that the narrow fixated location of the ICL between the iris and ciliary sulcus may not contribute to any clinically significant tilt or decentration of the ICL, thus causing only a small amount of intraocular scattering, as suggested by the low postoperative OSI value equivalent to that of healthy eyes.

With regard to higher order aberrations and contrast sensitivity, we showed previously that ICL implantation induced significantly fewer ocular higher order aberrations than did wavefront-guided LASIK, and that it increases contrast sensitivity significantly, not only in the treatment of high myopia,²⁵ but also in the treatment of low to moderate myopia.²⁶ Bühren et al. also reported that the number of higher order aberrations increased slightly after implantation of the Artisan phakic IOL.²⁷ ICL and Artisan lens implantation are considered to induce fewer higher order aberrations than wavefront-guided LASIK, possibly because of the retention of an unchanged corneal prolate shape as well as the negative spherical aberration of ICLs, regardless of the amount of myopic correction. The United States Food and Drug Administration (FDA) ICL trial demonstrated no loss of contrast at any partial frequency, and a significant improvement at 6 and

TABLE 2. Optical Quality Parameters in Eyes Undergoing ICL Implantation and Normal Eyes

	ICL Group	Control Group	P Value
MTF cutoff frequency (cpd)	28.69 ± 8.59 (range 12.49–46.86)	30.44 ± 9.52 (range 14.46–50.95)	0.31
Strehl ratio	0.17 ± 0.04 (range 0.10–0.26)	0.18 ± 0.05 (range 0.09–0.28)	0.46
OSI	1.06 ± 0.48 (range 0.40–2.80)	1.03 ± 0.65 (range 0.40–3.00)	0.30
OV100%	0.96 ± 0.29 (range 0.42–1.56)	1.01 ± 0.32 (range 0.48–1.70)	0.51
OV 20%	0.83 ± 0.31 (range 0.34–1.70)	0.85 ± 0.22 (range 0.52–1.35)	0.46
OV 9%	0.83 ± 0.32 (range 0.36–1.54)	0.85 ± 0.20 (range 0.47–1.32)	0.36

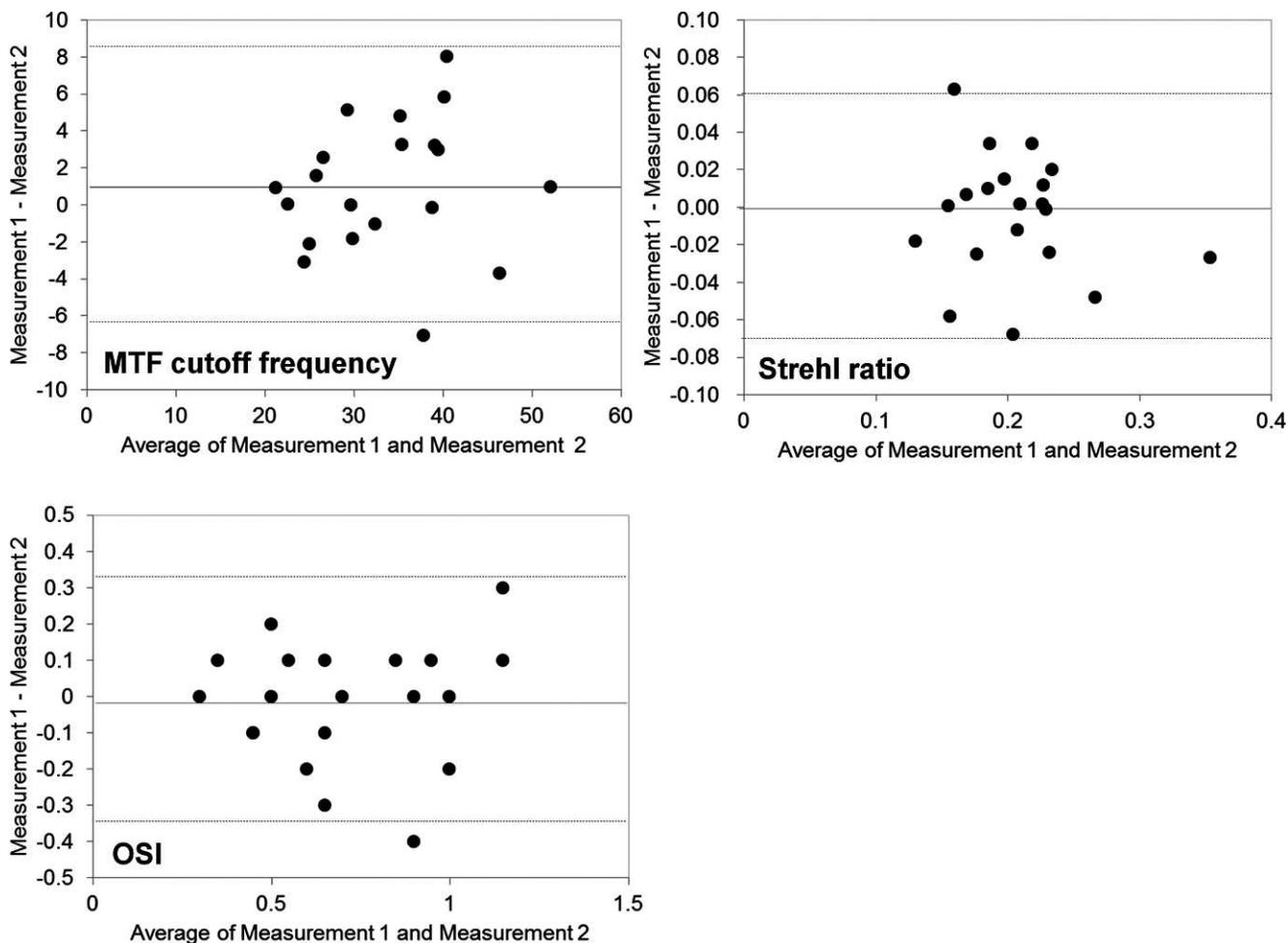


FIGURE 2. Bland-Altman plots represent the difference between two measurements divided by the mean of these measurements. The solid lines represent mean differences between 3 consecutive measurements of MTF cutoff frequency, Strehl ratio, and OSI. Dotted lines are the upper and lower borders of the 95% limit of agreement (mean difference \pm 1.96 multiplied by SD of the mean difference).

18 cycles per degree in the mesopic contrast sensitivity without glare. It also demonstrated a significant improvement at 4 of 5 spatial frequencies tested in the contrast sensitivity with glare.⁶ Igarashi et al. reported that ICL implantation increases contrast sensitivity for the correction of high myopia.²⁵ Lombardo et al. demonstrated that contrast sensitivity under photopic conditions was increased after Artisan lens implantation, but it was decreased slightly under mesopic conditions.²⁸ We reported previously that the theoretical retinal magnifications after phakic IOL implantation, and spectacle correction for the correction of high myopia were 1.00 and 0.88 times, respectively.²⁹ This implies that approximately 0.5 of a LogMAR line (2.5 letters) are gained after phakic IOL implantation. A smaller increase in the number of higher order aberrations^{25,26} and a smaller decrease in retinal magnification²⁹⁻³² may contribute to excellent visual performance after ICL implantation. Our findings of excellent optical quality after ICL implantation are in line with these previous studies on visual performance.

It is important to assess the repeatability of the measurements with this instrument to confirm the applicability of the data. It has been demonstrated that the device has good repeatability,^{23,24} and that the realignment of the eyes does not impose any additional variation on the measurements.²³ As shown in Figure 2, we confirmed the good repeatability of the measurements in the current study, as evidenced by the

narrow 95% LoA. Hence, we believe that this device offers reasonable repeatability in the clinical evaluation of the optical quality of the eye.

There are two limitations to this study. One is that we did not assess the optical quality parameters of all eyes before ICL implantation. We tried to assess these optical variables before surgery, but this was not very reproducible for quantitative evaluation of these parameters, especially in high myopic (higher than -8.00 D) and astigmatic eyes, requiring the combined use of external spherical and cylindrical lenses, possibly because this combination may induce some additional reflection. Therefore, it still remains unclear whether ICL implantation itself does not induce a change in the optical quality and the intraocular scattering of the eye. We believe that this information will be meaningful clinically because it has been shown that the optical quality and intraocular scattering after ICL implantation essentially are equivalent to that of normal eyes. We found no significant differences in the MTF cutoff frequency, Strehl ratio, OSI, or OV_s at contrasts of 100%, 20%, and 9% before and after ICL implantation in moderate myopic eyes that could be compensated only by using the Badal system, suggesting that the optical quality including the intraocular scattering was unchanged fundamentally after ICL implantation, at least in such eyes. Another limitation is that we assessed these optical parameters only for a 4.0-mm pupil. Pupil diameter has a vital role in determining

the optical quality of the eye. Although we confirmed that all eyes had pupil diameters of more than 4.0 mm in our study, this does not reflect accurately the actual status of the optical quality under natural viewing conditions. Further studies are required to determine the optical quality parameters after ICL implantation under natural viewing conditions.

In conclusion, our comparative study demonstrated that the optical quality parameters, such as the MTF cutoff frequency, Strehl ratio, OSI, or OVs at contrasts of 100%, 20%, and 9%, of eyes undergoing ICL implantation were not significantly different from those of normal eyes. It is suggested that the optical quality, including the intraocular scatter of eyes undergoing ICL implantation, is nearly equal to that of normal eyes. We believe that this information will be of clinical importance for the prevalence of this surgical approach

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