

Optical quality of foldable monofocal intraocular lenses before and after injection

Comparative evaluation using a double-pass system

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PURPOSE: To use the double-pass technique to evaluate the in vitro optical quality of foldable monofocal intraocular lenses (IOLs) used to correct aphakia.

SETTING: Universitat Politècnica de Catalunya, Terrassa, and Instituto de Microcirugía Ocular de Barcelona, Barcelona, Spain; Universidad Nacional de Tucumán, Tucumán, Argentina.

METHODS: This study assessed the in vitro optical quality of 7 IOLs before and after injection in an artificial eye that was attached to a double-pass system (Optical Quality Analysis System [OQAS]). The procedure imitated the conventional in vivo technique used to assess the optical quality of eyes with an IOL. The following parameters were evaluated: point-spread function, modulation transfer function (MTF), MTF cutoff frequency, Strehl ratio, and OQAS values.

RESULTS: The in vitro optical quality of most IOLs was as good after injection as before injection. In 1 IOL, the post-injection optical quality was statistically significantly different but the optical quality remained high.

CONCLUSIONS: Results indicate that after an IOL is placed in the eye, its optical performance will be good, providing good visual quality. The eye cell model attached to the double-pass system was useful and effective for fully characterizing the optical quality of IOLs and evaluating variations resulting from the injection process.

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Cataract extraction with intraocular lens (IOL) implantation^{1–3} is one of the most frequently performed surgical procedures today. In this surgery, the cataractous crystalline lens is removed from the eye and an IOL is implanted to replace it. Today, many commercially available IOLs are foldable and can be placed in the eye through a small incision during surgery.

Several studies have evaluated the visual performance of patients who have had cataract surgery. These studies assessed the patients' quality of vision using subjective or objective methods, depending on the type of cataract as well as the IOL used and its effect over time. Subjective evaluation studies^{4–8} often include refraction and visual acuity measurements, and some use contrast sensitivity testing. Methods for objective evaluation of optical quality^{9–12} include measurement of the eye's aberrations with a wavefront aberrometer,^{13,14} assessment of retinal images using a double-pass system,^{9,15,16} evaluation of corneal topography, and biometry of the eye.¹⁷

The in vitro optical quality associated with IOLs has also been assessed,^{18–20} although there are fewer published studies because specific instrumentation is required. Thus, IOL manufacturers and research laboratories perform most in vitro evaluations of IOLs. These studies use the modulation transfer function (MTF) to evaluate the imaging quality of the IOLs. The MTF is usually measured with a standard single-pass setup in accordance with methodology specified by the corresponding International Organization for Standardization standard.²¹ Lesser known methodologies, such as examination of Airy disks,²² have also been used.

When foldable IOLs are used to correct aphakia, they are placed in the eye with an injector (usually provided by the manufacturer). This process can affect the final quality of the implanted IOL and, therefore, the patient's vision. During injection, the IOL is completely compressed and folded, after which it is inserted in the eye through a relatively small incision (approximately 2.0 to 3.0 mm). This can cause

variations in optical quality. It is important to control and analyze these variations to determine whether they will negatively affect the patient's visual perception.

There are few studies of whether the optical quality of IOLs changes after their injection.^{23,24} Several commercially available IOLs have been analyzed by physical methods, such as microscopic observation and standard single-pass optical techniques.²¹ These methods can be used to measure parameters for assessing IOL image quality, such as IOL power, the MTF, and the Strehl ratio. Other studies²⁵ used scanning electron microscopy and x-ray spectroscopy to evaluate the effect of injectors that require silicone oil on the physical and optical quality of IOLs. Barbero et al.²⁶ studied the *in vivo* aberrations in eyes that had cataract surgery and compared the results with *in vitro* IOL measurements using a laser ray-tracing technique.²⁷ They found good agreement between the 2 data sets, although they observed increased 3rd-order aberrations *in vivo*. The authors state that IOL tilt and decentration might have contributed to the increased aberrations *in vivo*, although they did not separately analyze the changes resulting from the injection of the IOL.

In this study, we objectively evaluated the effect of injection on the *in vitro* optical quality of foldable IOLs used to correct aphakia. We performed this evaluation with a commercially available double-pass system that is commonly used to assess visual quality in real eyes and simulates *in vivo* conditions. This technique was proposed half a century ago as a means of

estimating retinal image quality.²⁸ Over time, the method incorporated technical advancements²⁹ and was shown to provide accurate estimates of the eye's image quality. The double-pass technique has been widely used to evaluate retinal image quality in situations in which the optical quality in the human eye might be known, such as in the normal population as a function of age,³⁰ in contact lens wearers,^{31,32} in laser *in situ* keratomileusis patients,¹⁵ and in patients with monofocal^{9,15} or multifocal¹⁶ IOLs. However, the technique has not often been used to obtain the imaging quality of IOLs; that is, for *in vitro* measurements.

We present a technique to measure *in vitro* IOL optical quality under conditions similar to those for *in vivo* measurements. We used a commercial double-pass system and an eye cell model that can be easily attached and aligned to the system. This device evaluates the objective optical quality of an IOL using the retinal image acquired by the double-pass system and can detect significant statistical differences. In this study, we used the system to evaluate the optical quality of 7 commercially available foldable monofocal IOLs in their original state and 1 hour after they were injected into the eye model.

MATERIALS AND METHODS

Table 1 shows the characteristics of the 7 commercially available monofocal foldable IOLs evaluated. All IOLs had a power of +20.00 diopters (D) but had different manufacturers, optical designs, diameters, and materials. They were chosen as a good representation of IOLs commonly used in cataract surgery. Each IOL was injected using the injector provided by the respective manufacturer in accordance with the instructions for use. In all cases, sodium hyaluronate 1% (Healon) and a balanced salt solution were used. The optical quality of the IOLs was measured before and 1 hour after they were injected.

Figure 1 shows the eye cell model attached and aligned to a double-pass system. The eye cell model consisted of an optical achromatic doublet lens (focal length 30.0 mm, diameter 12.5 mm), which simulated an artificial cornea; an IOL support with a diameter of 5.0 mm immersed in a tank full of watery solution to simulate *in vivo* conditions; and a mobile artificial retina of plastic diffuser material. The power and diameter of the doublet lens, chosen to obtain a light beam on the IOL with characteristics similar to those *in vivo*, were calculated using Gullstrand's eye model and a wavelength of 780 nm (same wavelength as the double-pass system's). The IOLs were immersed in a physiological serum tank and then properly aligned, centered, and tilted with respect to the eye cell model using micrometric (x-y-z)- α positioning controls with steps of 0.01 mm (x-y-z) and 0.5 degrees (α). The mobile retina made it possible to change the axial length of the artificial eye using another micrometric control and, therefore, to focus the retinal image in the double-pass system as a function of the power of the IOL being evaluated. Furthermore, the retina allowed the correction of small mismatches of the IOL position in the eye cell model,

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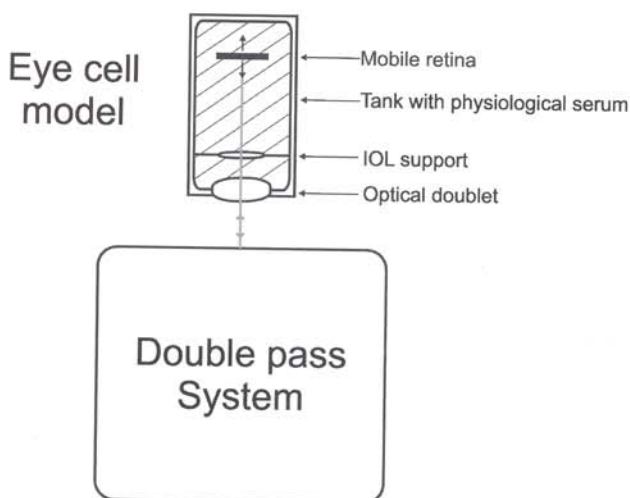
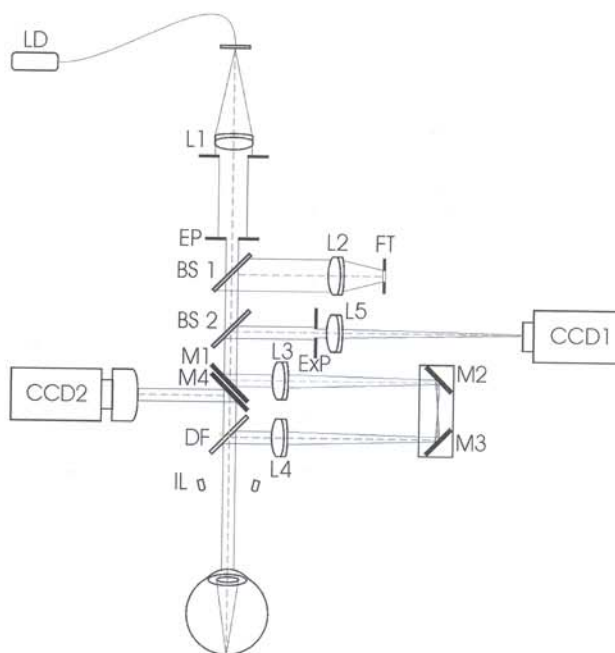
Table 1. Optical features of the analyzed IOLs.

Manufacturer	Type	Power (D)	Optical Design	Total Diameter (mm)	Optical diameter (mm)	Material	Refractive Index
Laboratoires Cornéal	ACR6D	20	Biconvex	12.00	6.0	Hydroxyethyl methacrylate copolymer	1.465
AJL Ophthalmics	Ophthalmic	20	Asymmetric biconvex	10.75	6.0	Acrylic copolymer	1.460
Alcon Laboratories	AcrySof SN60WT	20	Anterior asymmetric biconvex	13.00	6.0	Acrylate/methacrylate copolymer (blue light absorbing filter)	1.550
Alcon Laboratories	AcrySof SA60AT	20	Anterior asymmetric biconvex	13.00	6.0	Acrylate/methacrylate copolymer	1.550
LCA Pharmaceutical	Istacryl AFP 6,2	20	Anterior asymmetric biconvex, elliptical	11.00	6.2	Hydroxyethyl methacrylate & methyl methacrylate copolymer	1.462
Bausch & Lomb	Akreos Adapt	20	Biconvex	10.50	6.0	Hydrophilic acrylic copolymer	1.459
Abbott Medical Optics*	Tecnis CL	20	Biconvex anterior aspheric surface	13.00	6.0	Polysiloxane	1.460

*Formerly Advanced Medical Optics

obtaining the best retinal image quality in the measurements performed.

Figure 2 shows the configuration of the double-pass system (Optical Quality Analysis System, Visiometrics S.L.)³³ used to analyze the IOLs with respect to the artificial eye. The instrument records the retinal image corresponding to a point-source object in near-infrared light, consisting of a laser diode (wavelength 780 nm) coupled to an optical fiber, after reflection on the retina and a double pass through the ocular media. Near-infrared light is used because it is

**Figure 1.** Schematic view of the eye cell model and double-pass system used to evaluate the optical quality of the IOLs.**Figure 2.** Double-pass experimental setup (BS1 and BS2 = beam splitters 1 and 2, respectively; CCD1 and CCD2 = CCD cameras 1 [infrared video camera] and 2 [additional camera], respectively; DF = dichroic filter; IL = infrared light-emitting diode; EP = entrance pupil; ExP = exit pupil; FT = fixation test; LD = laser diode; L1, L2, L3, L4, and L5 = lenses 1, 2, 3, 4, and 5, respectively, with L3 and L4 being part of the motorized optometer; M1, M2, M3, and M4 = mirrors 1, 2, 3, and 4, respectively, with M2 and M3 being part of the motorized optometer).

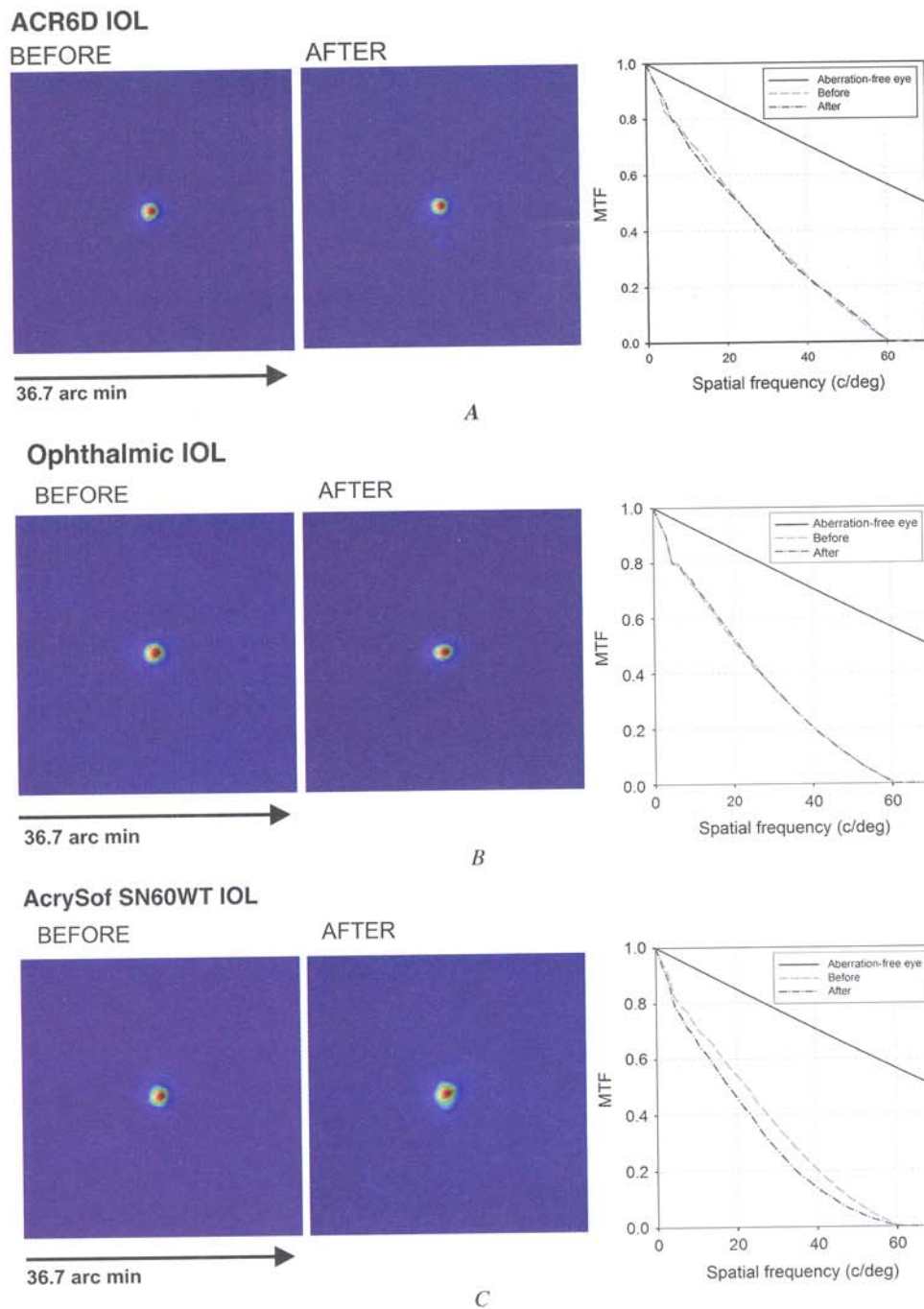


Figure 3. Mean double-pass retinal images (PSF and MTF) of the 7 IOLs before and after injection and a plot of the MTF corresponding to the aberration-free eye with a 4.0 mm pupil (c/deg = cycles per degree; IOL = intraocular lens; MTF = modulation transfer function).

more comfortable for the subject and provides retinal image quality estimates comparable to those obtained with visible light.³⁴ A motorized optometer, which consists of 2 lenses with a 100.0 mm focal length and 2 mirrors, is used to measure the subject's defocus correction. An infrared video camera with a pixel size of 8.4 μm records the double-pass images after the light is reflected on the retina and on a beam splitter (BS2 in Figure 2). Pupil alignment is controlled with an additional camera. A fixation test helps the

subject during the measurements. The instrument has an artificial and variable exit pupil that is controlled by a diaphragm wheel, whose image is formed on the subject's natural pupil plane. In this study, the optical quality measurements were performed using a double-pass symmetrical configuration and a pupil diameter of 4.0 mm,¹⁹ which is a standard size used in clinical double-pass studies.

Quantitative information about the optical quality of the artificial eye was obtained from the point-spread function

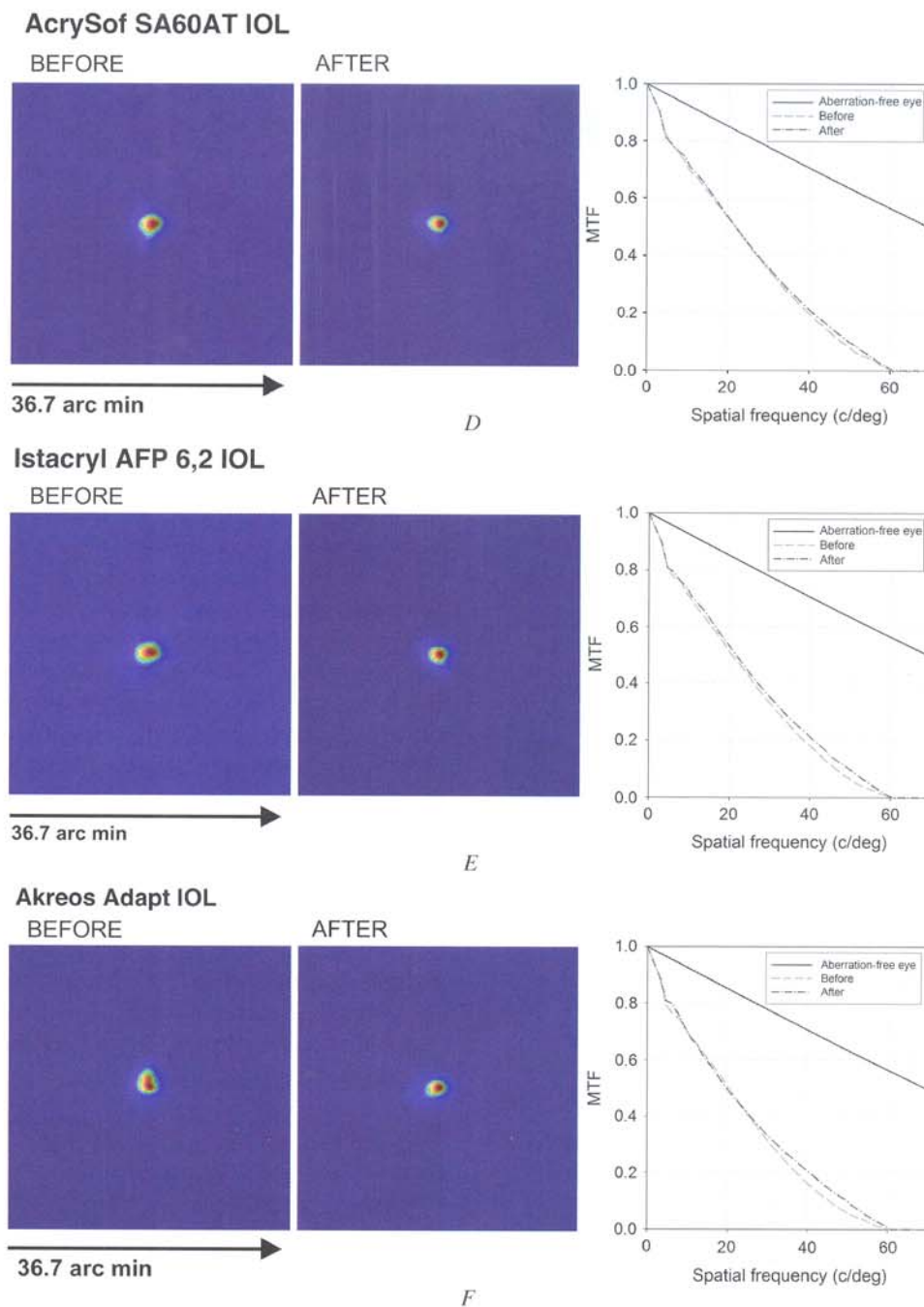


Figure 3. (continued).

(PSF) recorded with the double-pass system. For each measurement by the double-pass system, the PSF was calculated as the mean of 6 individual acquisitions. The MTF, which represents the loss of contrast produced by the eye's optics as a function of spatial frequency, can be directly computed from the PSF. In this study, the optical quality of the IOLs and the artificial eye was quantified using the optical parameters of MTF cutoff frequency and the Strehl ratio,³⁵ which is the ratio between the areas under the MTF curve of the measured eye and the aberration-free eye.³⁶ Optical quality was also assessed by 3 values known

as OQAS values (OVs) obtained with the double-pass system¹⁵; these values are related to MTF values and correspond to 3 spatial frequencies that describe visual quality at 3 contrasts (100%, 20%, and 9%), which are levels commonly used in ophthalmology practice. Specifically, the OV 100% value is equivalent to the MTF cutoff frequency but has a different normalization factor. The Strehl ratio provides more global information about the optical quality of the analyzed system because it is computed as an integration of the whole area below the MTF profile.²³ The 3 OV values can be used to obtain more specific information

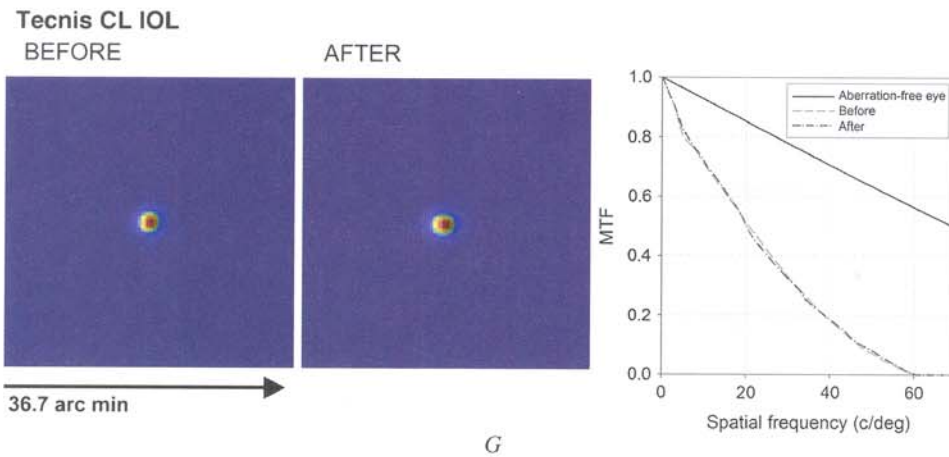


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about the behavior of the system at different contrasts. This information, which may otherwise remain hidden, can be used for clinical evaluations.

Each IOL was inserted in the eye cell model and was properly aligned to obtain the optimum optical quality. Then, the IOL was extracted and injected using the steps described above. One hour later, the IOL was placed in the same position and its optical quality evaluated again. At each stage and for each IOL, each measurement was repeated 6 times to quantify the repeatability and reproducibility of the whole system for each optical parameter. The corresponding mean values and standard deviations are reported here. Furthermore, to measure the statistical significance of the changes in the optical parameters between the 2 stages (ie, before injection and after injection), the repeated measurements for each IOL were analyzed using the Student *t* test and SPSS for Windows (version 8.0, SPSS, Inc.). A *P* value less than 0.05 was considered statistically significant.

To quantify the change in optical quality from before injection to after injection of each IOL, the quality ratio (ie, ratio between the mean values of each optical parameter at each of the 2 stages) was calculated as follows:

$$QR = (\text{after}/\text{before})\text{parameter} \quad (1)$$

where QR is the quality ratio, *after* is after injection, *before* is before injection, and *parameter* is the optical parameter.

To further evaluate the results, the quality percentage (ie, percentage of variation between mean optical parameters before and after injection) was calculated as follows:

$$QP(\%) = |1 - (\text{after}/\text{before})\text{parameter}| \times 100 \quad (2)$$

where QP(%) is the percentage, *after* is after injection, *before* is before injection, and *parameter* is the optical parameter.

RESULTS

Figure 3 shows the mean double-pass retinal images (PSFs) and MTFs corresponding to the 7 IOLs before and after the injection process. The MTF curve corresponding to the aberration-free eye for a 4.0 mm pupil size is also shown.

Table 2 shows the mean MTF cutoff frequency of the IOLs before and after injection as well as the quality ratio and quality percentage values. Table 3 shows

the mean Strehl ratios and the quality ratio and quality percentage values. Tables 4 to 6 show the OV values at the 3 contrasts and the quality ratio and quality percentage values.

The PSFs of the retinal images recorded by the double-pass system before injection and were small for all IOLs; the corresponding MTFs also indicated good optical quality. There were no significant qualitative differences in optical quality between the IOLs. In general, the double-pass images remained good after injection, and the differences between the MTF values before injection and after injection were not statistically significant. There was a slight increase in the PSF after injection of the AcrySof SN60WT IOL. The corresponding MTF curve for this IOL also showed a slight drop after injection. However, the optical quality of this IOL remained high.

All IOLs had a mean MTF cutoff frequency of 58 cycles per degree (cpd) or higher before injection, indicating

Table 2. Mean MTF cutoff frequencies before and after injection and the quality ratio and quality percentage values.

IOL Type	Mean MTF Cutoff (cpd) ± SD		Quality Ratio	Quality %
	Before Injection	After Injection		
ACR6D	59.24 ± 0.89	59.38 ± 0.59	1.00	0.00
Ophthalmic	58.84 ± 0.59	59.47 ± 0.83	1.01	1.00
AcrySof SN60WT*	58.98 ± 0.88	57.26 ± 0.69	0.97	3.00
AcrySof SA60AT	58.91 ± 0.29	59.29 ± 0.18	1.01	1.00
Istacyl AFP 6,2	58.72 ± 0.41	58.92 ± 0.41	1.00	0.00
Akreos Adapt	58.18 ± 1.15	59.00 ± 1.12	1.01	1.00
Tecnis CL	58.52 ± 0.60	58.35 ± 0.82	1.00	0.00

cpd = cycles per degree; IOL = intraocular lens; MTF = modulation transfer function
 *Difference between means before and after injection statistically significant (*P* < .05)

Table 3. Mean Strehl ratios before and after injection and the quality ratio and quality percentage values.

IOL Type	Mean Strehl Ratio \pm SD		Quality Ratio	Quality %
	Before Injection	After Injection		
ACR6D	0.356 \pm 0.007	0.352 \pm 0.004	0.990	1.000
Ophthalmic	0.334 \pm 0.005	0.337 \pm 0.005	1.009	0.900
AcrySof SN60WT*	0.339 \pm 0.006	0.293 \pm 0.004	0.866	13.400
AcrySof SA60AT	0.334 \pm 0.002	0.336 \pm 0.001	1.008	0.800
Istacryl AFP 6,2	0.322 \pm 0.002	0.329 \pm 0.002	1.020	2.000
Akreos Adapt	0.319 \pm 0.004	0.326 \pm 0.006	1.021	2.100
Tecnis CL	0.320 \pm 0.003	0.318 \pm 0.003	0.994	0.600

IOL = intraocular lens

*Difference between means before and after injection statistically significant ($P < .05$)**Table 4.** Mean OV 100% before and after injection and the quality ratio and quality percentage values.

IOL Type	Mean Value at 100% Contrast \pm SD		Quality Ratio	Quality %
	Before Injection	After Injection		
ACR6D	1.97 \pm 0.02	1.97 \pm 0.02	1.00	0.00
Ophthalmic	1.96 \pm 0.02	1.96 \pm 0.03	1.00	0.00
AcrySof SN60WT*	1.96 \pm 0.03	1.92 \pm 0.02	0.98	2.00
AcrySof SA60AT	1.96 \pm 0.02	1.96 \pm 0.01	1.00	0.00
Istacryl AFP 6,2	1.95 \pm 0.00	1.95 \pm 0.00	1.00	0.00
Akreos Adapt	1.93 \pm 0.02	1.94 \pm 0.04	1.01	1.00
Tecnis CL	1.95 \pm 0.01	1.95 \pm 0.02	1.00	0.00

IOL = intraocular lens

*Difference between means before and after injection statistically significant ($P < .05$)

good optical quality. Similar or slightly higher values (with no statistical significance [$P > .05$]) were observed after injection for all IOLs except the AcrySof SN60WT, for which a lower MTF cutoff value was observed; in this case, the difference was statistically significant ($P < .05$, *t* test).

The Strehl ratio showed the same behavior. Small variations were seen in this parameter before and after injection, although most of the IOLs did not show a statistically significant difference associated with the 6 measurements performed at the 2 stages. In the AcrySof SN60WT, there was a significant change. The OV parameters at different contrasts behaved in the same manner.

Table 5. Mean OV 20% before and after injection and the quality ratio and quality percentage values.

IOL Type	Mean Value at 20% Contrast \pm SD		Quality Ratio	Quality %
	Before Injection	After Injection		
ACR6D	2.62 \pm 0.03	2.61 \pm 0.03	1.00	0.00
Ophthalmic	2.58 \pm 0.04	2.59 \pm 0.01	1.00	0.00
AcrySof SN60WT*	2.57 \pm 0.05	2.43 \pm 0.04	0.95	5.00
AcrySof SA60AT	2.57 \pm 0.08	2.60 \pm 0.07	1.01	1.00
Istacryl AFP 6,2	2.50 \pm 0.07	2.57 \pm 0.06	1.03	3.00
Akreos Adapt	2.49 \pm 0.05	2.56 \pm 0.06	1.03	3.00
Tecnis CL	2.51 \pm 0.05	2.50 \pm 0.05	1.00	0.00

IOL = intraocular lens

*Difference between means before and after injection statistically significant ($P < .05$)**Table 6.** Mean OV 9% before and after injection and the quality ratio and quality percentage values.

IOL Type	Mean Value at 9% Contrast \pm SD		Quality Ratio	Quality %
	Before Injection	After Injection		
ACR6D	3.82 \pm 0.06	3.83 \pm 0.04	1.00	0.00
Ophthalmic	3.68 \pm 0.04	3.69 \pm 0.02	1.00	0.00
AcrySof SN60WT*	3.62 \pm 0.08	3.40 \pm 0.09	0.94	6.00
AcrySof SA60AT	3.60 \pm 0.12	3.70 \pm 0.11	1.03	3.00
Istacryl AFP 6,2	3.48 \pm 0.09	3.59 \pm 0.07	1.03	3.00
Akreos Adapt	3.45 \pm 0.04	3.56 \pm 0.04	1.03	3.00
Tecnis CL	3.47 \pm 0.07	3.46 \pm 0.08	1.00	0.00

IOL = intraocular lens

*Difference between means before and after injection statistically significant ($P < .05$)

DISCUSSION

In this study, we used a commercially available double-pass system to assess the in vitro optical quality of 7 commercially available foldable monofocal IOLs before and 1 hour after they were injected into an artificial eye. The resulting PSF and MTF values showed that all IOLs had good optical quality before they were injected. There were no significant differences between the IOLs in any qualitative parameter. After injection, the PSF and MTF values remained good, with little difference between the values before injection and the values after injection. Although after injection the AcrySof SN60WT IOL had a slight increase in the PSF and a slight decrease in the corresponding MTF curve, indicating slightly worse optical quality, the optical quality remained high.

The quantitative data (MTF cutoff frequency, Strehl ratio, OV values) confirmed the qualitative results. The mean MTF cutoff frequency before injection was 58 cpd or higher, which corresponds to good optical quality. The mean value after injection was similar or slightly higher except for the AcrySof SN60WT IOL, which had a slightly lower MTF cutoff frequency and a statistically significant difference between the mean value before injection and the value after injection. Most of the IOLs had standard deviations that were less than 2% of the mean value. This can be attributed to the reproducibility of the measurement methodology and not to changes in the optical quality of the IOLs. Several factors can affect these measurements, including the placement of the IOL on the artificial eye's IOL support, which can lead to slight decentration or tilt; the procedure used to focus the retinal image of the lens, which involves moving the retina of the eye cell model; and the repeatability of the double-pass system. These can cause to small increases and decreases in the MTF cutoff frequency. Most IOLs we evaluated had quality ratios close to unity and quality percentages smaller than 2%, which shows no statistically significant variation in quality. The AcrySof SN60WT was the only IOL with a decrease in MTF cutoff frequency after injection that was greater than the variations associated with the system measurements. This IOL had a quality percentage greater than 2% (ie, 3%), which indicates slight worsening of the optical quality.

There were also small variations between the Strehl ratio before injection and the ratio after injection, although for most IOLs there were no statistically significant differences in the 6 measurements between the 2 stages. In almost all cases, the quality ratios were close to unity, meaning the ratio was nearly the same before injection as after injection. The quality percentage was also smaller (close to 2%) for most IOLs, with no statistically significant difference between the 2 stages. Again, the exception was the AcrySof SN60WT IOL, which had a ratio of 13%. This high percentage clearly reflects the change in the optical quality of the IOL after it was injected. These findings show that the Strehl ratio has greater variability than the MTF cutoff frequency.

The OV 100% before injection and after injection were similar, with standard deviations of less than 2% of the mean value. The quality ratio was near 1 for most IOLs, and the quality percentage (ie, percentage of variation after injection) was almost zero. The AcrySof SN60WT IOL had a higher percentage (2%). Statistical analysis showed the mean for this IOL before injection and the mean after injection were significantly different; therefore, the quality of the IOL changed after injection. This parameter behaved

similarly to the MTF cutoff frequency. This is a logical result because the 2 parameters are related and account for the cutoff frequency of the MTF function.

The standard deviations for the mean OV 20% were slightly higher, which means that this parameter was less stable with the methodology used. Moreover, the quality ratios were close to 1, although they showed more variability than they with the 100% contrast parameter; some IOLs had quality percentages close to 3%. The AcrySof SN60WT IOL again had a higher quality percentage (5%), likely as a result of the worsening of optical quality after injection. Statistical analysis confirmed this ($P < .05$).

The results for the OV 9% were similar to the 20% results. The standard deviation was 3% of the mean value for some IOLs. Most quality percentages were within this range, with the exception of that for the AcrySof SN60WT IOL. This IOL had a slightly higher value (6%), perhaps because of the poorer optical quality after injection, which the statistical analysis results also suggested.

The AcrySof SN60WT is the only IOL studied that incorporates a blue light-filtering chromophore. This changes the transmission of the IOL in the blue region of the visible spectrum. However, we do not believe this is the main reason this IOL underperformed in terms of optical quality because the double-pass system assesses only monochromatic aberrations and intraocular scattering. One possible explanation is the physical properties of the material used or the IOL design. However, even with the variability in values, the optical quality of the IOL remained high after injection. Thus, we believe the IOL can be used in patients without noticeable effects on their visual quality.

In conclusion, we found that double-pass technique combined with the eye cell model was useful for characterizing the in vitro optical quality of IOLs and evaluating changes related to the injection process. Our results indicate that after an IOL is placed in the eye, its optical performance will be good and thus the patient will have good quality of vision.

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