

Optical quality of hyperopic and myopic phakic intraocular lenses

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Aims: To assess and compare the optical quality of the myopic and hyperopic implantable collamer lens (ICL) from its wavefront aberrations for different powers and pupil diameters. **Settings and Design:** Prospective study. **Material and Methods:** The wavefront aberrations of two myopic (−3 and −6 diopters (D)) and two hyperopic V4b ICLs (+3 and +6D) were measured *in vitro*. To assess and compare the optical quality of different powers of ICLs, we analyzed the root mean square (RMS) of total higher order aberrations (HOAs), trefoil, coma, tetrafoil, secondary astigmatism, and spherical aberration at 3- and 4.5-mm pupil. In addition, the point spread functions (PSFs) of each ICL evaluated were calculated from the wavefront aberrations at 3- and 4.5-mm pupil. **Statistical Analysis:** A Student's *t*-test for unpaired data was used for comparison between myopic and hyperopic ICLs. **Results:** Myopic ICLs showed negative spherical aberration, in contrast hyperopic ICLs showed positive spherical aberration, which increases when the ICL power increases, due to the innate optical properties of the lens. All ICLs evaluated had negligible amounts of other aberrations. We did not find statistical significant differences in any Zernike coefficient RMS values analyzed between myopic and hyperopic ICLs at 3- and 4.5-mm pupil ($P > 0.05$). **Conclusions:** Myopic and hyperopic ICLs provide good and comparable optical quality for low to moderate refractive error. The ICLs evaluated showed values of wavefront aberrations clinically negligible to affect the visual quality after implantation.

Key words: Hyperopic implantable collamer lens, myopic implantable collamer lens, optical quality, wavefront aberrations

The Visian implantable collamer lens (ICL, STAAR Surgical, Nidau, Switzerland) is a posterior chamber phakic intraocular lens (pIOL) approved by the United States Food and Drug Administration (USFDA) for the treatment of moderate to severe myopia. In order to reduce contact of the ICL with central anterior capsule of the crystalline lens, the ICL integrated a forward vault into its plate haptic design with a central convex/concave optical zone. The ICL lenses are foldable, allowing for posterior chamber injection through a microscopic incision of 3.5 mm or smaller. When properly placed, the ICL should be positioned completely within the posterior chamber between the iris and crystalline lens with support on ciliary sulcus. Several studies have demonstrated that the ICL implantation is an effective procedure to correct myopia,^[1-7] hyperopia,^[6-9] and astigmatism.^[10,11] The ICLs may induce higher order aberrations (HOAs) by the innate optical properties of lenses (i.e. spherical aberration increases with the ICL power) and also due to the incision type during the surgical procedure.^[12] Like all surgeries, the ICL implantation also shows some disadvantages and complications.^[13]

The goal of the present study was to assess and compare the optical quality *in vitro* provided by myopic and hyperopic ICLs from their wavefront aberrations.

Material and Methods

The Visian ICL (STAAR Surgical, Nidau, Switzerland) is a

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phakic lens made from collamer; a flexible, hydrophilic, and biocompatible material. In this study we have analyzed the V4b model for two myopic ICLs: −3.00, −6.00 diopter (D) and two hyperopic ICLs: +3.00 and +6.00D. The overall diameter of both myopic ICLs was 13.7 mm and optical diameter was 5.5 mm. In the hyperopic ICLs, the overall diameter was 13.2 mm and the optical diameter was 5.8 mm.

The Nimo TR0805 instrument (Lambda X, Belgium) was used to analyze and measure wavefront aberrations of the lenses [Fig. 1].^[14] The working principle of the Nimo instrument is based on a phase-shifting schlieren technique.^[15] The principle of schlieren imaging has been known for some time and is commonly used to visualize variations in density for gas flows. By combining this principle with a phase-shifting method, the Nimo instrument allows the measurement of light beam deviations, which can be used to calculate the power characteristics of lenses and wavefront analysis considering 36 Zernike coefficients. In this study, we analyzed the root mean square (RMS) of total HOAs (third to seventh order), trefoil (Z3-3; Z33), coma (Z3-1; Z31), tetrafoil (Z4-4; Z44), secondary astigmatism (Z4-2; Z42), and spherical aberration (Z40) for 3 and 4.5-mm pupils. Zernike coefficient values were retained as the average of ten measurements.

Data analysis

A Student's *t*-test for unpaired data was used for the comparison between myopic and hyperopic ICLs. Results are presented as the mean \pm standard deviation (SD) and statistical significance was set at $P < 0.05$.

Results

Fig. 2 shows the RMS of trefoil (Z3-3; Z33), coma (Z3-1; Z31), tetrafoil (Z4-4; Z44), secondary astigmatism (Z4-2; Z42), and

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spherical aberration (Z40) for the four ICL powers evaluated at 3- and 4.5-mm pupils. The myopic ICLs had negative spherical aberration, instead the hyperopic ICLs showed positive spherical aberration. In both cases, the spherical aberration value varied with the refractive optical power, being greater when the refractive optical power is increased. When the refractive power increases, spherical aberration was more negative for myopic ICLs and it was more positive for the hyperopic ICLs. The values of other aberrations evaluated were minimal.

The -3 and +3D ICLs showed around 0.003 and 0.015 μm of spherical aberration RMS at 3- and 4.5-mm pupils, respectively; and negligible amounts of other aberrations, without statistical significant differences between them ($P > 0.05$). The -6 and +6D ICLs showed around 0.003 and 0.023 μm of spherical aberration RMS at 3- and 4.5-mm pupils, respectively, and negligible amounts of other aberrations, without statistical significant differences between them ($P > 0.05$). Although the spherical aberration increased as a function of the ICL power, we did not find statistically significant differences in spherical aberration between -3 and -6D ICLs, neither between +3 and +6D ICLs ($P > 0.05$).

Fig. 3 shows the RMS of total HOA for the two myopic and two hyperopic ICLs evaluated at 3- and 4.5-mm pupils. No statistically significant differences were found between them for any pupil size evaluated ($P > 0.05$).

Fig. 4 and 5 show the images of point spread functions (PSFs) computed from the wavefront aberrations obtained using the Nimo TR0805 at 3- and 4.5-mm, respectively, for the four ICL powers. We may observe that the spread out of the PSFs was similar in all ICLs evaluated, the differences were minimal.

Discussion

The myopic and hyperopic ICLs evaluated showed similar values of spherical aberration, but with opposite sign. The myopic ICLs showed negative values of spherical aberration, whereas the hyperopic ICLs presented positive values. We did not find statistical significant differences between myopic and hyperopic ICLs for spherical aberration RMS at 3- and 4.5-mm pupil ($P > 0.05$). Regarding to the increment of spherical

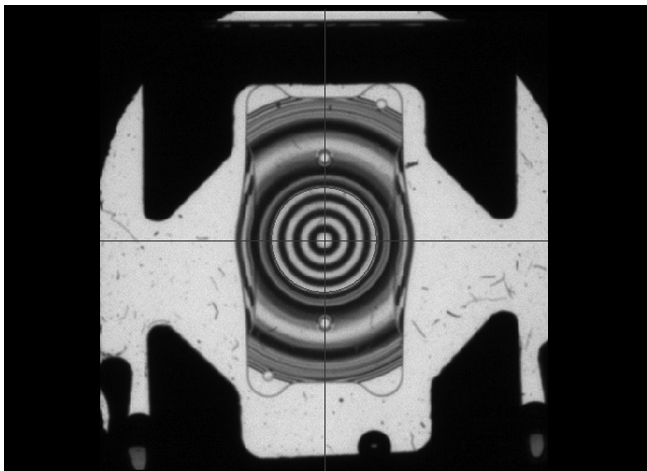


Figure 1: Nimo instrument image of the v4b ICL used to measure this lens chart

aberration when increases the refractive optical power, due to innate properties of the lens, we did not find statistical significant differences between both myopic ICLs evaluated, neither between both hyperopic ICLs evaluated ($P > 0.05$). The values of other Zernike coefficients RMS evaluated were minimal for all ICL powers, no statistically significant differences were found between them for both pupil diameters ($P > 0.05$, Fig. 2).

We did not find statistical significant differences in total RMS between myopic and hyperopic ICLs at 3- and 4.5-mm pupils ($P > 0.05$; Fig. 3). Although the total RMS increases with the ICL power, no statistically significant differences were found between both myopic and both hyperopic ICLs at 3- and 4.5-mm pupils ($P > 0.05$).

Rocha *et al.*,^[16] studied the changes in visual acuity (VA) induced by individual Zernike coefficients of various RMS magnitudes, using an adaptive optics visual simulator. They found that at 5-mm pupil, the spherical aberration with a coefficient of 0.1 μm did not result in any significant change. In the present study, all ICLs evaluated showed values of spherical aberration RMS below 0.1 μm , therefore the aberrations induced by ICLs evaluated does not have a significant effect in the VA.

These outcomes were correlated with the PSF images [Figs. 4 and 5], where the spread out were minimal and very similar between all ICLs evaluated, showing good and similar optical quality.

Kim *et al.*,^[12] measured *in vitro* three myopic ICLs with different powers (-5.5, -16.5 and -19.5D) in a wet chamber using a Shack-Hartmann wavefront sensor. The spherical aberration values at 5.5-mm pupil were -0.03, -0.21, and -0.19 μm for -5.5, -16.5, and -19.5D ICLs, respectively. Our outcomes for myopic ICLs were quite similar; we found a spherical aberration value of -0.023 μm for -6D ICLs at 4.5-mm pupil. Besides, they also found negative spherical aberration and negligible amounts of other types of aberrations in the three ICLs measured and the magnitude of spherical aberration was more negative values in more myopic ICLs. As per our knowledge, no published data exist about the rest of Zernike coefficients of this lens and for hyperopic ICLs to be compared.

Several studies evaluated the changes in wavefront aberrations *in vivo* in eyes implanted with myopic ICLs. Igarashi *et al.*,^[17] compared the visual function after ICL implantation and after wavefront-guided LASIK in eyes with -6D of myopia. They evaluated the changes in coma-like, spherical-like, and total HOA at 4-mm pupil. Total HOA increased from 0.11 μm before ICL implantation to 0.13 μm after surgery. Therefore, the change induced by a -6D ICL on total HOA was 0.02 μm . Kamiya *et al.*,^[18] also compared postoperative visual function after ICL implantation and after wavefront-guided LASIK in eyes with low to moderate myopia (from -3.00 to -5.88D). They measured the contrast sensitivity and ocular HOA pre- and postoperatively at 4- and 6-mm pupils. They also reported a change of 0.02 μm on total HOA after ICL implantation (from 0.10 μm before surgery to 0.12 μm after surgery) at 4-mm pupil. These outcomes agree with those obtained in our study, we found the changes on total HOA were 0.02 and 0.03 μm for a -3 and -6D ICL, respectively, at 4.5-mm pupil.

To our knowledge, no published data exists about wavefront aberrations and changes in ocular aberrations induced by

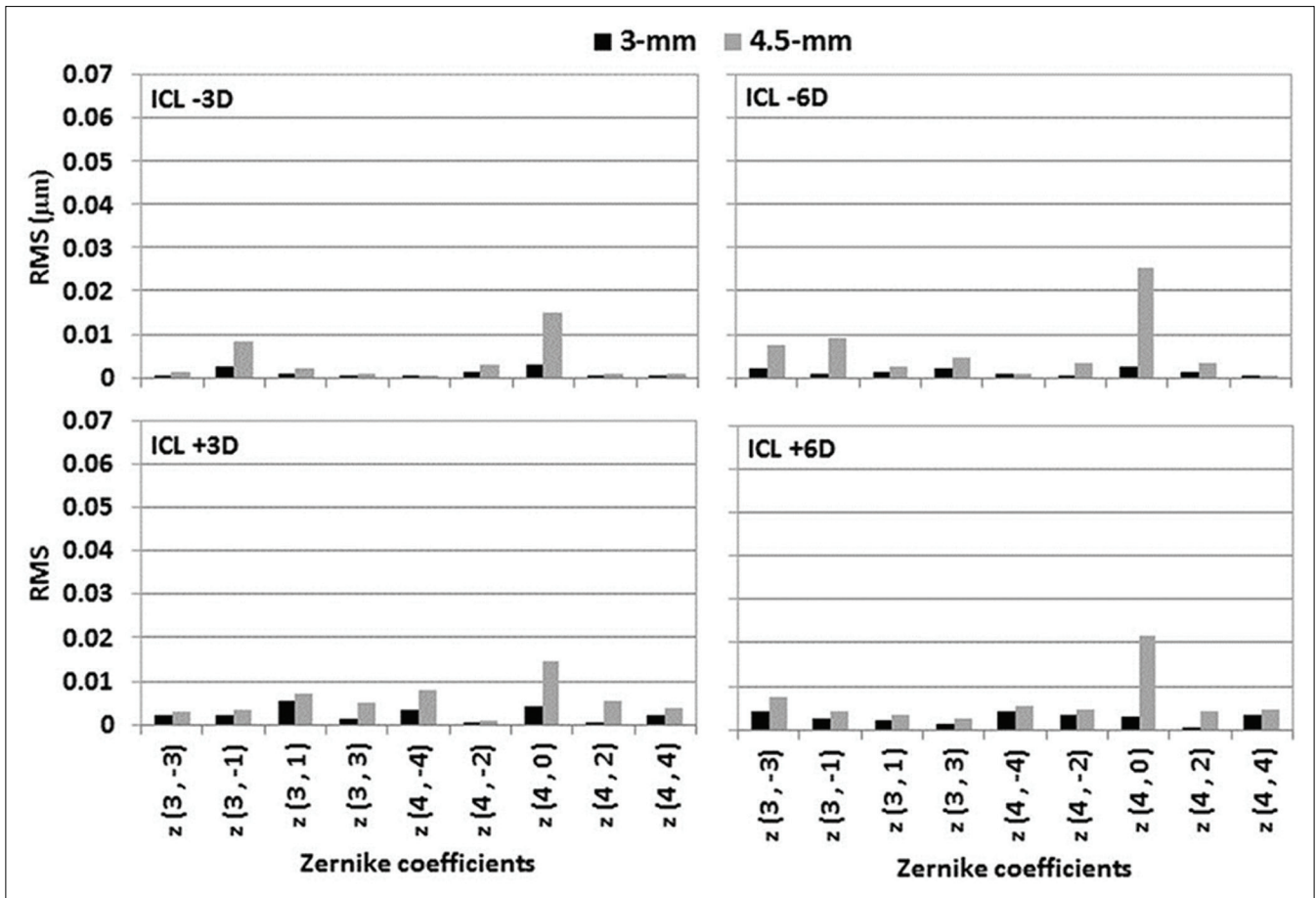


Figure 2: Root mean square (RMS) of trefoil (Z3-3; Z33), coma (Z3-1; Z31), tetrafoil (Z4-4; Z44), secondary astigmatism (Z4-2; Z42), and spherical aberration (Z40) for the two myopic ICLs (top left: -3D ICL and top right: -6D ICL) and two hyperopic ICLs evaluated (bottom left: +3D ICL and bottom right: +6D ICL), at 3- (black bars) and 4.5-mm pupils (grey bars)

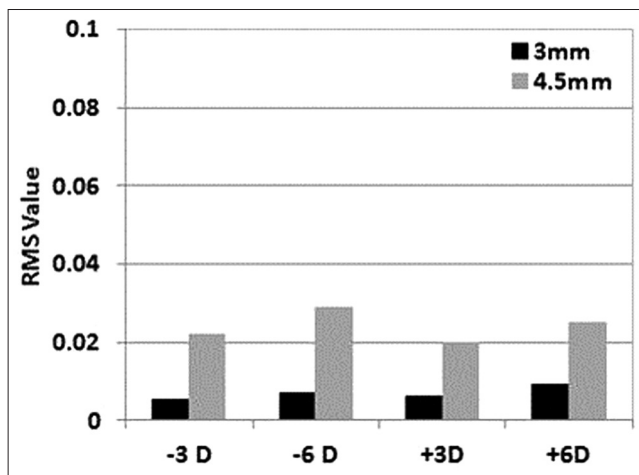


Figure 3: Root mean square (RMS) of total higher order aberrations (HOAs; from third to seventh order) for the four ICL powers evaluated (-3, -6, +3, and +6D ICL), at 3- (black bars) and 4.5-mm pupils (grey bars)

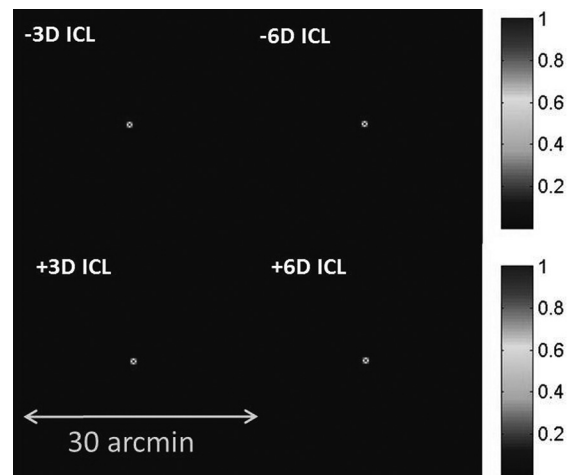


Figure 4: Point spread function (PSF) computed from the wavefront aberrations at 3-mm pupil for the two myopic ICLs (top left: -3D ICL and top right: -6D ICL) and two hyperopic ICLs evaluated (bottom left: +3D ICL and bottom right: +6D ICL)

hyperopic ICLs, neither induced by other types of hyperopic pIOLs.

There are a lot of studies,^[1-9] that evaluate the visual outcomes after myopic and hyperopic ICLs implantation. The

FDA study^[1] evaluated the safety and efficacy of ICLs to treat moderate to high myopia. Five hundred and twenty-three eyes having myopia between - 3.00 and - 20.00D were assessed, and in all of them a V4 model ICL was inserted through a small (3-mm) clear corneal incision. The best

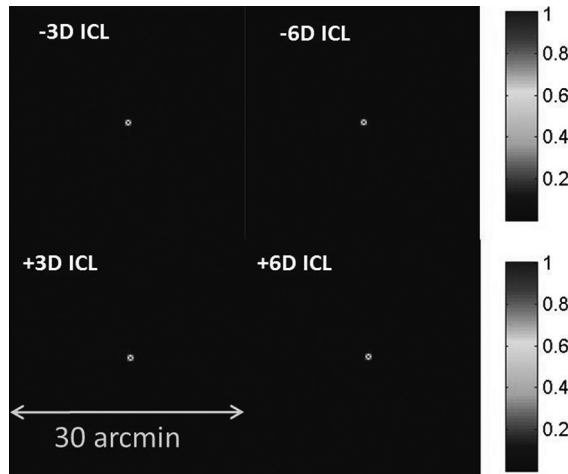


Figure 5: Point spread function (PSF) computed from wavefront aberrations at 4.5-mm pupil for two myopic ICLs (top left: -3D ICL and top right: -6D ICL) and two hyperopic ICLs evaluated (bottom left: +3D ICL and bottom right: +6D ICL)

spectacle correction visual acuity (BSCVA) improved after ICL implantation compared with preoperative levels. At 12-months, 82.4% of eyes had a BSCVA of 20/20 or better compared with only 67.7%, preoperatively. Only six cases (1.1%) lost two lines of BSCVA due to postoperative complications. Lackner *et al.*^[6] analyzed long-term results after insertion of myopic (65 eyes) and hyperopic ICLs (ten eyes). Preoperative mean spherical equivalent was -16.23D for myopic eyes and +7.88D for hyperopic eyes. Comparing preoperative and postoperative BSCVA, they obtained an improvement of Snellen 0.17 for myopic patients and decrease of Snellen 0.02 for hyperopic patients. These differences are due to the spectacle correction in hyperopic patients produced magnification, instead myopic patients go with thick diverging lenses that are the result of optical minification of retinal images and limited visual field. Pesando *et al.*^[9] evaluated the ICL to correct hyperopic refractive errors in 59 eyes (spherical equivalent from +2.50 to +11.75D). On follow-up after 10 years, the BSCVA was unchanged in 64.4% of eyes; improved by one Snellen line in 15.2%, two snellen lines in 8.3%, and three Snellen lines in 8.3%; and reduced by one snellen line in 8.3%.

These results are in agreement with our outcomes in optical quality of the myopic and hyperopic ICLs. We found that myopic and hyperopic ICLs showed good optical quality and the wavefront aberrations induced by an ICL do not effect on the VA after their implantation, being able to provide VA values higher than 20/20. However, we must take into account some limitations of our study, since these ICLs should be implanted, so the characteristics of the patients' eye, effects of the surgical procedure (i.e. surgeon's incision, ICL's decentration or tilt) and postoperative complications could affect the final optical and visual quality.^[13] In this study we only measured the optical quality *in vitro* without its implantation. However, in these papers the VA normally improved after ICL implantation, achieving VA values in most patients of 20/20 or better. Although in some patients VA decreased, due to the surgical procedure or postoperative complications. Future studies could include the visual simulations through ICLs evaluated in the

present study, in order to evaluate the visual quality that they are capable of achieving when they are implanted.

In summary, myopic and hyperopic ICLs provides good and comparable optical quality for low to moderate refractive error. The ICLs evaluated, showed values of wavefront aberrations clinically negligible to affect the visual quality after implantation.

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