Tolerance to residual refractive errors after trifocal and trifocal toric intraocular lens implantation

Running title: Tolerance to defocus with trifocal and trifocal toric intraocular lenses

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ABSTRACT

Objective: To assess the impact of 0.50 diopter (D) positive or negative defocus on visual function in patients implanted with trifocal and trifocal toric intraocular lenses (IOLs).

Methods: The study included patients implanted with the AcrySof® IQ PanOptix™ IOL or the PanOptix™ Toric. Visual acuity (VA) at high (100%), medium (50%) and low (10%) contrast, contrast sensitivity function (CSF) and halo perception were assessed three months after surgery. Explorations were performed with distance correction (CDVA), with a positive defocus of +0.50D (myopization) and with a negative defocus of -0.50D (hyperopization).

Results: The study included 60 eyes of 60 patients (30 eyes with PanOptix and 30 eyes with PanOptix Toric). For both groups, VA was better for all contrast settings at the CDVA situation ($p<0.05$ in all cases). For low spatial frequencies, no differences in CSF were found among the three refractive situations in either group. For higher frequencies, the results showed an overall trend for better CSF results for the CDVA situation. The halo effect was lower for the CDVA situation if compared to myopization and hyperopization in both the PanOptix and the PanOptix Toric group ($p<0.05$ for all cases).

Conclusions: There is an impact on visual quality and halo perception in patients implanted with trifocal or trifocal toric IOLs even for low residual refractive errors.

Key words: defocus, trifocal, trifocal toric, intraocular lenses, photic phenomena

Trifocal and trifocal toric IOLs have become popular among cataract surgeons due to the satisfactory clinical outcomes and the high rates of spectacle independence achieved by their patients.[1-3] However, in order to reach optimal visual results residual refraction should be close to emmetropia, otherwise residual refractive errors might reduce visual quality and increase the rate of dysphotopsias.

Different studies have reported excellent refractive outcomes after the implantation of trifocal IOLs, with approximately 95% of patients with spherical equivalent (SE) values within ±0.50 diopters (D) of emmetropia,[2,4-6] although other authors reported lower values [4,7] In patients with residual refractive errors that have an important effect on visual function, corneal refractive surgery may be performed with good clinical outcomes.[8,9] Nonetheless, it is difficult to accurately correct residual refractions of less than 0.50 D.

Therefore, it would be of interest to evaluate the visual performance of patients who have received a trifocal intraocular lens who have small refractive errors. One of the ways to do this is to induce either myopia or hyperopia over an ideal emmetropic situation. Thus, the aim of the present study is to assess visual quality and halo perception when a certain amount (0.50D) of positive or negative defocus is induced in patients implanted with trifocal and trifocal toric IOLs.

PATIENTS AND METHODS

This prospective study was performed at Clínica Rementería, Madrid, Spain and comprised patients who were looking for spectacle independence after cataract surgery and scheduled for bilateral implantation of the same diffractive trifocal IOL. Only one eye of each patient was evaluated in this study. The study followed the tenets of the Declaration of Helsinki and was reviewed and approved by the pertinent Ethics Committee. Informed consent was obtained from all patients after the nature of the study had been explained.

Exclusion criteria included amblyopia, preoperative angle kappa > 0.4mm, previous ocular surgery and presence of ocular pathologies and abnormal iris. Patients with intra- or postoperative complications and with residual spherical equivalent over 0.50D were also excluded.

The study evaluated two groups of patients. One group included eyes that were implanted with the non-toric trifocal AcrySof IQ PanOptix™ IOL (Alcon Laboratories, USA). The AcrySof® IQ PanOptix™ has been described in detail in previous studies.[1,6] In summary, this IOL has a diffractive design with a negative spherical aberration (-0.1 µm) in the anterior surface. It creates three effective foci at far, intermediate (60cm / +2.17D add) and near distance (40cm / +3.25 D).[1,6] The hydrophobic acrylic material of the IOL incorporates ultraviolet and blue light filtration.

The other group of eyes received a toric trifocal AcrySof IQ PanOptix Toric™ (Alcon Laboratories, USA). The AcrySof® IQ PanOptix™ Toric shares the same design and material with the spherical version. However, in order to correct corneal astigmatism, this lens has a biconical posterior surface. It can correct up to 3.75D of astigmatism.[1]

All patients underwent an extensive ophthalmologic examination prior to surgery, including refraction and visual acuity measurement, slit-lamp biomicroscopy, corneal topography, optical coherence tomography of the macula and optic nerve and fundus examination under pharmacological midriasis. Angle kappa was measured with the Pentacam® HR (Oculus, Wetzlar, Germany). At the same time, patients were examined with the IOL Master 700 for intraocular lens calculation. Patients with more than 0.8D astigmatism in corneal topography were also examined with the VERION™ Image Guided System (Alcon Laboratories, USA).[1] Toric IOLs were implanted in eyes with more than 0.8D astigmatism.

All cataract surgeries were performed by two experienced surgeons (LA.R.C and JL.G.P) under topical and intracameral anesthesia, with a 2.2 mm clear-cornea incision at 135 degrees and "stop and chop" phacoemulsification. Toric IOL implantation was guided by the VERION System.

All patients were evaluated one day, one week, one month and three months after surgery, but only data from the third month visit was taken into consideration for this study. In the three-month visit, patients included in the study underwent visual acuity for different contrasts, contrast sensitivity and halo size evaluation. Initially, uncorrected distance visual acuity with an ETDRS chart was measured, followed by subjective refraction (best distance correction). All other measurements were then performed first with the best distance correction and then with +0.50D (myopization) and -0.50D defocus (hyperopization) over this best distance corrected situation (as the reference situation).

The different contrast visual acuity evaluation procedures were performed with the FrACT3.9.9a version of the Freiburg Acuity Test software package[10,11]. Acuity software was run on a separate laptop screen that was calibrated to be presented at 4 meters. A black Landolt C was presented to the subjects and, among 8 different possibilities, they indicated the orientation of the optotype on a numeric keypad. This test minimizes the observer's bias because the presented optotype depends on the patient´s previous responses. That is, when the observer responds to a certain optotype, the software automatically modifies the size of the next optotype according to parameter estimation by a sequential test method. Monocular visual acuity was evaluated at low (10%), medium (50%) and high (100%) contrast.

Monocular contrast sensitivity function (CSF) was measured for spatial frequencies of 3, 6, 12 and 18 cycles per degree (cpd) using the functional acuity contrast test (Test SV-1000) of the CC-100 HW 5.0 Series system. CSF values were analysed as Absolute log10 (log10 CS).

The halo size perceived by patients in response to glare conditions was analyzed through the Halo v1.0 (Laboratory of Vision Sciences and Applications, University of Granada, Spain). The Halo v1.0 is an open-access software package that has been used in previous investigations that included multifocal IOLs analysis.[12-16] This test was also performed with a laptop screen at 4 m and the measurements were performed monocularly under scotopic conditions. The software calculates a "discrimination index" (a numerical value) depending on the size of the halo reported.[13] This index ranges from 0 to 1 in decimal scale where the higher index represents a lesser halo impact.

Data analysis was performed using SPSS for Windows V.20.0 (SPSS Inc, Chicago, IL). The normal distribution of variables was assessed using the Kolmogorov-Smirnov test. A repeated-measures analysis of variance (ANOVA) was used to gauge any statistically significant difference within the different situations. Post hoc multiple comparison testing was performed using the Holm-Sidak method. Differences were considered to be statistically significant when the P value was <0.05 (i.e., at the 5% level).

RESULTS

A total of 60 eyes of 60 patients were included in this study: 30 eyes implanted with a PanOptix IOL of 30 patients with a mean age of 67.15 ± 10.60 years and 30 eyes implanted with PanOptix Toric IOL of 30 patients with a mean age of 66.33 ± 7.96 years (p=0.46). Demographic preoperative data of each group are shown in table 1. Furthermore, all surgeries were successfully performed and there were no intra or postoperative complications.

Visual acuity at different contrast levels

Distance visual acuity values at the different measured contrast levels are recorded in Figure 1. For both the spherical and the toric group, visual acuity for all contrast settings was better when measured with best distance correction (CDVA) compared with both defocus situations, with no significant differences between +0.50 and -0.50 defocus.

Figure 2 shows the proportion of eyes in which 100% contrast visual acuity dropped 2 or more lines with 0.50D defocus. For the PanOptix group (figure 2.A), when a positive defocus was induced, 37% of the eyes lost ≥ 2 lines of vision. When a negative defocus was induced the proportion of eyes that lost ≥ 2 lines of vision was 33%. In the toric group (figure 2.B) 42% and 50% of the eyes lost ≥ 2 lines of vision when +0.50D and -0.50D of defocus were induced, respectively.

Contrast Sensitivity Function (CSF)

Figure 3 shows CSF results for both groups and for all situations. Regarding the PanOptix group (Figure 3A), for the lower spatial frequency (3 cycles per degree), no statistically significant differences were found between best distance correction, +0.50D and -0.50D defocus (p=0.16). At 6 cycles per degree, better contrast sensitivity was found with the best distance correction, although a post hoc comparison showed that only the difference with +0.50 defocus was statistically significant (p=0.02). At 12 cycles per degree, better results were again recorded with the best distance correction compared with the myopic (p=0.01) and the hyperopic situation (p=0.01) with no significant differences between both defocus situations (p=0.19). Finally, for the highest spatial frequency (18 cycles per degree), the overall results were better with best distance correction, although the difference was statistically significant only compared to +0.50D defocus (p=0.01). For the toric group (Figure 3B), the CSF results followed a very similar pattern. For 3 cycles per degree, the three focal positions showed similar results (p=0.09). For 6 cycles per degree, better contrast was found with best distance correction, although the difference was only statistically significant when compared with +0.50D defocus (p<0.001). For the mid-high frequency of 12 cycles per degree contrast sensitivity was better with the best distance correction compared to both defocus situations (p=0.03 and p=0.01 for +0.50D and -0.50D, respectively). For this spatial frequency, no differences were found between +0.50D and -0.50D defocus (p=0.24). For the highest spatial frequency (18 cycles per degree), contrast sensitivity was statistically higher with best distance correction only when compared with -0.50D defocus (p=0.02).

Halo effect – Index of discrimination

Figure 4 shows the halo results (index of discrimination) for both study groups. In both groups, the highest discrimination index (lowest halo effect) was found with the best distance correction compared to both defocus situations (p=0.01 for +0.50D and p=0.03 for -0.50D in the PanOptix group and p<0.001 for +0.50D and p<0.001 for -0.50D in the PanOptix Toric group), with no statistically significant differences between both defocus situations (p=0.13 for the PanOptix and p=0.37 for the PanOptix Toric group respectively).

In order to properly assess the impact of residual refractive errors on halo perception, figure 5 shows the proportion of patients in both groups that, after inducing +0.50D or -0.50D defocus, showed a loss ≥10% of discrimination index (potential complains due to halo perception or due to a significant visual acuity loss) as well as those that showed a loss ≥10% of discrimination index while their visual acuity remained stable (patients that might complain only due to photic phenomena). For the PanOptix group (figure 5.A), 30% eyes lost ≥ 10% of the discrimination index and 17% lost ≥ 10% of the discrimination index without a visual acuity drop with +0.50 defocus (myopization). When -0.50D defocus was induced (hyperopization), 16% of eyes lost ≥ 10% of the discrimination index and 13% lost ≥ 10% of the discrimination index without a visual acuity drop. For the PanOptix Toric group (figure 5.B), 38% of eyes lost ≥ 10% of the discrimination index and 15% lost ≥ 10% of the discrimination index without a visual acuity drop with +0.50 defocus. With -0.50 defocus 26% of eyes lost ≥ 10% of the discrimination index and 11% lost ≥ 10% of the discrimination index with a stable visual acuity.

DISCUSSION

Inaccurate IOL calculation prior to cataract surgery might lead to residual refractive errors and for Premium IOLs, this could lead to decreased visual quality.[17] The question is whether small refractive errors, which have been traditionally regarded as successful refractive outcomes, might have a significant impact on visual function and therefore on patients' satisfaction. Common complaints in patients after multifocal IOL implantation, with good visual acuities measured in an office, are the need for a potent light source in order to function correctly or the presence of halos and glare[18]. These complaints might be related to the presence of small refractive errors. Therefore, the current study assessed the impact of both positive and negative residual refractive errors on visual quality and halo perception in patients implanted with trifocal and trifocal toric IOLs.

We found that distance visual acuity dropped as expected with lower contrast settings, with better values with the best distance correction compared to small defocus situations (±0.50D). It should be noted that visual acuity showed similar drops when a positive or negative residual refractive error of 0.50D is induced in both groups and for all contrast settings, reflecting the importance of avoiding residual refractive errors when trifocal IOLs are implanted. This agrees with a previous study that also showed a worsening of high contrast visual acuity values when some positive or negative refractive error is induced in patients implanted with the same trifocal IOL.[17]

In addition, in order to better discern the impact of the type of over-refraction, we analysed the proportion of patients that undergo a significant visual acuity loss: when a positive defocus of +0.50D is induced (myopization), the proportion of eyes that lost ≥ 2 lines was 37%, with 33% of eyes losing ≥ 2 lines when a negative defocus of -0.50D (hyperopization) was induced in the Panoptix group. For the PanOptix Toric group, the percentage of eyes that lost ≥ 2 lines of vision was 42% and 50% after myopization and hyperopization. Therefore, regardless of the type of defocus, a similar and substantial proportion of patients could experience a deterioration in visual acuity with low residual refractive errors.

It must be taken into account that although we have found that residual refractive errors can lead to a deterioration in distance visual acuity with trifocal IOLS; the impact of positive or negative over-refractions should not affect visual acuity at intermediate and/or near vision but only induce a displacement (forwards or backwards) of all focal points of the defocus curve.[1-7] As a consequence, residual refractive errors with trifocal IOLs would modify the preferred distances for intermediate or near activities but not the vision at these distances.

In order to evaluate more comprehensively visual quality, CSF was also measured in the three situations for both groups. It should be noted that for low frequencies (3 cycles per degrees), that is, low detail-demanding visual situations, no differences were found among the three situations and for both IOLs groups. As the frequencies become higher and the resolution of fine details is more demanding, the results showed more variability. The overall trend at higher frequencies shows that CSF is better when no residual refractive error is induced. Thus, for gross visual details, some degree of residual refractive error seems to be negligible, while fine detail resolution could be affected even with low residual refractive errors, whether they are positive or negative.

Another issue in patients who have been implanted with multifocal IOLs is the impact of photic phenomena. We found that the mean halo effect was lower (higher discrimination index) when no residual refractive error is induced, with a higher halo perception with defocus, which again is similar both for negative and positive defocus. A previous study performed with an optical bench suggested that in trifocal IOLs, the halo in distance vision is produced by the joint contribution of the out of focus images corresponding to the intermediate and near add powers.[15] Therefore, the displacement (backwards or forwards) of the three foci induced by residual refraction could modify their contribution to halo perception at distance vision. However, the averaged results of the discrimination index showed that although even low over-refractions increase halo perception, there are no significant differences between positive or negative defocus.

Alba Bueno et al also analysed psychophysical assessment of halos perception and clinical subjective complaints of patients due to photic phenomena.[15] The authors reported that a 10% decrease in the discrimination index was correlated to significant subjective patient complaints. In order to further measure the impact of the type of defocus on halo perception, the proportion of patients that lost ≥ 10% of the discrimination index and also the proportion of eyes that lost ≥ 10% of the discrimination index without a significant visual acuity was analyzed. With this analysis, the proportion of patients that might complain only due to photic phenomena would be determined independently from those whose visual complaints might be related to a significant visual acuity loss. Our results found that a low defocus of ±0.50D could have a significant impact on halo perception in between 11% and 17% of the patients implanted with trifocal IOLs with no significant changes in distance visual acuity. Therefore in a clinical setting we must bear in mind that complaints about photic phenomena might be related to the presence of low residual refractive errors that seem to have no influence on visual acuity.

In the current study, no post-operative misalignments of the IOLs were found and patients presented regular corneal profiles. Intraocular lens decentration, tilt or rotation might further compromise the optical performance of the IOLs and patient visual quality.[19-22] Hence, it would be interesting to analyse the effect of the combination of misalignments and residual refractive errors in patients with trifocal IOLs. At the same time, dramatic changes on corneal profiles, such as those present in some patients with previous corneal refractive surgery, could also deteriorate their visual quality and/or halo perception.[23,24] In upcoming years, a large number of patients who have undergone corneal refractive surgery will develop cataracts and will probably seek spectacle independence, therefore studies to assess the potential effects of residual refractive errors in these patients after trifocal or trifocal toric IOL implantation will be of great interest.

In conclusion, the results of the present study suggest that, regardless of their nature, low residual refractive errors might be tolerated by most patients implanted with trifocal or trifocal toric IOLs. However, a significant number of patients will probably complain due to decreased visual quality, increased photic phenomena or a combination of both situations. Therefore, residual refractive errors within ±0.50D after surgery should not always be considered a refractive success after premium IOL implantation.

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FIGURE LEGENDS

Figure 1. Visual acuity at 100%, 50% and 10% of contrast with best distance correction (CDVA) and with +0.50 and –0.50 diopters (D) defocus for the PanOptix (TOP) and PanOptix Toric groups (BOTTOM). * represent statistically significant differences between the best distance correction situation and +0.50D of defocus (myopization). ** represent statistically significant differences between the best distance correction situation and -0.50D of defocus (hyperopization)

Figure 2. Proportion of eyes in which the visual acuity (VA) at distance and at 100% of contrast remained unchanged or dropped only 1 line and those eyes in which VA decreased ≥ 2 lines of vision for the best distance correction situation, with +0.50D and -0.50D of defocus. A) PanOptix group. B) PanOptix toric group.

Figure 3. Contrast sensitivity function (CSF) under photopic conditions (85 cd/m^2) 3 months after the cataract surgery for the three refractive situations (best distance correction, +0.50D and -0.50D defocus). A) PanOptix group. B) PanOptix Toric group. * represent statistically significant differences between the best distance correction situation and +0.50D defocus (myopization). ** represent statistically significant differences between the best distance correction situation and -0.50D defocus (hyperopization).

Figure 4. Discrimination index (halo effect) for the three refractive situations (best distance correction, +0.50D and -0.50D defocus). A higher discrimination index reflects a lower halo perception. A) PanOptix group. B) PanOptix Toric group. * represent statistically significant differences between the best distance correction situation and +0.50D defocus (myopization). ** represent statistically significant differences between the best distance correction situation and -0.50D defocus (hyperopization).

Figure 5. Proportion of patients that showed a loss ≥10% of discrimination index and those in which the index loss ≥10% while their visual acuity remained unchanged or loss ≤ 1 lines with +0.50D or -0.50D of defocus. A) PanOptix group. B) PanOptix Toric group.