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Complete List of Authors:	Garzón, Nuria; Universidad Complutense de Madrid Facultad de Optica y Optometria, Departamento de Optometría y Visión; Miranza Group Poyales, Francisco; Miranza Group García Montero, María; Universidad Complutense de Madrid Facultad de Optica y Optometria Vega, Fidel; Universitat Politecnica de Catalunya, Departament d'Òptica i Optometria Millan, Maria Sagrario; Universitat Politécnica de Catalunya - Campus Terrassa, Departament d'Òptica i Optometria, Albarran-Diego, Cesar; Universidad de Valencia Facultad de Ciencias Biologicas, Optics, Optometry and Vision Science Department; Clínica Baviera Castellón; Clínica Oftalmológica Dr Gonzalo Muñoz
Keywords:	Optics, Refraction, intraocular lens, trifocal diffractive, hydrophobic, hydrophilic

TITLE PAGE

TITLE

IMPACT OF LENS MATERIAL ON OBJECTIVE REFRACTION IN EYES WITH TRIFOCAL DIFFRACTIVE INTRAOCULAR LENSES

Authors

Nuria Garzón, PhD [1,2]

María García-Montero *, PhD [1,2]

Francisco Poyales, MD [1]

Fidel Vega, PhD [3]

María Sagrario Millán, PhD [3]

César Albarrán-Diego, PhD [4,5,6]

1. *Miranza Group, Madrid, C/Galileo 104, 28003 Madrid, Spain.*
2. *Optometry and Vision Department, Faculty of Optics and Optometry, Complutense University of Madrid, 28037, Madrid, Spain.*
3. *Departament d'Òptica i Optometria, Universitat Politécnica de Catalunya, BarcelonaTech, Violinista Vellsolà 37, 08222 Terrassa, Spain.*
4. *Optics, Optometry and Vision Science Department. Faculty of Physics, University of Valencia. Dr Moliner 50, 46100-Burjassot, Spain.*
5. *Clínica Baviera Castellón. C/Mayor 69, 12001 Castellón de la Plana, Spain.*
6. *Clínica Oftalmológica Dr Gonzalo Muñoz. C/Marqués de Sotelo 5, 46002 Valencia, Spain.*

Corresponding Author:

María García-Montero

Optometry and Vision Department

Faculty of Optics and Optometry

Complutense University of Madrid

28037, Madrid. Spain.

Email: mgarc01@ucm.es

SHORT TITLE

Lens material on refraction with diffractive IOLs

IMPACT OF LENS MATERIAL ON OBJECTIVE REFRACTION IN EYES WITH TRIFOCAL DIFFRACTIVE INTRAOCULAR LENSES

ABSTRACT

Purpose: compare subjective (Rx) and objective (ObjRx) refractions outcomes with two autorefractors models and an aberrometer in eyes implanted with a hydrophobic trifocal IOL (FineVision POD F GF, Physiol, Liége, Belgium) and a hydrophilic one (FineVision POD F, Physiol, Liége, Belgium).

Methods: prospective comparative cohort study, with 100 subjects randomly assigned to either the POD F group (n=50) or the POD F-GF group (n=50). Postoperative eye examinations at 1-month visit included 7 result sets, one for each assessment method: Rx, AR (automated refraction measured with the autorefractor KR8800), WF-P (Zernike-coefficients-based objective refraction, photopic pupil size), WF-M (Zernike-coefficients-based objective refraction, mesopic pupil size), WF-4 (Zernike-coefficients-based objective refraction, 4 mm pupil), OPD-C (automated refraction measured with the aberrometer OPD in the central pupil/photopic conditions), and OPD-M (automated refraction measured with the aberrometer OPD under mesopic conditions).

Results: Mean differences between ObjRx and Rx reached statistical significance for sphere and spherical equivalent (M) only with OPD-C in the POD F-GF group. All ObjRx methods showed significant differences with Rx in the POD F group, with some values differing by more than 0.50 D (-0.58 D in M for the WF-P). Bland Altman plots showed better agreement for astigmatic components, and for sphere and spherical equivalent in both IOL groups measured with AR and OPD-M.

Conclusions: None of the objective methods of refraction evaluated in this study were as reliable as the subjective refraction, irrespective of the lens material, but POD F-GF ObjRx seem to differ less with Rx than POD F ObjRx values.

Keywords: Optics, refraction, intraocular lens, trifocal diffractive, hydrophobic, hydrophilic

INTRODUCTION

Cataract surgery is one of the most common operations nowadays, with an increasing rate of growth worldwide. Currently, there are in the market many multifocal intraocular lenses (IOL) designed to provide good vision at several distances due to the patient's demand. Depending on the lens design, several addition powers, distribution of energy between the foci, and depth of focus are available with different models [1].

In any type of multifocal IOL, in which the light is split into two or more images, one image can be on focus, while the others can be hardly perceived or blurred, depending on the distance of observation. In diffractive lenses this phenomenon leads to what is usually called the blur circle,[2] and is also found in parallel complaints with radially asymmetric lenses.

Automated refraction (AR) after cataract surgery with monofocal IOLs is considered a proper starting point for subjective manifest refraction [3,4]. It has been shown that with bifocal diffractive IOL, there is a good correlation between AR and subjective refraction [5], while with bifocal refractive IOLs, there was a lesser correlation between those parameters.[6] [7] With trifocal diffractive lenses, objective refraction methods showed more negative sphere values than manifest refraction [8].

The current study aims to compare subjective (Rx) and objective (ObjRx) refraction outcomes with two autorefractor models and an aberrometer in eyes implanted with a hydrophobic trifocal IOL (FineVision POD F GF, Physiol, Liége, Belgium) and a hydrophilic one (FineVision POD F, Physiol, Liége, Belgium). Both lenses are based on the same optical design regarding asphericity and diffractive profile [9], but differ in the material they are made from, which results in significant differences in the thickness of the IOLs, and chromatic aberration. Although the optical properties of the POD F IOL have been previously reported [10], to the best of our knowledge, this is the first study that compare the influence of different IOL materials in the objective and subjective refractions values obtained by means of autorefractometry or aberrometry when trifocal and monofocal diffractive IOLs are implanted.

PATIENTS AND METHODS

Study design and patient population

This is a prospective comparative cohort study on patients undergoing cataract surgery and bilateral trifocal IOL implantation at Miranza IOA, Madrid, Spain. Patients were randomly assigned to two groups: POD F group (bilateral implantation with hydrophilic trifocal POD F IOL) and POD F-GF group (bilateral implantation with hydrophobic trifocal POD F-GF IOL). When the investigator considered that the patient could be included in the study, and after the patient accepted the enrollment and signed the inform consent, the randomization was performed. Only right eyes were considered for the study.

Sample size was calculated according to the paper published by Garzon et al[8] accepting an alpha risk of 0.05 and a beta risk of 0.2 in a two-sided test. Forty-seven (47) subjects per group are necessary to recognize as statistically significant a difference in visual acuity (VA) greater than or equal to 0.05 logMAR units. The standard deviation is assumed to be 0.46. It has been anticipated a drop-out rate of 10%. A total of 100 eyes from 100 patients were initially included in the study, 50 patients and eyes in each group.

Inclusion criteria were the desire for spectacle independence after surgery with realistic expectations, and availability and willingness to comply with all the study visits and eye examination. Exclusion criteria were a history of ocular disease other than cataract (e.g., uveitis, amblyopia, glaucoma), corneal astigmatism above 1.25 D, any acute or chronic condition that would increase the risk or confound study results, any capsule or zonular abnormalities that may affect post-operative centration or tilt of the IOL and the presence of pupil abnormalities.

All patients provided written informed consent before enrollment. This study was approved by the clinical research ethics committee of the Hospital Clinico San Carlos de Madrid (Madrid, Spain) under code number 17/165-R_P and was performed in accordance with the Declaration of Helsinki.

Surgical procedure

All surgeries were carried out by the same surgeon (FP) under topical anesthesia. Anterior capsulotomy and nuclear fragmentation were performed with a femtosecond laser (CATALYS Precision System, Johnson & Johnson, Santa Ana, CA). A 2.2 mm corneal incision and a paracentesis were made with a surgical knife, and for lens phacoemulsification a commercial microsurgical system (Centurion Vision System; Alcon Laboratories, Inc., Fort Worth, TX) was employed. Two ophthalmic viscosurgical devices were used throughout the entire procedure: the cohesive Healon (Johnson & Johnson, Santa Ana, CA) and the dispersive Amvisc (Bausch & Lomb, Inc., Rochester, NY). The chosen IOL was then implanted into the capsular bag with a single-use injection system (Microset; PhysIOL, Lieje, Belgium). In all cases, a capsular tension ring was inserted. All surgeries were supported by the computer-assisted cataract surgery system (CALLISTO Eye from Zeiss' Cataract Suite Markerless; Carl Zeiss, Jena, Germany).

Intraocular lenses

Two types of acrylic foldable trifocal intraocular lenses with a similar optical design but different material were implanted in this study. The POD F-GF IOL (Physiol, Liége, Belgium) is made of glistening-free hydrophobic acrylate with refractive index of 1.52 and Abbe number of 42. The POD F IOL (Physiol, Liége, Belgium) is a 26% hydrophilic acrylic lens with refractive index of 1.46 and Abbe number of 58. Both lenses have 5 degrees' angulation, with spherical aberration (SA) induction of -0.11 µm (6.0 mm pupil), and an ultraviolet and blue light filter. Both combine the same two diffractive structures with the same additions of +1.75 D for intermediate vision and +3.50 D for near vision at the IOL plane, resulting in effective additions at the corneal plane of +1.2 D and +2.4 D respectively [11].

Postoperative eye examinations

Subjective refraction

Patients were examined 1 day, 1 week, and 1 month after surgery, although the data reported in this paper were the ones taken at the 1-month visit.

All refraction assessments were carried out by the same optometrist (NG, Miranza IOA). Rx at far distance was always performed under constant illumination conditions, using the ETDRS chart with a trial frame. The starting point for the subjective refraction was an automated objective refraction (Topcon KR8000) with fogging ensuring a VA under 20/40. At the best visual-acuity scenario, Rx was then further fine-tuned —both spherical and cylindrical components—by means of cross-cylinders in steps of 0.25 D.

Objective refraction

The objective refraction (ObjRx) was obtained with two methods. The first one was by using the KR8800 (Topcon Inc, Tokyo, Japan) autorefractor, a multifunctional device that determines corneal curvature and objective refraction. This device relies on the Scheiner double-pinhole principle for data capture: two light sources are imaged onto the pupil plane to simulate the Scheiner pinhole apertures. Automatic capture of four measurements was repeated three times and the average values were used for statistical analysis [12,13] . The objective refraction obtained with this device was named AR (automated refraction measured with the autorefractor KR8800).

The second method to measure ObjRx was with the Nidek OPD-Scan III (Nidek Technologies, Gamagori, Japan). The measurement was performed three times before calculating the mean value. This aberrometer/corneal topographer workstation combines a wavefront aberrometer, an autorefractor, and a pupilometer. The autorefractor relies on the principle of scanning-slit retinoscopy, where the retina is scanned with an infrared slit beam. The device calculates the patient's refraction (spherical and cylindrical refractive errors, as well as cylinder axis' angle) based on the wavefront phase differences [14]. As well as providing objective refraction in the form of a spherocylindrical reading, the aberrometer also computes the Zernike coefficients for low- and high-order aberrations. The Zernike coefficients corresponding to low-order aberrations (Z_0^2, Z_2^{+2} and Z_2^{-2}) can be used to calculate ObjRx in vector notation (M, J0 and J45) according to the expressions described by Micó et al. [15] and Garzon et al. [8]

For each eye included in the study we collected 7 result sets, one for each assessment method: Rx (manifest refraction), AR (automated refraction measured with the autorefractor KR8800), WF-P (Zernike-coefficients-based objective refraction, photopic pupil size), WF-M (Zernike-coefficients-based objective refraction, mesopic pupil size), WF-4 (Zernike-coefficients-based objective refraction, 4 mm pupil), OPD-C (automated refraction measured with the aberrometer OPD in the central pupil/photopic conditions), and OPD-M (automated refraction measured with the aberrometer OPD under mesopic conditions).

Statistical analysis

Rx and ObjRx values obtained in clinical spherocylindrical notation, were converted into power-vector notation for comparison purposes [15]. A set of three objective refraction calculations of the Zernike coefficients were performed: one for photopic pupil, other for mesopic pupil, and other for a "standard" pupil fixed at 4 mm, as this was the value yielding the best agreement for spherical equivalent in a previous study by Campbell [16].

SigmaPlot v.12 for Windows was used for statistical analysis and graphic plotting. For each of the two groups (POD F and POD F-GF), the Friedman repeated measurements analysis of variance on ranks was used to look for differences between any of the six ObjRx assessment methods and the Rx, for each of the refraction vector components. When differences were found, pairwise multiple comparison testing was applied by the Tukey test to identify those differences. Agreement was evaluated by means of Bland-Altman plots and intraclass correlation coefficients (ICC) were calculated with Medcalc v.12.5 software for Windows to study the strength of the agreement between methods [17]. Statistical significance was set at $\alpha=0.05$. For each of the IOL groups, since 4 Friedman test were applied -one for each refractive component (S, M, J0, J45)-, the Bonferroni correction was applied to the Friedman test results to account for the multiple comparisons that could increase Type I error, so results for the Friedman test will be significant if $p<0.013$ (0.05/4).

RESULTS

Initially, a total of 100 subjects were randomly assigned to either the POD F group (n=50) or the POD F-GF group (n=50). Forty-nine eyes in the POD F group and forty- eight eyes in the POD F-GF group were finally analyzed. Mean age was 66.8 ± 6.3 years in the POD F group and 67.7 ± 7.1 years in the POD F-GF group. Mean pupil size was 3.22 ± 0.52 mm and 4.46 ± 0.63 mm under photopic and mesopic conditions, respectively for the POD F group, and 3.37 ± 0.56 mm and 4.73 ± 0.71 mm for the POD F-GF group. No differences between both groups were found in terms of age (Mann-Whitney Rank Sum Test, p=0.546), photopic pupil (Student's t-test, p=0.173) or mesopic pupil (Student's t-test, p=0.052).

Table 1 shows a summary of the surgical outcomes in terms of subjective refraction and VA for both groups (POD F and POD F-GF). The average refractive result was very close to emmetropia, with a mean spherical equivalent of 0.01 D and 0.09 D for POD F and POD F-GF groups respectively and both astigmatic components being below 0.06 D in average for both groups.

[insert here Table 1]

Table 2 shows mean and SD values obtained in each group (POD F and POD F-GF) for each of the ObjRx methods under study.

[insert here Table 2]

Figure 1 shows a boxplot illustrating the differences between Rx outcomes and each of the 6 ObjRx measuring approaches under evaluation, for sphere (Sph), spherical equivalent (M) and astigmatism components (J0 and J45) in both the hydrophilic (POD F) and hydrophobic (POD F-GF) IOL groups.

[insert here Figure 1]

For the POD F group, the Friedman repeated measures analysis of variance on ranks revealed no differences among any of the ObjRx methods and Rx for the sphere (Friedman test, $p<0.0097$). M showed differences (Friedman test, $p<0.001$), for the comparison among all the ObjRx methods and the Rx (Tukey Test < 0.015 in all cases). Differences were found for the J0 astigmatic component (Friedman test, $p=0.012$) just for the comparison AR vs Rx (Tukey test, $p=0.038$). No differences were found for the J45 astigmatic component (Friedman test, $p=0.356$).

For the POD F-GF group, the Friedman repeated measures analysis of variance on ranks revealed differences for the sphere (Friedman Test, $p<0.001$) just for the comparison Rx vs OPDC (Tukey Test $p=0.043$). The same way, the Friedman test found differences for the M (Friedman Test, $p<0.001$) just located in the comparison Rx vs OPDC (Tukey Test $p<0.001$). No differences among ObjRx and Rx results were found in the POD F-GF group in astigmatism, neither for the J0 component (Friedman Test, $p=0.753$) nor for the J45 component (Friedman Test, $p=0.069$).

Table 3 shows all the mean differences obtained between Rx and all the ObjRx methods, for all the refractive parameters and for both groups. Statistically significant values appear in boldface.

[insert here Table 3]

Figures 2 to 5 show the Bland Altman plots for the sphere and M component of the power vector analysis, both for POD F and POD F-GF groups, and supplementary figures (supplementary figures 1 to 4) show the J0 and J45 component. In each plot the vertical axis represents the difference found between each objective method and the subjective (manifest) refraction (Rx) outcomes, whereas the horizontal axis indicates the corresponding Rx value. The authors decided to plot this absolute Rx value—instead of the average across all methods—because subjective refraction is considered the Gold-Standard measuring technique for refractive status determination [18]. The Bland-Altman pots include a zero-bias line (solid line) as well as 95% limits of agreements (dotted lines)

[insert here Figures 2 to 5]

Both spherical components of refraction (Sph and M) showed narrower 95% limits of agreement for AR, WF-M and OPD-M, with worst results (wider 95% limits) for WF-P, both in the PODF and in the PODF-GF groups. The better result in terms of agreement regarding Bland Altman plots was obtained in the POD F group for M measured by OPD-M (95% limits between +0.37 D and -0.93 D). In the PODF-GF the better results were also obtained for M measured by OPD-M (95% limits between +0.37 D and -0.93 D) and M measured by WF-M (95% limits between +0.47 D and -0.67 D). In both groups Sph and M measured by WF-P showed the worst agreement results with Rx, with 95% limits of agreement as wide as 3.00 D

Astigmatic components of refraction showed a similar behaviour, with better agreement in both J0 and J45 components for the OPD-C, OPD-M and AR measurements in both groups, and worst results for WF-P measurements. In general terms, J45 showed better agreement than J0 in both groups.

Table 4 shows the ICCs assessing the degree of agreement with Rx for each ObjRx method and for each refractive component, for both groups.

[insert here Table 4]

As can be seen from Table 4, the strongest correlation with Rx for sphere (Sph) was found for OPD-M in the POD F-GF group (ICC=0.90), whereas the weakest was for OPD-C in the POD F-GF group (ICC=-0.35). For the spherical equivalent (M), the strongest and weakest correlations with Rx were for WF-M in the POD F-GF group (ICC=0.89) and OPD-C in the POD F-GF group (ICC=-0.39) respectively. OPD-M in the POD F-GF group showed the strongest correlation with Rx for astigmatism (ICC=0.86 for J0 and ICC=0.80 for J45) whereas OPD-C for J45 in the POD F group showed the weakest correlation (ICC=-0.58) and for J0 in the POD F-GF ICC=-0.01)

DISCUSSION

Subjective or manifest refraction (Rx) is still considered as the Gold Standard method to determine the eye's refractive status after cataract surgery, and for prescribing eyeglasses [19]. Subjective refraction can be measured without a reliable objective refraction value as a starting point, but the procedure will be more time-consuming, increasing both the patient's fatigue and the probability of inaccuracies in the obtained value [20]. The techniques for ObjRx measurement include AR, keratometry, aberrometry and retinoscopy. In the general population, retinoscopy is superior to AR as starting point to non-cycloplegic Rx [21], but retinoscopy needs experienced clinicians. In pseudophakic eyes, with no accommodation, AR can be a good starting point for Rx [19,22] since it requires less training than retinoscopy.

This prospective study has studied whether the change of material while maintaining the same optical design of trifocal diffractive LIOs causes changes in the objective refraction values obtained by autorefractometry or aberrometry after surgery.

AR after cataract surgery shows proper reliability when monofocal IOLs are implanted [23,24], although cannot totally replace subjective refraction for prescribing purposes. But different authors have shown that the precision of objective methods to obtain the patients' refraction are less accurate when evaluating patients implanted with multifocal intraocular lenses than with monofocal ones [7,25,26].

With multifocal IOLs, the simultaneous presence of two or more foci makes it more difficult to determine unambiguously a unique focal plane, and thus to accurately measure the patients' objective or subjective manifest refraction [27].

Concerning the use of aberrometry to assess multifocal IOL wearers, Charman [28] concluded that a Shack-Hartmann aberrometer may not provide reliable information on the wavefront aberration associated with either the distance or the near components of diffractive IOLs, since the results could depend on factors such as the power of the diffractive addition and the relative amplitudes of the distance and near wavefronts.

Garzon et al. [8] studied the AR reliability with a hydrophilic trifocal IOL implantation. The present work extends this study to a hydrophobic material with the same IOL optical design. There are several articles [29-31] that compare the biocompatibility and behaviour of the hydrophilic or hydrophobic materials of intraocular lenses but, to our knowledge, none of them has evaluated whether the hydrophilic or hydrophobic characteristics of the material may have an influence on the objective refraction outcome. Implantation of a lens made of one of these two polymers is not problematic in normal pseudophakic eyes but selecting the right IOL material is very important in complicated and special cataract surgeries such as cataracts accompanied by diabetic retinopathy, uveitis, and young pseudophakic eyes. The age of patients operated and implanted with multifocal intraocular lenses is getting younger, so it is important to know the behaviour of the lenses, even with regard to the refraction methods.

In natural conditions, both monochromatic and chromatic aberrations play a role in determining retinal image quality.[32,33] The optical system of the human eye is affected by a relatively high amount of longitudinal chromatic aberration (LCA) –about 2 D in the visible spectral range (400-700nm).[34] The contribution of the crystalline lens to chromatic aberrations is reported to be about 28.5% of the entire ocular media.[35] Nakajima et al reported that the LCA derived from the cornea alone does not depend on age.[36]

Diffraction and refraction induce chromatic aberration by dividing light in its colour spectrum in the opposite way. A refractive element works by refracting short-wavelength light more (blue spectrum), and long-wavelength light less (red spectrum). With diffraction the opposite happens, so that a diffractive element acts as if it had more refractive power for long-wavelength light than for short-wavelength light. This behaviour is the key for chromatic aberration correction solutions combining refractive and diffractive elements. Given that POD F and POD F-GF have the same diffractive pattern but different material with different Abbe number , a different chromatic aberration behaviour can be expected [37,38]. Since AR works with infrared light to not stimulate accommodation, different AR reliability could be expected for POD F and POD F-GF. The same can be suspected with aberration ObjRx measurement methods using a different wavelength.

Concerning hypothesis testing for mean values, our results show that for both IOLs, the sphere (Sph), spherical equivalent (M) and the 180º-90º astigmatism component (J0) are statistically different when we compare the values obtained with the subjective (manifest) refraction to the values taken with some of the objective methods studied.

Comparing the groups implanted with hydrophilic (POD F) and hydrophobic (POD F-GF) lenses, the hydrophilic one showed greater differences between ObjRx and the subjective results (see Figure 1 and Table 3).

Spherical equivalent (M) showed statistically significant differences between Rx and all the ObjRx methods for the POD F IOL, with some of those statistical differences being clinically relevant (as for instance the mean difference of -0.58 D in M for the WF-P in the hydrophilic POD F group). For the POD F-GF, only OPD-C ObjRx showed statistically significant differences with Rx (see Figure 1). Comparison between ObjRx and Rx for astigmatic components showed a more discrete difference, with a mean difference of only -0.10 D in J0 obtained with the AR for the hydrophilic POD F group. Even this difference reached the statistical signification, it has little clinical relevance. Then, the ObjRx evaluated methods seem to estimate astigmatic components better than spherical refractive components, and better for the POD F-GF IOL.

Regarding the Bland-Altman plots showing differences between ObjRx and Rx with the 95% limits of agreements (dotted lines in Figures 2-5 and supplementary figures), it could be stated that objective and subjective refraction variables may be considered equivalent if 95% of the data points fall within a range that would be considered clinically meaningful. Sphere (S) and

Spherical equivalent (M) show differences in Bland Altman plots with 95% limits of agreement between +1.00 D and -1.00 D, or wider, for both IOLs, with AR and OPD-M showing narrower limits (better agreement) both for the POD F and POF-FG IOLs. Astigmatic components J0 and J45 presented narrower limits of agreement, but with values ranging in some cases between -0.50 D and +0.50 D (and wider for the WF-P values in both IOL models).

The 95% limits of agreement in Bland Altman plots were wider (worst agreement) in both lenses for the values of ObjRx mathematically obtained from the lower order Zernikes (WF-P, WF-M and WF-4). This can be due to an error induced by the simplification of calculating refraction from wavefront aberration using only lower order Zernikes. On the contrary, AR and OPD-M showed narrower 95% intervals (better agreement).

A good agreement between methods would yield ICC values above 0.7. Both AR and OPD-M showed in general the best ICC results with Rx, with OPD-C showing the worst results. Wavefront derived objective refractions were not superior to AR values. It can be concluded from this results that AR is not a worst estimating technique than more complex techniques as OPD and wavefront-derived refractions.

Garzón et al. [8] reported that objective methods tend to yield more negative sphere values than manifest refraction with a trifocal hydrophilic lens, in agreement with our present results with the same lens. Muñoz et al. [26] reported that the mean spherical power difference between autorefraction and subjective refraction was near zero for the bifocal diffractive hydrophobic IOL models considered in their study. Similar results were reported by Bissen-Miyajima [5] with another diffractive hydrophobic lens. It is difficult to determine if this minor refractive defect when comparing the objective method with the subjective one was due to the bifocal design or the hydrophobic material. No studies have been found evaluating this parameter in hydrophilic bifocals that could have helped us to confirm which factor was determining. The addition of a third focus could be one of the reasons, but material could also be a factor explaining this behavior.

In our study, we used two autorefractor models that were based on very different principles: The Scheiner double-pinhole principle (autorefractor keratometer) and the principle of scanning-slit retinoscopy with an aberrometer. Although the objective methods were very different from each other, what is observed is that with all of them, the myopic shift was always higher in the case of the hydrophilic lens, which shows that it is a common pattern to that lens. It marks a clear difference with the results obtained with the hydrophobic IOL. In the case of the spherical equivalent (M) those differences reach clinical relevance.

The discrepancies between objective aberrometer-based refraction and subjective refraction have been attributed to different variables, including the image noise in the objective measurements [39], or the merit function chosen to determine the best focus [40], but the lens material has not been considered yet in these evaluations even though it can affect other parameters such as the longitudinal chromatic aberration, which in turn, can directly influence the objective measurements.

Rohart et al. [41] found some differences in the ocular aberrations in pseudophakic eyes after insertion of two different monofocal acrylic IOLs measured with the OPD Scan as we used in our study. They reported that tilt and coma aberrations were greater with the hydrophobic than with hydrophilic acrylic IOLs evaluated. Our results are not directly comparable with Rohart's since we only considered lower order aberrations to calculate ObjRx, but Rohart et al reported no significant differences between lenses for the secondary astigmatism, which could be in accordance with our results showing no relevant differences in astigmatic components between both lenses.

Taketani et al.[42] , evaluating monofocal lenses, reported that the IOL shape was an important factor in spherical aberration induction. The POD F and POD F GF lenses differ significantly in their thickness and curvatures, because of the differences in the refractive index and Abbe number of the materials. Based on the technical specifications provided by the manufacturer, both IOLs have equiconvex spherical surfaces, which may lead to similar amounts of spherical aberration in both group of patients. Moreover, the lenses also have similar diffractive optical profiles [9]. On the other hand, the material and the overall shape (thickness and curvature) of the two lenses implanted in this study are different which could explain the different results obtained with them.

Generally, patients with pseudophakic IOLs should always be examined using subjective refraction, rather than objective refraction only, especially with multifocal IOLs. However, in some settings, clinicians only use objective refraction. As this study shows, this would lead to false results, since differences between the objective and subjective refraction with the trifocal lenses studied have been found. Then, we consider that it´s mandatory to perform a subjective evaluation to know the real status of the patient, and, more important, when the patient show some degree of discomfort that could lead to prescribe glasses or refractive surgery to compensate the residual refractive error.

Based on the outcomes of our study about hydrophobic and hydrophilic trifocal IOLs, we conclude that no current objective measuring technique is as reliable as the subjective method with which the patient gets their best visual acuity possible. Better results, with differences between Rx and ObjRx very close to zero, were obtained for the hydrophobic material with all the methods evaluated. With both lenses, the best results were achieved with the autorefractor keratometer and the autorefraction with the aberrometer under mesopic conditions.

Measurements with AR were as accurate as those obtained with OPD, and better than those derived from wavefront error, so there seems to be no reason in investing in more expensive technology than AR just to have a proper starting point for Rx determination.

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TABLES

Table 1. Descriptive statistics obtained after surgery for subjective refraction and visual acuity in both groups.

	Group	**Subjective refraction (D)**					**Visual acuity (LogMAR)**	
		M	**J0**	**J45**	**Sph**	**Cyl**	**UDVA**	**DCVA**
Mean	POD F	0.01	0.00	0.02	0.07	-0.12	0.05	0.01
	POD F-GF	0.09	-0.05	0.03	0.23	-0.28	0.08	0.01
SD	POD F	0.34	0.10	0.11	0.36	0.27	0.10	0.04
	POD F-GF	0.42	0.18	0.12	0.50	0.34	0.09	0.03
Min	POD F	-0.75	-0.29	-0.25	-0.75	-1.00	-0.10	-0.10
	POD F-GF	-1.00	-0.49	-0.22	-1.00	-1.00	-0.04	-0.04
Max	POD F	1.25	0.47	0.43	1.50	0.00	0.40	0.14
	POD F-GF	1.00	0.38	0.35	1.25	0.00	0.40	0.18

LogMAR = logarithm of the minimum angle of resolution; POD F = Hydrophilic group; POD F-GF = Hydrophobic group; M = spherical equivalent; J0 = vertical Jackson cross-cylinder, axes at 180 degrees and 90 degrees; J45 = oblique Jackson cross-cylinder, axes at 45 degrees and 135 degrees; Sph = sphere; Cyl = cylinder; D=diopters; UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity; SD = standard deviation.

Table 2: Descriptive statistics for the objective refractions obtained with all the evaluated methods, for both groups (POD F = Hydrophilic group; POD F-GF = Hydrophobic group).

Parameter		**Group**	**Objective method**					
			AR	**WF-P**	**WF-M**	**WF-4**	**OPD-C**	**OPD-M**
Sph (D)	**Mean**	POD F	-0.02	-0.05	-0.02	-0.06	-0.17	-0.08
		POD F-GF	0.27	0.59	0.30	0.32	-0.17	0.32
	SD	POD F	0.53	0.83	0.42	0.56	0.47	0.40
		POD F-GF	0.57	1.11	0.59	0.76	0.42	0.54
Cyl(D)	**Mean**	POD F	-0.54	-1.04	-0.54	-0.68	-0.35	-0.39
		POD F-GF	-0.54	-1.19	-0.61	-0.83	-0.36	-0.50
	SD	POD F	0.36	0.50	0.27	0.36	0.33	0.31
		POD F-GF	0.33	0.71	0.38	0.51	0.28	0.39
M(D)	**Mean**	POD F	-0.28	-0.57	-0.29	-0.40	-0.34	-0.27
		POD F-GF	0.00	-0.01	-0.01	-0.09	-0.35	0.07
	SD	POD F	0.48	0.74	0.37	0.52	0.41	0.36
		POD F-GF	0.54	0.93	0.49	0.70	0.42	0.47
J0(D)	**Mean**	POD F	-0.11	-0.16	-0.08	-0.10	-0.04	-0.06
		POD F-GF	-0.05	-0.17	-0.10	-0.14	-0.04	-0.07
	SD	POD F	0.23	0.40	0.21	0.27	0.18	0.17
		POD F-GF	0.26	0.55	0.28	0.38	0.16	0.24
J45(D)	**Mean**	POD F	0.04	0.05	0.03	0.03	-0.03	0.00
		POD F-GF	0.04	-0.01	0.00	-0.01	-0.02	-0.02
	SD	POD F	0.20	0.39	0.21	0.26	0.15	0.17
		POD F-GF	0.17	0.40	0.20	0.28	0.16	0.20

Sph=sphere; Cyl = cylinder; M= spherical equivalent; J0 = vertical Jackson cross-cylinder, axes at 180 degrees and 90 degrees; J45 = oblique Jackson cross-cylinder, axes at 45 degrees and 135 degrees; SD = standard deviation; D: diopters; AR = autorefraction; WF-P = wavefront photopic; WF-M = wavefront mesopic; WF-4 = wavefront 4.0 mm; OPD-C = autorefraction measured with the 3-dimension wavefront topography aberrometer system in the central pupil/photopic conditions; OPD-M = autorefraction measured with the 3-dimension wavefront topography aberrometer system under mesopic conditions.

Table 3: Mean differences for both groups of patients (POD F and POD F-GF) between ObjRx and Rx for the 6 ObjRx methods under study.

		Objective – subjective refraction difference											
		AR		WFP		WFM		WF4		OPDC		OPDM	
		MEAN	SD	MEAN	SD	MEAN	SD	MEAN	SD	MEAN	SD	MEAN	SD
Sph(D)	POD F	-0.08	0.45	-0.12	0.77	-0.09	0.45	-0.12	0.52	**-0.23**	**0.62**	-0.14	0.41
	POD F-GF	0.04	0.38	0.35	0.77	0.06	0.35	0.09	0.46	**-0.40**	**0.70**	0.09	0.32
M(D)	POD F	**-0.30**	**0.36**	**-0.58**	**0.66**	**-0.30**	**0.37**	**-0.40**	**0.48**	**-0.35**	**0.54**	**-0.28**	**0.33**
	POD F-GF	-0.09	0.38	-0.10	0.64	-0.10	0.29	-0.19	0.45	**-0.44**	**0.64**	-0.02	0.29
J0(D)	POD F	**-0.10**	**0.20**	-0.15	0.41	-0.08	0.22	-0.10	0.28	-0.04	0.18	-0.05	0.20
	POD F-GF	0.00	0.20	-0.11	0.42	-0.04	0.17	-0.08	0.26	0.01	0.24	-0.02	0.14
J45(D)	POD F	0.01	0.18	0.03	0.36	0.00	0.18	0.01	0.22	-0.05	0.21	-0.02	0.15
	POD F-GF	0.00	0.15	-0.04	0.33	-0.04	0.15	-0.05	0.21	-0.05	0.21	-0.05	0.14

Sph=sphere; M= spherical equivalent; J0 = vertical Jackson cross-cylinder, axes at 180 degrees and 90 degrees; J45 = oblique Jackson cross-cylinder, axes at 45 degrees and 135 degrees; SD = standard deviation; D: diopters; AR = autorefraction; WF-P = wavefront photopic; WF-M = wavefront mesopic; WF-4 = wavefront 4.0 mm; OPD-C = autorefraction measured with the 3-dimension wavefront topography aberrometer system in the central pupil/photopic conditions; OPD-M = autorefraction measured with the 3-dimension wavefront topography aberrometer system under mesopic conditions.

Table 4: Intraclass correlation coefficients (ICC) assessing the degree of agreement between each of the objective methods under study and the subjective refraction, for both groups.

		ICC					
		AR	**WF-P**	**WF-M**	**WF-4**	**OPD-C**	**OPD-M**
Sph	**POD F**	0.67	0.43	0.53	0.54	-0.16	0.61
	POD F-GF	0.85	0.75	0.89	0.86	-0.35	0.90
M	**POD F**	0.78	0.51	0.62	0.57	-0.03	0.72
	POD F-GF	0.82	0.76	0.89	0.83	-0.39	0.88
J0	**POD F**	0.50	0.02	0.05	0.02	0.32	-0.04
	POD F-GF	0.77	0.63	0.84	0.75	-0.01	0.86
J45	**POD F**	0.55	0.38	0.59	0.56	-0.58	0.59
	POD F-GF	0.67	0.54	0.77	0.69	-0.08	0.80

Sph =sphere; M = spherical equivalent; J0 = vertical Jackson cross-cylinder, axes at 180 degrees and 90 degrees; J45 = oblique Jackson cross-cylinder, axes at 45 degrees and 135 degrees; D: diopters; AR = autorefraction; WF-P = wavefront photopic; WF-M = wavefront mesopic; WF-4 = wavefront 4.0 mm; OPD-C = autorefraction measured with the 3-dimension wavefront topography aberrometer system in the central pupil/photopic conditions; OPD-M = autorefraction measured with the 3-dimension wavefront topography aberrometer system under mesopic conditions.

FIGURE LEGENDS

Figure 1. Objective – subjective (manifest) refraction difference of Sph (sphere), M (spherical equivalent), and J0 and J45 (vector components of astigmatism) versus the objective refraction method and the IOL material. There are six objective refraction scenarios under assessment (AR = autorefraction; WF-P = wavefront photopic; WF-M = wavefront mesopic; WF-4 = wavefront 4.0 mm pupil; OPD-C = autorefraction measured with the 3-dimension wavefront topography aberrometer system in the central pupil/photopic conditions; OPD-M = autorefraction measured with the 3-dimension wavefront topography aberrometer system under mesopic conditions) and two IOL materials according to the hydrophilic (F) and hydrophobic (F-GF) IOL groups. The asterisks (*) indicate statistically significant differences from zero.

Figure 2. Bland-Altman plots for the subjective sphere showing the objective – subjective refraction difference sphere value for each of the six objective-refraction approaches (AR: autorefractor; WF-P: wavefront photopic; WF-M: wavefront mesopic; WF-4: wavefront 4mm; OPD-C: OPD photopic; OPD-M: OPD mesopic) for the group implanted with the hydrophilic POD F IOL.

Figure 3. Bland-Altman plots for the subjective spherical equivalent (M) showing the objective – subjective refraction difference M value for each of the six objective-refraction approaches (AR: autorefractor; WF-P: wavefront photopic; WF-M: wavefront mesopic; WF-4: wavefront 4mm; OPD-C: OPD photopic; OPD-M: OPD mesopic) for the group implanted with the hydrophilic POD F IOL.

Figure 4. Bland-Altman plots for the subjective sphere showing the objective – subjective refraction difference sphere value for each of the six objective-refraction approaches (AR: autorefractor; WF-P: wavefront photopic; WF-M: wavefront mesopic; WF-4: wavefront 4mm; OPD-C: OPD photopic; OPD-M: OPD mesopic) for the group implanted with the hydrophobic POD F-GF IOL.

Figure 5. Bland-Altman plots for the subjective spherical equivalent (M) showing the objective – subjective refraction difference M value for each of the six objective-refraction approaches (AR: autorefractor; WF-P: wavefront photopic; WF-M: wavefront mesopic; WF-4: wavefront 4mm; OPD-C: OPD photopic; OPD-M: OPD mesopic) for the group implanted with the hydrophobic POD F-GF IOL.

Supplementary Figure 1. Bland-Altman plots for subjective J0 (one of the vector components of astigmatism) showing the objective – subjective refraction difference J0 value for each of the six objective-refraction approaches (AR: autorefractor; WF-P: wavefront photopic; WF-M: wavefront mesopic; WF-4: wavefront 4mm; OPD-C: OPD photopic; OPD-M: OPD mesopic) for the group implanted with the hydrophilic POD F IOL.

Supplementary Figure 2. Bland-Altman plots for subjective J45 (one of the vector components of astigmatism) showing the objective – subjective refraction difference J45 value for each of the six objective-refraction approaches (AR: autorefractor; WF-P: wavefront photopic; WF-M: wavefront mesopic; WF-4: wavefront 4mm; OPD-C: OPD photopic; OPD-M: OPD mesopic) for the group implanted with the hydrophilic POD F IOL.

Supplementary Figure 3. Bland-Altman plots for subjective J0 (one of the vector components of astigmatism) showing the objective – subjective refraction difference J0 value for each of the six objective-refraction approaches (AR: autorefractor; WF-P: wavefront photopic; WF-M: wavefront mesopic; WF-4: wavefront 4mm; OPD-C: OPD photopic; OPD-M: OPD mesopic) for the group implanted with the hydrophobic POD F-GF IOL.

Supplementary Figure 4. Bland-Altman plots for subjective J45 (one of the vector components of astigmatism) showing the objective – subjective refraction difference J45 value for each of the six objective-refraction approaches (AR: autorefractor; WF-P: wavefront photopic; WF-M: wavefront mesopic; WF-4: wavefront 4mm; OPD-C: OPD photopic; OPD-M: OPD mesopic) for the group implanted with the hydrophobic POD F-GF IOL.

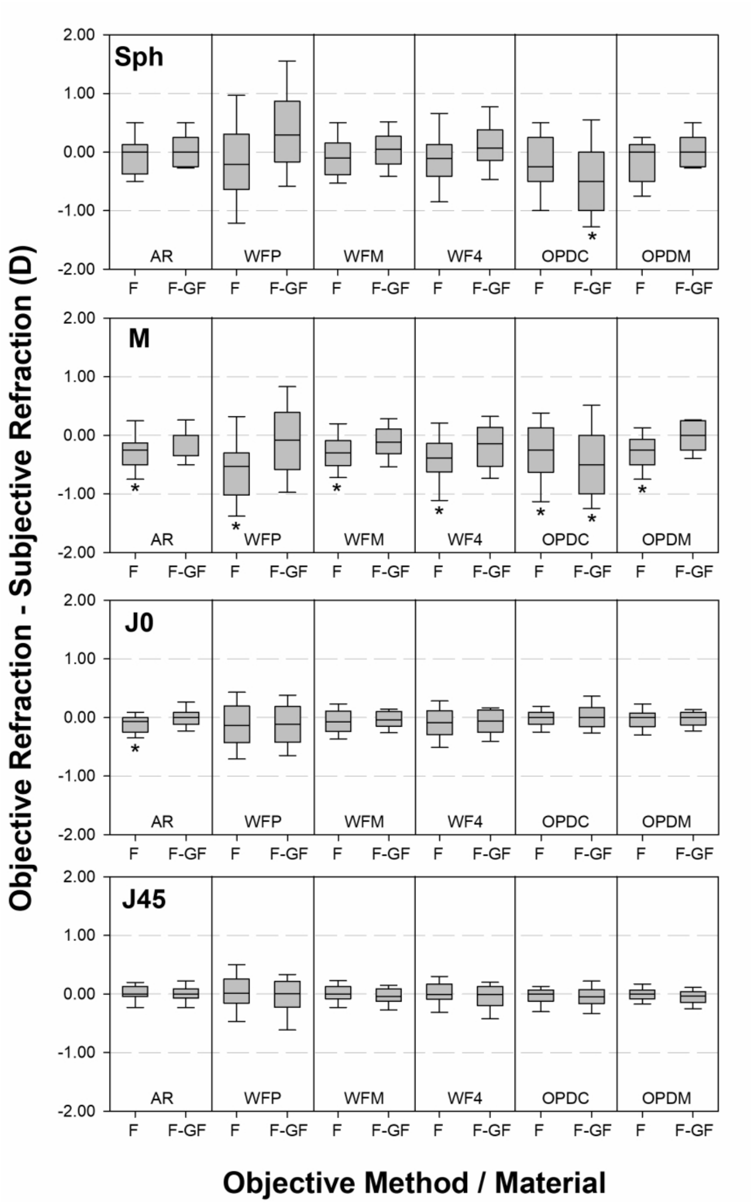

Figure 1. Objective – subjective (manifest) refraction difference of Sph (sphere), M (spherical equivalent), and J0 and J45 (vector components of astigmatism) versus the objective refraction method and the IOL material. There are six objective refraction scenarios under assessment (AR = autorefraction; WF-P = wavefront photopic; WF-M = wavefront mesopic; WF-4 = wavefront 4.0 mm pupil; OPD-C = autorefraction measured with the 3-dimension wavefront topography aberrometer system in the central pupil/photopic conditions; OPD-M = autorefraction measured with the 3-dimension wavefront topography aberrometer system under mesopic conditions) and two IOL materials according to the hydrophilic (F) and hydrophobic (F-GF) IOL groups. The asterisks (*) indicate statistically significant differences from zero.

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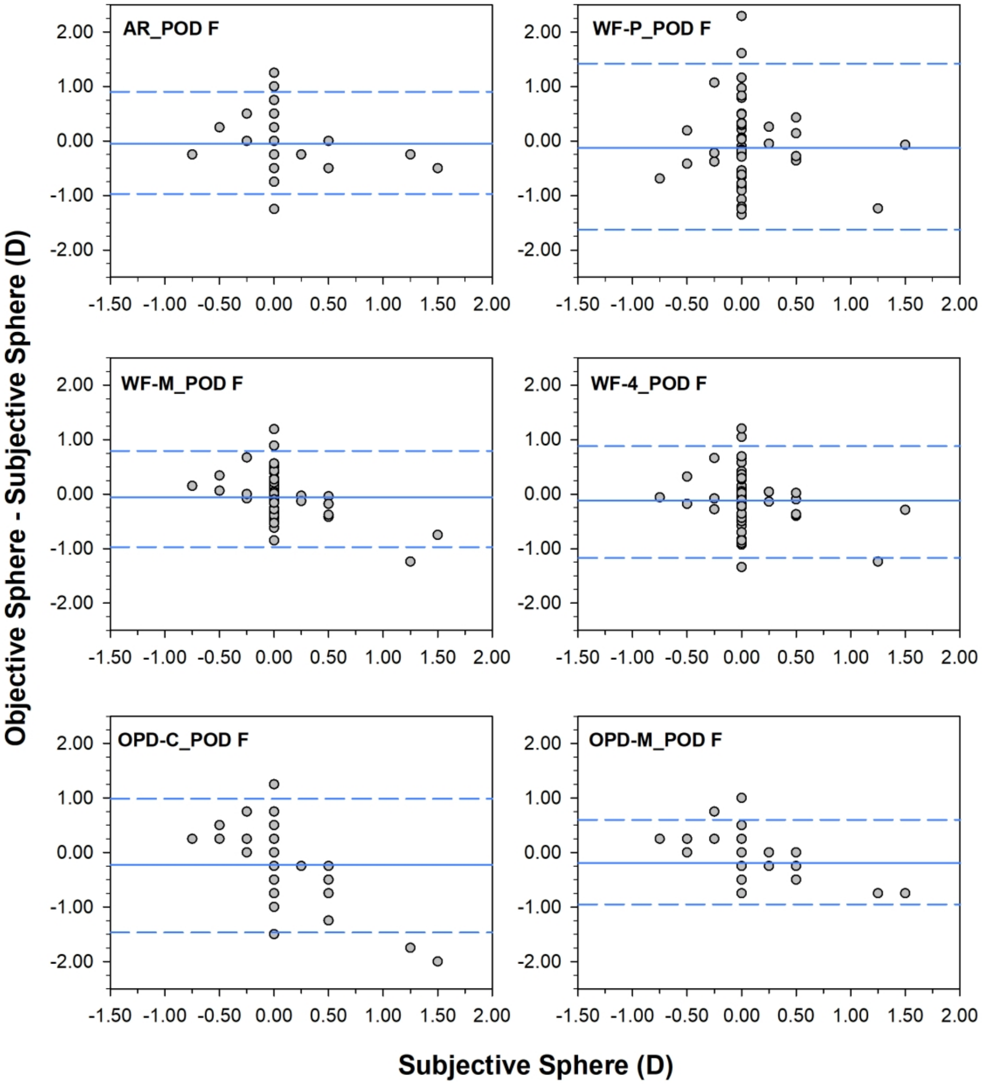

Figure 2. Bland-Altman plots for the subjective sphere showing the objective – subjective refraction difference sphere value for each of the six objective-refraction approaches (AR: autorefractor; WF-P: wavefront photopic; WF-M: wavefront mesopic; WF-4: wavefront 4mm; OPD-C: OPD photopic; OPD-M: OPD mesopic) for the group implanted with the hydrophilic POD F IOL.

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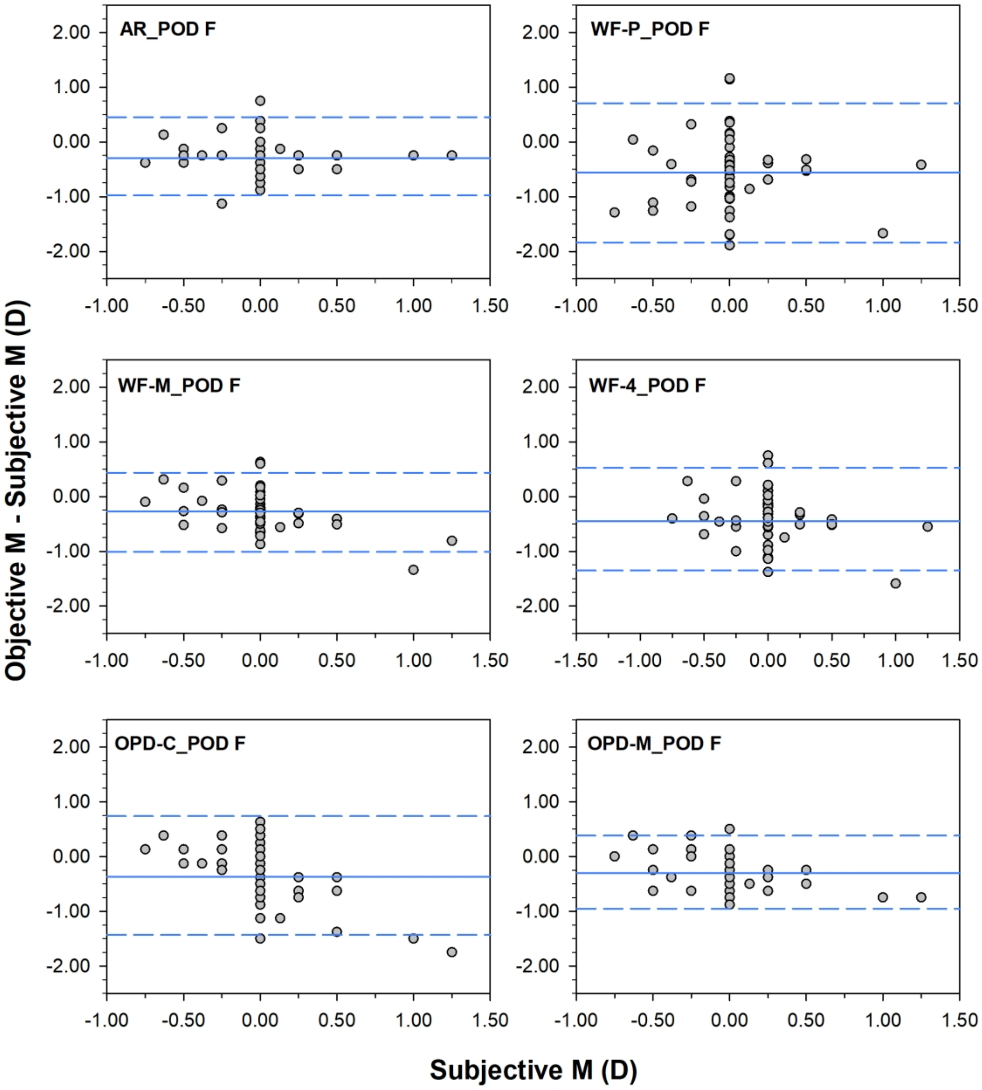

Figure 3. Bland-Altman plots for the subjective spherical equivalent (M) showing the objective – subjective refraction difference M value for each of the six objective-refraction approaches (AR: autorefractor; WF-P: wavefront photopic; WF-M: wavefront mesopic; WF-4: wavefront 4mm; OPD-C: OPD photopic; OPD-M: OPD mesopic) for the group implanted with the hydrophilic POD F IOL.

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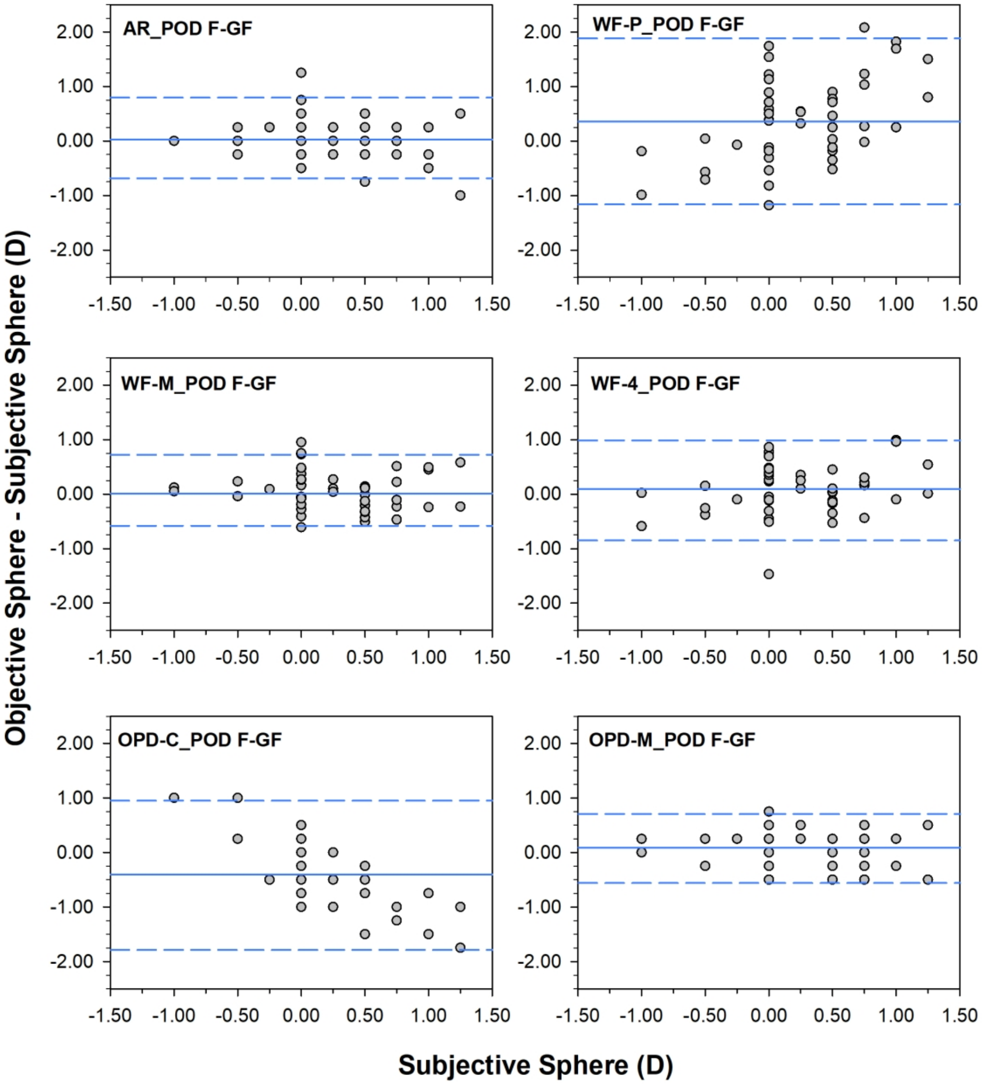

Figure 4. Bland-Altman plots for the subjective sphere showing the objective – subjective refraction difference sphere value for each of the six objective-refraction approaches (AR: autorefractor; WF-P: wavefront photopic; WF-M: wavefront mesopic; WF-4: wavefront 4mm; OPD-C: OPD photopic; OPD-M: OPD mesopic) for the group implanted with the hydrophobic POD F-GF IOL.

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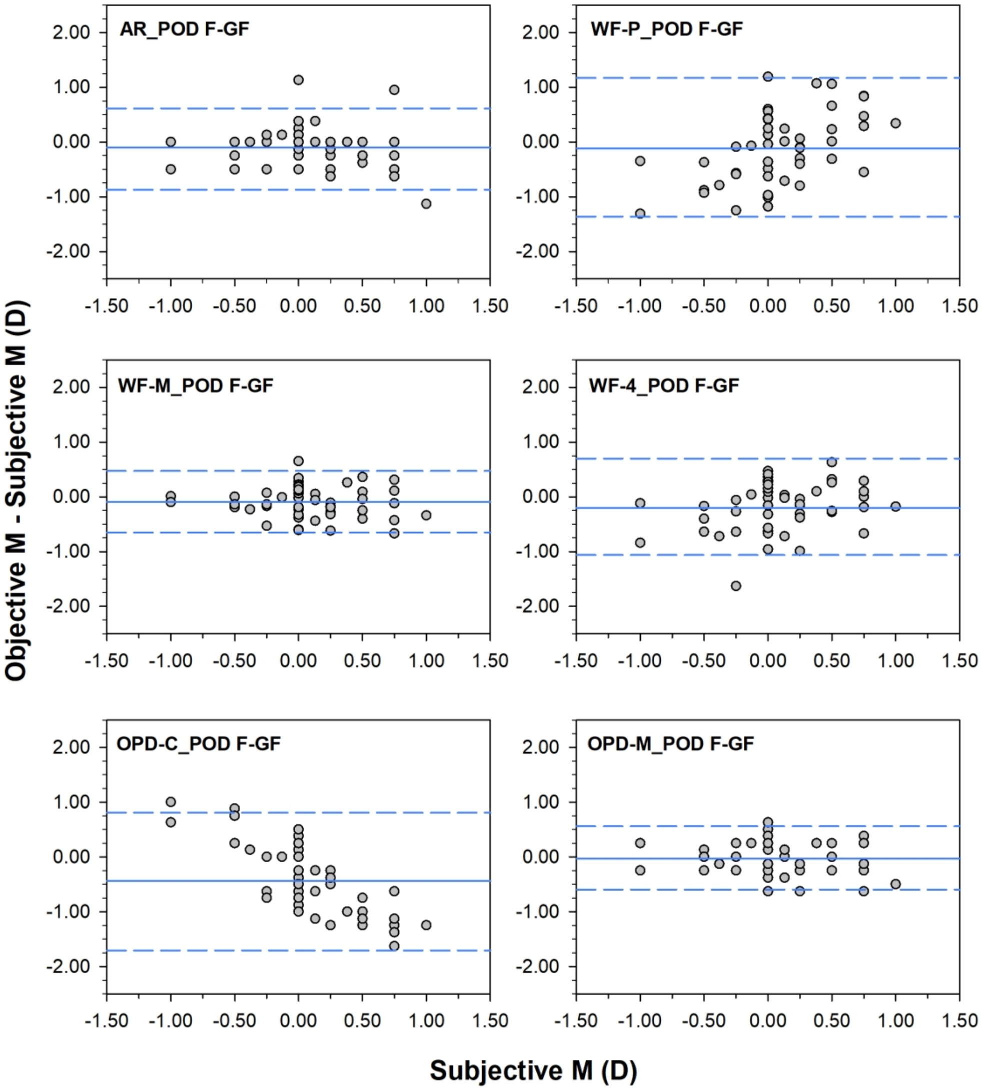


Figure 5. Bland-Altman plots for the subjective spherical equivalent (M) showing the objective – subjective refraction difference M value for each of the six objective-refraction approaches (AR: autorefractor; WF-P: wavefront photopic; WF-M: wavefront mesopic; WF-4: wavefront 4mm; OPD-C: OPD photopic; OPD-M: OPD mesopic) for the group implanted with the hydrophobic POD F-GF IOL.

182x210mm (300 x 300 DPI)

Table 1. Descriptive statistics obtained after surgery for subjective refraction and visual acuity in both groups.

	Group	**Subjective refraction (D)**					**Visual acuity (LogMAR)**	
		M	**J0**	**J45**	**Sph**	**Cyl**	**UDVA**	**CDVA**
Mean±SD	POD F	0.01±0.34	0.00±0.10	0.02±0.11	0.07±0.36	-0.12±0.27	0.05±0.10	0.01±0.04
	POD F-GF	0.09±0.42	-0.05±0.18	0.03±0.12	0.23±0.50	-0.28±0.34	0.08±0.09	0.01±0.03
Min	POD F	-0.75	-0.29	-0.25	-0.75	-1.00	-0.10	-0.10
	POD F-GF	-1.00	-0.49	-0.22	-1.00	-1.00	-0.04	-0.04
Max	POD F	1.25	0.47	0.43	1.50	0.00	0.40	0.14
	POD F-GF	1.00	0.38	0.35	1.25	0.00	0.40	0.18

LogMAR = logarithm of the minimum angle of resolution; POD F = Hydrophilic group; POD F-GF = Hydrophobic group; M = spherical equivalent; J0 = vertical Jackson cross-cylinder, axes at 180 degrees and 90 degrees; J45 = oblique Jackson cross-cylinder, axes at 45 degrees and 135 degrees; Sph = sphere; Cyl = cylinder; D=diopters; UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity; SD = standard deviation.

Table 2: Descriptive statistics for the objective refractions obtained with all the evaluated methods, for both groups (POD F = Hydrophilic group; POD F-GF = Hydrophobic group).

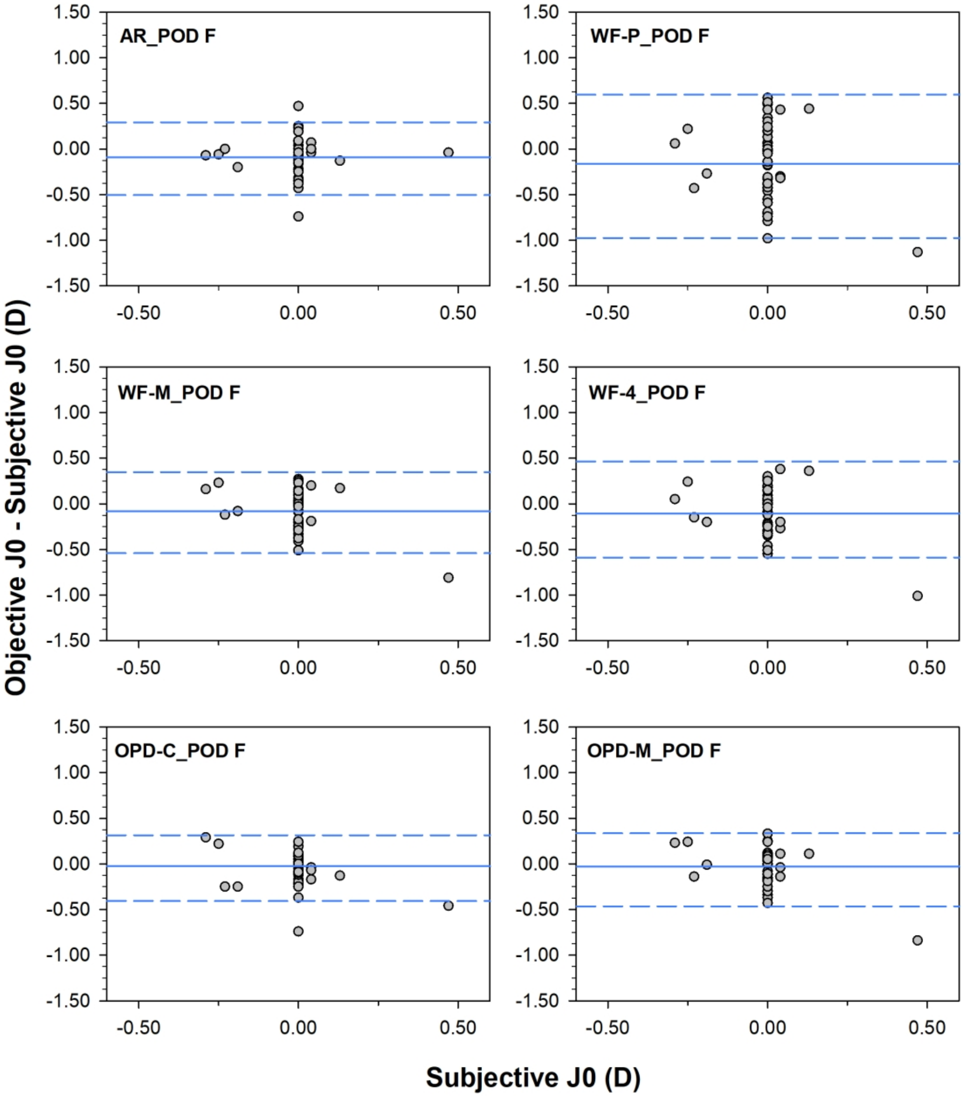
Parameter		**Group**	**Objective method**					
			AR	**WF-P**	**WF-M**	**WF-4**	**OPD-C**	**OPD-M**
Sph (D)	**Mean±SD**	POD F	-0.02±0.53	-0.05±0.83	-0.02±0.42	-0.06±0.56	-0.17±0.47	-0.08±0.40
		POD F-GF	0.27±0.57	0.59±1.11	0.30±0.59	0.32±0.76	-0.17±0.42	0.32±0.54
Cyl(D)	**Mean±SD**	POD F	-0.54±0.36	-1.04±0.50	-0.54±0.27	-0.68±0.36	-0.35±0.33	-0.39±0.31
		POD F-GF	-0.54±0.33	-1.19±0.71	-0.61±0.38	-0.83±0.51	-0.36±0.28	-0.50±0.39
M(D)	**Mean±SD**	POD F	-0.28±0.48	-0.57±0.74	-0.29±0.37	-0.40±0.52	-0.34±0.41	-0.27±0.36
		POD F-GF	0.00±0.54	-0.01±0.93	-0.01±0.49	-0.09±0.70	-0.35±0.42	0.07±0.47
J0(D)	**Mean±SD**	POD F	-0.11±0.23	-0.16±0.40	-0.08±0.21	-0.10±0.27	-0.04±0.18	-0.06±0.17
		POD F-GF	-0.05±0.26	-0.17±0.55	-0.10±0.28	-0.14±0.38	-0.04±0.16	-0.07±0.24
J45(D)	**Mean±SD**	POD F	0.04±0.20	0.05±0.39	0.03±0.21	0.03±0.26	-0.03±0.15	0.00±17
		POD F-GF	0.04±0.17	-0.01±0.40	0.00±0.20	-0.01±0.28	-0.02±0.16	-0.02±0.20

Sph=sphere; Cyl = cylinder; M= spherical equivalent; J0 = vertical Jackson cross-cylinder, axes at 180 degrees and 90 degrees; J45 = oblique Jackson cross-cylinder, axes at 45 degrees and 135 degrees; SD = standard deviation; D: diopters; AR = autorefraction; WF-P = wavefront photopic; WF-M = wavefront mesopic; WF-4 = wavefront 4.0 mm; OPD-C = autorefraction measured with the 3-dimension wavefront topography aberrometer system in the central pupil/photopic conditions; OPD-M = autorefraction measured with the 3-dimension wavefront topography aberrometer system under mesopic conditions.

Table 3: Mean differences for both groups of patients (POD F and POD F-GF) between ObjRx and Rx for the 6 ObjRx methods under study.

		Objective – subjective refraction difference					
		AR	WFP	WFM	WF4	OPDC	OPDM
		Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD
Sph(D)	POD F	-0.08±0.45	-0.12±0.77	-0.09±0.45	-0.12±0.52	**-0.23±0.62**	-0.14±0.41
	POD F-GF	0.04±0.38	0.35±0.77	0.06±0.35	0.09±0.46	**-0.40±0.70**	0.09±0.32
M(D)	POD F	**-0.30±0.36**	**-0.58±0.66**	**-0.30±0.37**	**-0.40±0.48**	**-0.35±0.54**	-0.28±0.33
	POD F-GF	-0.09±0.38	-0.10±0.64	-0.10±0.29	-0.19±0.45	**-0.44±0.64**	-0.02±0.29
J0(D)	POD F	**-0.10±0.20**	-0.15±0.41	-0.08±0.22	-0.10±0.28	-0.04±0.18	-0.05±0.20
	POD F-GF	0.00±0.20	-0.11±0.42	-0.04±0.17	-0.08±0.26	0.01±0.24	-0.02±0.14
J45(D)	POD F	0.01±0.18	0.03±0.36	0.00±0.18	0.01±0.22	-0.05±0.21	-0.02±0.15
	POD F-GF	0.00±0.15	-0.04±0.33	-0.04±0.15	-0.05±0.21	-0.05±0.21	-0.05±0.14

Sph=sphere; M= spherical equivalent; J0 = vertical Jackson cross-cylinder, axes at 180 degrees and 90 degrees; J45 = oblique Jackson cross-cylinder, axes at 45 degrees and 135 degrees; SD = standard deviation; D: diopters; AR = autorefraction; WF-P = wavefront photopic; WF-M = wavefront mesopic; WF-4 = wavefront 4.0 mm; OPD-C = autorefraction measured with the 3-dimension wavefront topography aberrometer system in the central pupil/photopic conditions; OPD-M = autorefraction measured with the 3-dimension wavefront topography aberrometer system under mesopic conditions.



Supplementary Figure 1. Bland-Altman plots for subjective J0 (one of the vector components of astigmatism) showing the objective – subjective refraction difference J0 value for each of the six objective-refraction approaches (AR: autorefractor; WF-P: wavefront photopic; WF-M: wavefront mesopic; WF-4: wavefront 4mm; OPD-C: OPD photopic; OPD-M: OPD mesopic) for the group implanted with the hydrophilic POD F IOL.

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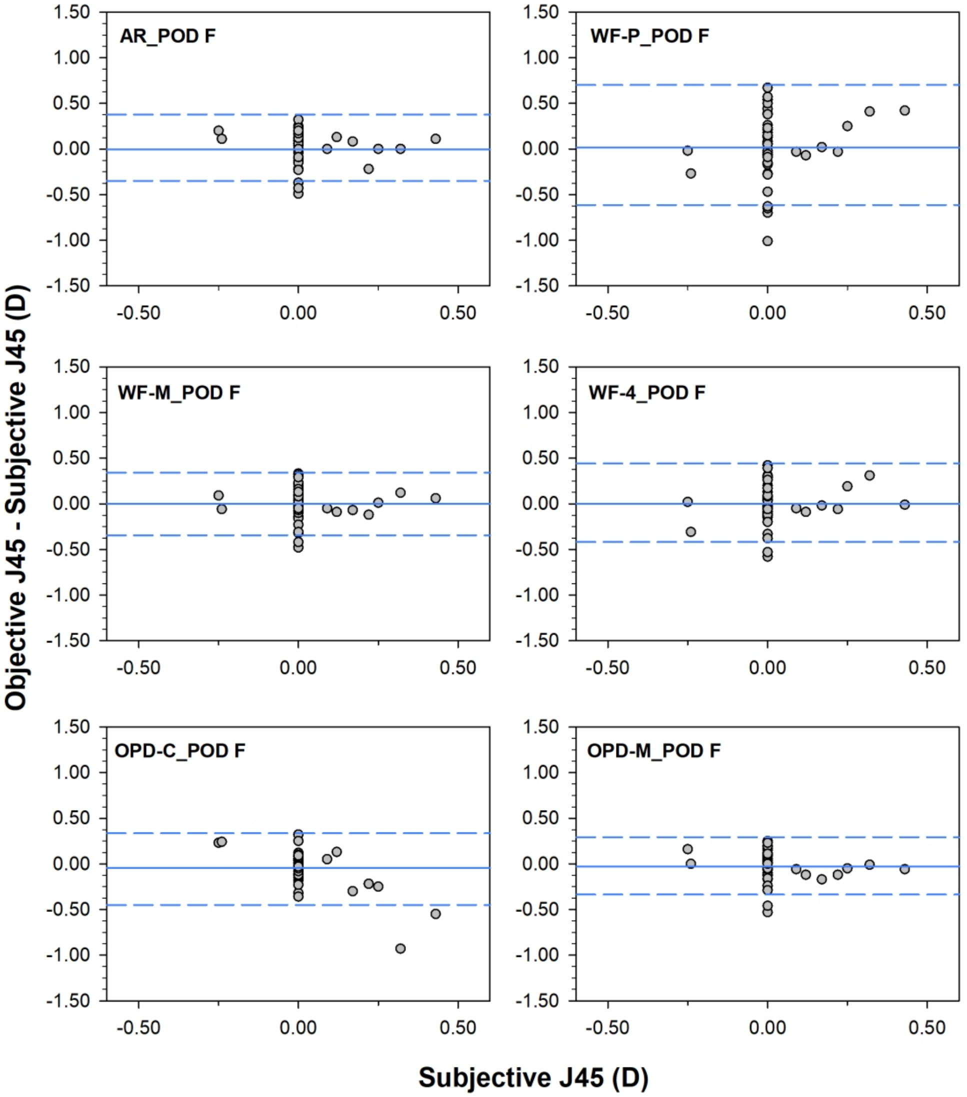

Supplementary Figure 2. Bland-Altman plots for subjective J45 (one of the vector components of astigmatism) showing the objective – subjective refraction difference J45 value for each of the six objective-refraction approaches (AR: autorefractor; WF-P: wavefront photopic; WF-M: wavefront mesopic; WF-4: wavefront 4mm; OPD-C: OPD photopic; OPD-M: OPD mesopic) for the group implanted with the hydrophilic POD F IOL.

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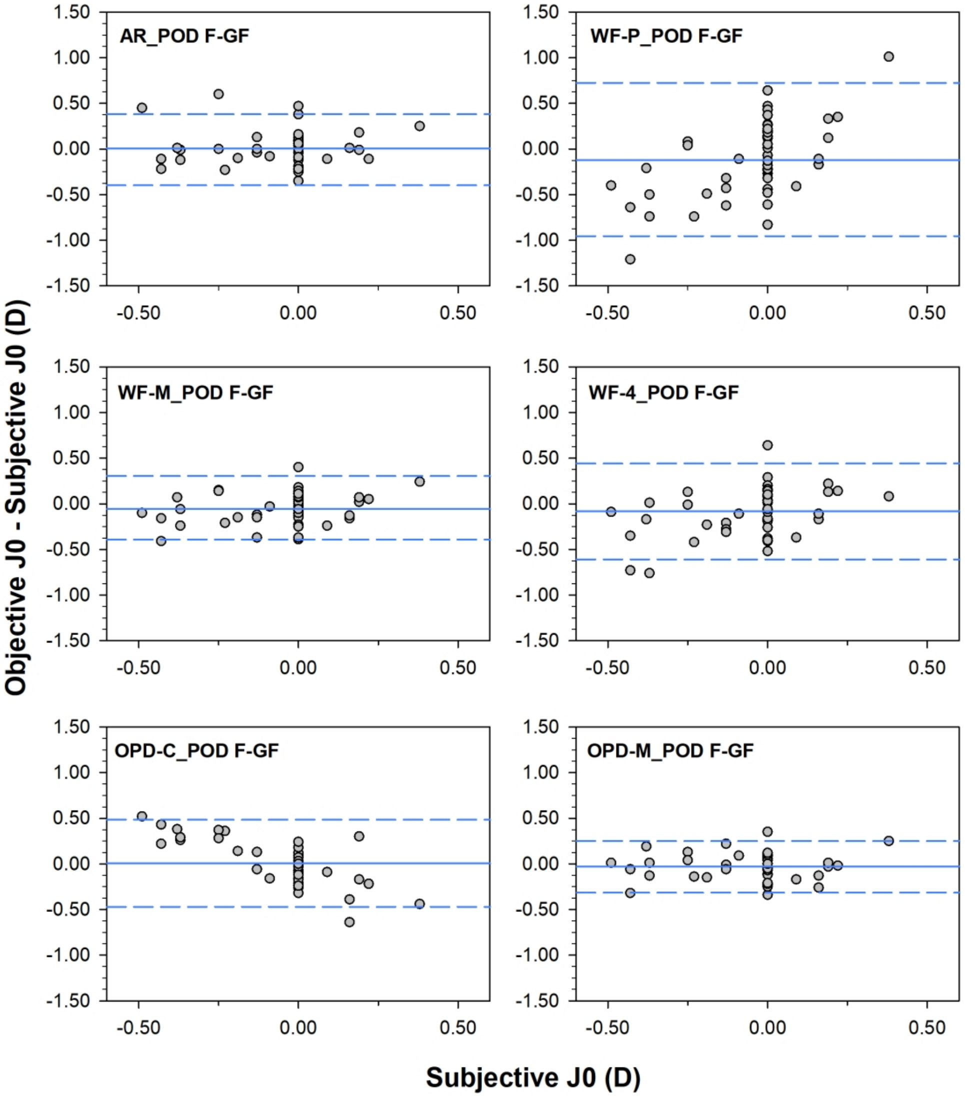

Supplementary Figure 3. Bland-Altman plots for subjective J0 (one of the vector components of astigmatism) showing the objective – subjective refraction difference J0 value for each of the six objective-refraction approaches (AR: autorefractor; WF-P: wavefront photopic; WF-M: wavefront mesopic; WF-4: wavefront 4mm; OPD-C: OPD photopic; OPD-M: OPD mesopic) for the group implanted with the hydrophobic POD F-GF IOL.

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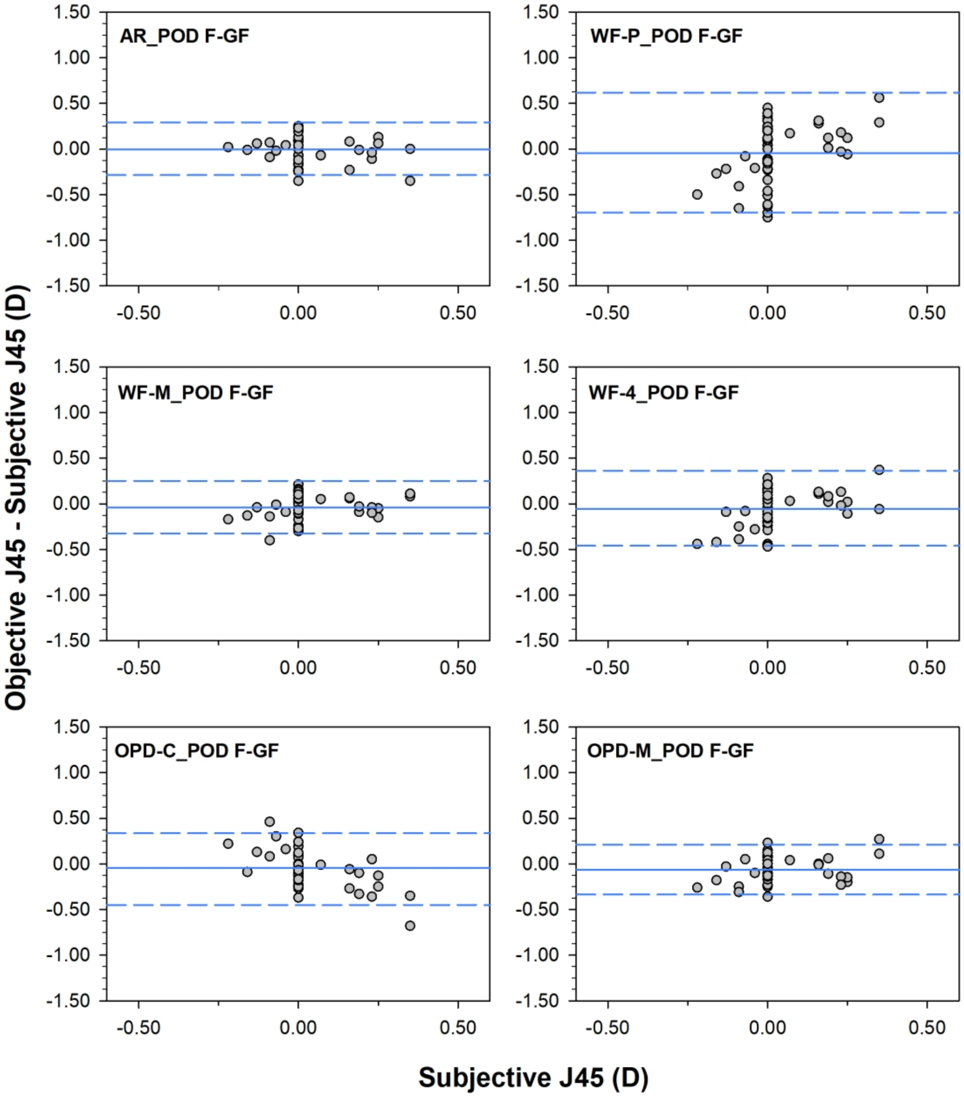

Supplementary Figure 4. Bland-Altman plots for subjective J45 (one of the vector components of astigmatism) showing the objective – subjective refraction difference J45 value for each of the six objective-refraction approaches (AR: autorefractor; WF-P: wavefront photopic; WF-M: wavefront mesopic; WF-4: wavefront 4mm; OPD-C: OPD photopic; OPD-M: OPD mesopic) for the group implanted with the hydrophobic POD F-GF IOL.

182x210mm (300 x 300 DPI)