ARTICLE

Comparison of intraocular lens decentration and tilt measurements using 2 Purkinje meter systems

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Purpose: To evaluate the difference in intraocular lens tilt and decentration measurements with 2 Purkinje meters.

Setting: Vienna Institute for Research in Ocular Surgery, Hanusch Hospital, Vienna, Austria.

Design: Prospective evaluation of diagnostic test.

Methods: This single-center study included pseudophakic patients in 2 substudies in which 3 consecutive measurements were performed with 2 Purkinje meters (Spanish and German). In substudy 1, an inexperienced examiner performed all measurements after a short learning period. In substudy 2, all measurements were taken by experienced examiners under direct supervision of the inventors of the devices.

Results: Substudy 1 included 53 pseudophakic eyes in which all 53 scans were successful with the Spanish device; however, only 35 measurements (66%) were successful with the German Purkinje meter. The mean tilt measured with the Spanish Purkinje meter was 4.35 degrees ± 2.50 (SD) and 9.20 ± 6.96 degrees with the German Purkinje meter. The mean decentration was 0.44 ± 0.19 mm and 0.74 ± 0.91 mm, ($P = .44$), respectively. In substudy 2 (29 pseudophakic eyes), the number of successful scans was 29 (100%) and 18 (62%) for the Spanish meter and German Purkinje meter, respectively. The mean horizontal and vertical tilt difference vector between the 2 systems was 4.89 ± 3.24 degrees and 7.57 ± 3.82 degrees, respectively.

Conclusions: Concerning clinical feasibility, the Spanish Purkinje meter had a greater percentage of successful scans than the German device. In addition, this device measured significantly higher tilt values than the Spanish Purkinje meter.

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The increasing number of implantations of aspheric, toric, and multifocal intraocular lenses (IOLs) during cataract surgery has improved postoperative visual quality of cataract patients.[1,2] However, exact alignment of these premium IOLs is mandatory because decentration, tilt, or rotation (in the case of toric IOLs) could result in reduced visual quality. Holladay et al.[3] showed in an eye model that decentration more than 0.4 mm or tilt more than 7 degrees result in a loss of the beneficial effect of an aspheric IOL compared with a spherical IOL. Piers et al.[4] found these critical values to be more tolerable with 0.8 mm of decentration and 10 degrees of tilt.

Several techniques have been used to measure IOL decentration and tilt, such as slitlamp examination, retroillumination photography,[5] rotating Scheimpflug imaging,[6–8] optical coherence tomography,[9–11] and the analysis of Purkinje reflexes.[12–17] Slitlamp examination is a subjective method that allows approximate decentration measurements but no quantitative tilt measurements. For this measurement, the pupil has to be dilated.

For Scheimpflug imaging, the pupil must be sufficiently dilated to make the optic edge and the posterior surface of the IOL visible.

The concept of Purkinje reflexes analysis dates back to the 19th century, when candles were used to generate

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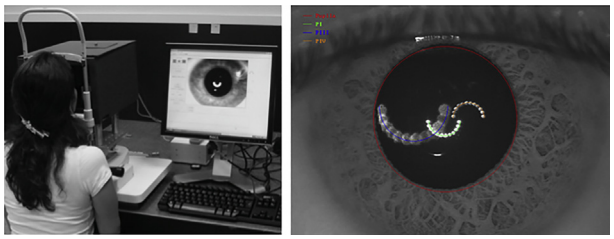

Figure 1. *Left*: Setup of the Spanish Purkinje meter. *Right*: Pupillary margin (*red*) and Purkinje reflexes I, III, and IV after manual marking with the meter's software (P = Purkinje reflex).

reflections of ocular optic surfaces.[18] In the 1990s, light-emitting diodes (LEDs) were used to analyze the alignment of Purkinje reflexes III and IV.[19,20] The analysis of Purkinje reflexes has been shown to be more accurate than using Scheimpflug images.[21] A Purkinje meter developed by Tabernero et al.[22] (called the Spanish Purkinje meter in this study) at the University of Murcia, Spain, was shown to be highly reproducible in assessing IOL tilt and decentration[14] and detecting differences in capsular bag performance of different IOL designs.[23] Another Purkinje meter device developed by Schaeffel[24] (called the German Purkinje meter in this study) has a setup similar to the construction of Tabernero et al.[22] As a potential advancement over the Spanish meter, this device is portable and includes a gaze tracker. It has been shown to measure crystalline lens tilt and decentration in healthy eyes even without pupil dilation.[25] Recently, it has been shown to have high reliability and reproducibility in pseudophakic eyes.[26,27]

The aim of this study was to evaluate the difference in IOL tilt and decentration measurements with 2 clinical Purkinje meter systems.

PATIENTS AND METHODS

This prospective single-center study included pseudophakic patients who had uneventful standard small-incision cataract surgery 3 to 12 months before recruitment and had otherwise healthy eyes. Exclusion criteria were complications during cataract surgery, severe opacities of the cornea or the IOL, posterior capsule opacification, or any pathologies preventing the patient from accurate fixation, such as significant macula pathologies or amblyopia. All the research and measurements followed the tenets of the Declaration of Helsinki.

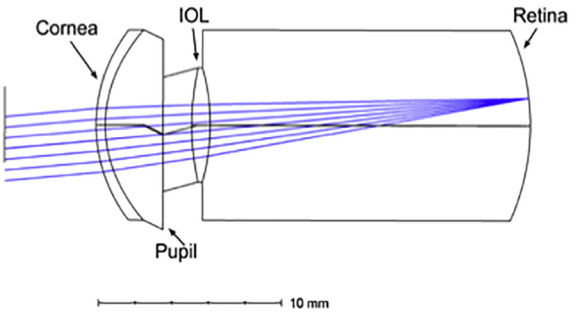

Figure 3. Pseudophakic eye modelled according to the Liou and Brennan eye model[28] (IOL = intraocular lens).

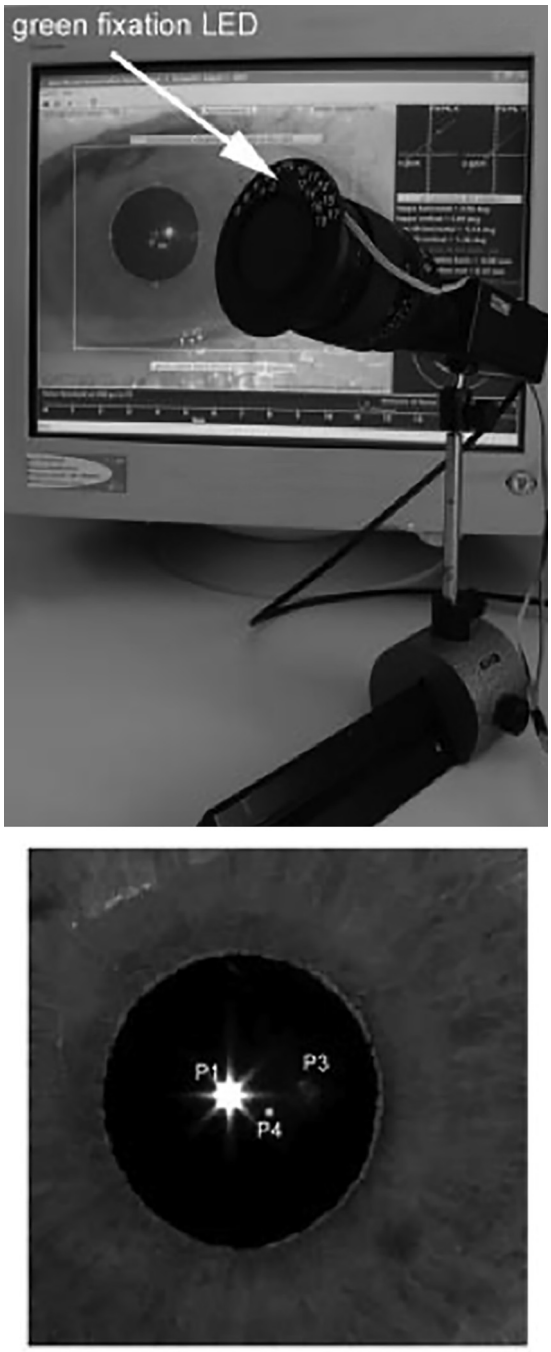

Figure 2. *Top*: Setup of German Purkinje meter. *Bottom*: Appearance of the 3 Purkinje images in the pupil (LED = light-emitting diode; P = Purkinje reflex).

This study consisted of 2 subgroups, for which only 1 visit was necessary. During this visit, pupils were dilated before examinations with tropicamide 1.0% (Mydriaticum) and phenylephrine 10.0% (Neosynephrin–POS 10.0%). In both substudies, 3 consecutive measurements were performed with the 2 Purkinje meters (1 from Spain [Figure 1] and 1 from Germany [Figure 2]). The device to be used for measurements first was chosen randomly in both substudies. Randomization was performed using an online random generator.[A]

In substudy 1, an inexperienced examiner performed all measurements after a short learning period of 20 measurements with both Purkinje meters. Measurements were performed on a continuous cohort.

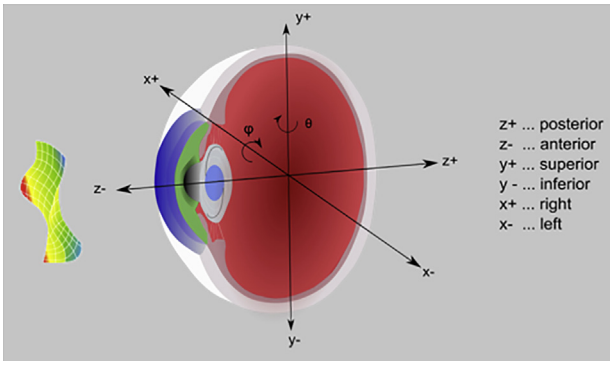

Figure 4. Cross-section and coordinate system of a pseudophakic human eye and the total wavefront map obtained by an aberrometer.

In substudy 2, pseudophakic patients were invited to participate in the study in which tilt and decentration measurements would be taken with both devices. All measurements were taken by experienced examiners under the supervision of the inventors of the devices (J.T. and F.S.). Between the consecutive 3 measurements, the patient was asked to sit back, after which the chinrest and the position of the Purkinje meter were changed slightly to allow system realignment. All measurements of substudy 2 were performed on the same day.

Spanish Purkinje Meter

The technical details of the Spanish Purkinje meter system have been described.[22,23] In short, a semicircular array of LEDs was projected on the patient's eye as the patient fixated on a light. The 3 reflexes (Purkinje I, III, and IV), reflected by the optical surface of the eye, were captured with the digital camera of the device. Then, the semicircles were marked manually by the operator. Afterward, the IOL tilt in relation to the pupillary axis ($tilt_{pup}$) and to the line of sight ($tilt_{LOS}$) as well as decentration were calculated automatically by the dedicated software according to misalignment of the Purkinje images. Figure 1 shows an image of the Purkinje reflections and the manual marking method.

German Purkinje Meter

The setting of this device has been described.[24] The patient's head was placed on a chinrest, and the device was positioned in front of him or her. Because this system is movable, focus is coded as sound with variable frequency to allow positioning the camera in the optimum focus to obtain a sharp image of the eye. The patient was asked to fixate on an LED target, and images of the Purkinje reflexes were captured. Subsequently, the observer manually marked the pupil margin and the reflexes. To stimulate changes in gaze position in consecutive measurements, the patient was asked to fixate on numbers printed on a plastic ring that was attached to the camera lens. Three images were captured. Then, the program performed regression analysis for the distance of Purkinje III and Purkinje IV in the x-direction and the y-direction versus the angular direction of the fixation axis in the x-direction and y-direction. The regression lines were then displayed automatically. In cases in which the significance of regression was too low (regression coefficient $R < 0.95$), an error message was displayed and image capture was repeated.

Statistical Analysis

For statistical analysis, Excel for Mac software (2011, Microsoft Corp.) and SPSS for Mac software (version 23.0, International Business Machines Corp.) were used. Tilt and decentration values are listed as vectors, if not stated otherwise. Descriptive data are shown as 95% confidence interval, means ± SD, and range. After the distribution of data was shown to be not normally distributed, a nonparametric test (Wilcoxon signed-rank test) was used for significance testing, if not stated otherwise.

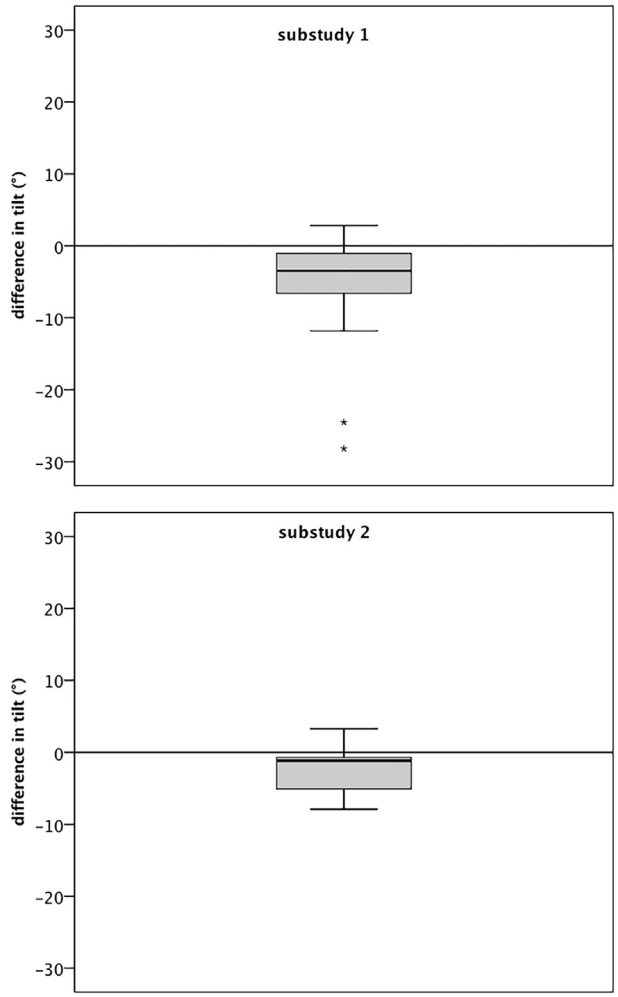

Figure 5. Differences between tilt measurements with both systems in substudy 1 and substudy 2. Positive values indicate that tilt measured with the Spanish meter is higher than with the German meter. Asterisks represent extreme outliers.

Computational Model

To show the effect of tilt and decentration of an aspheric IOL on optical lower-order aberrations (LOAs) and higher-order aberrations (HOAs), a ray-tracing simulation (Optic Studio 5, Zemax LLC) was calculated within an eye model. The tilt and decentration sensitivity of the MC6125AS aspheric IOL (Humanoptics AG) was tested using specifications of the Liou and Brennan schematic eye.[28] Within the model, a pupil decentration of 0.5 mm and a tilted visual axis of 5 degrees were simulated. Figure 3 shows the modeled pseudophakic eye. The natural lens was replaced with an aspheric IOL to simulate the influence of the IOL's position on the Zernike coefficients up to the 4th order.

During modeling, the IOL was positioned so that the anterior principal plane of the artificial implant coincided with the anterior principal plane of the natural lens. The study used a 3.0 mm pupil diameter. The wavelength used for simulation was 546 nm.

Figure 4 shows the displacements that were evaluated. The IOL tilt around the y-axis and around the x-axis was tested. Decentration of the IOL was determined along the $+x$-axis (nasally) and the $+y$-axis (superiorly).

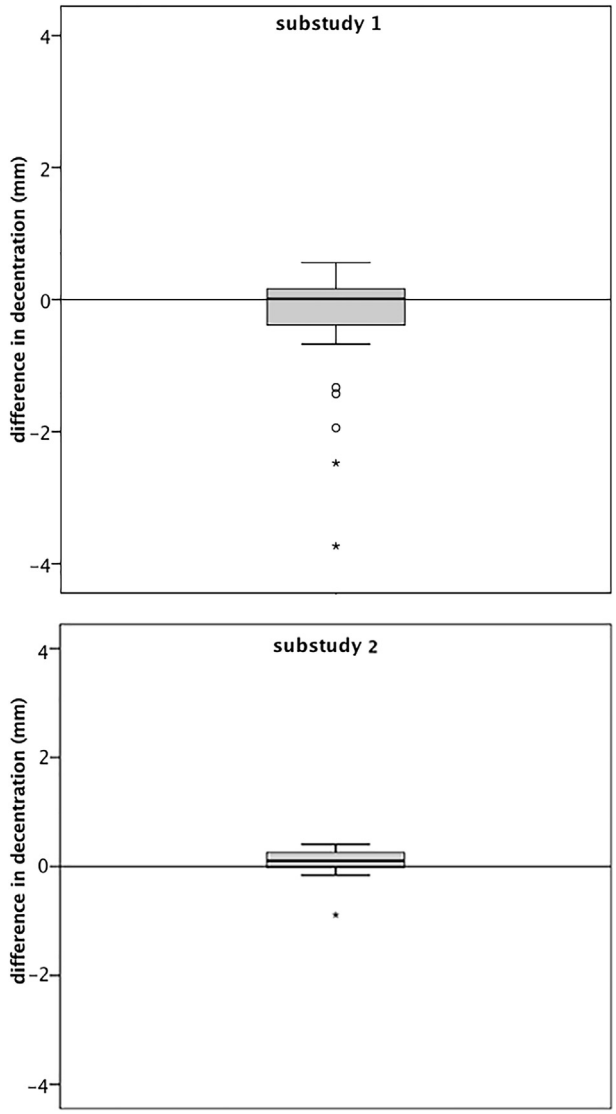

Figure 6. Differences between decentration measurements with both systems for substudy 1 and substudy 2. Positive values indicate that the decentration measured with the Spanish meter was higher than with the German meter. Circles represent outliers, and asterisks represent extreme outliers.

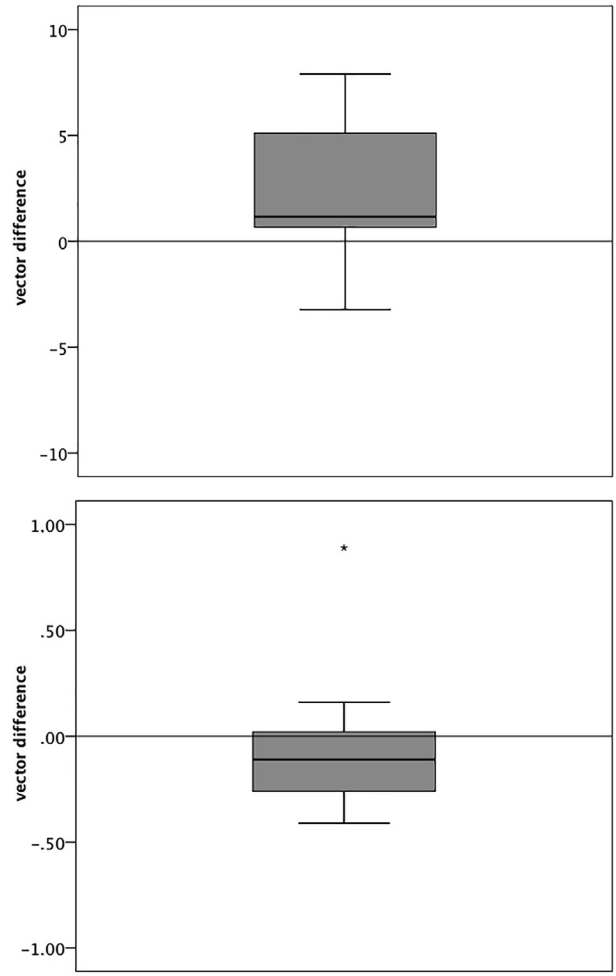

Figure 7. Vectors between tilt measurements (*top*) and decentration measurements (*bottom*) for both devices in substudy 2. Asterisk represents extreme outlier.

RESULTS

Substudy 1 comprised 53 pseudophakic eyes of 53 patients. All measured eyes had a 1-piece acrylic IOL with open-loop haptics implanted (Tecnis ZCB00, Abbott Medical Optics, Inc.; Superflex 620H, Rayner Intraocular Lenses Ltd.; or Idea Xcelens, Croma Pharma). After excluding the unsuccessful scans, the measurements of 35 eyes were included for further analysis.

The mean $tilt_{LOS}$ measure was 4.35 ± 2.50 degrees (range 1.15 to 11.36 degrees) with the Spanish meter and 9.20 ± 6.96 degrees (range 2.23 to 37.80 degrees) with the German meter. Both $tilt_{pup}$ and $tilt_{LOS}$ vectors were lower with the Spanish meter than with the German meter ($P < .01$). Figure 5 shows the differences between tilt vectors of the devices. Decentration values were similar for both devices with mean 0.44 ± 0.19 mm (range 0.08 to 0.85 mm) and 0.74 ± 0.91 mm (range 0.07 to 4.31 mm), respectively ($P = .44$) (Figure 6).

In substudy 2, 32 patients were invited to have measurements; however, 3 did not answer the letter of invitation, thus 29 patients attended on the day of measurements. Concerning clinical feasibility, the measurements in all 29 eyes of 29 patients (100%) were successful with the Spanish meter, whereas only 18 measurements (62%) with the German meter could be used for analysis.

The mean horizontal and vertical tilt difference vector between the 2 systems was 4.89 ± 3.24 degrees (Spanish meter) and 7.57 ± 3.82 degrees (German meter). The mean difference vectors for horizontal and vertical decentration measurements were 0.30 ± 0.28 mm and 0.35 ± 0.15 mm, respectively (Figures 7 and 8).

Concerning the direction of horizontal and vertical IOL tilt, the measurements with the 2 systems were in agreement

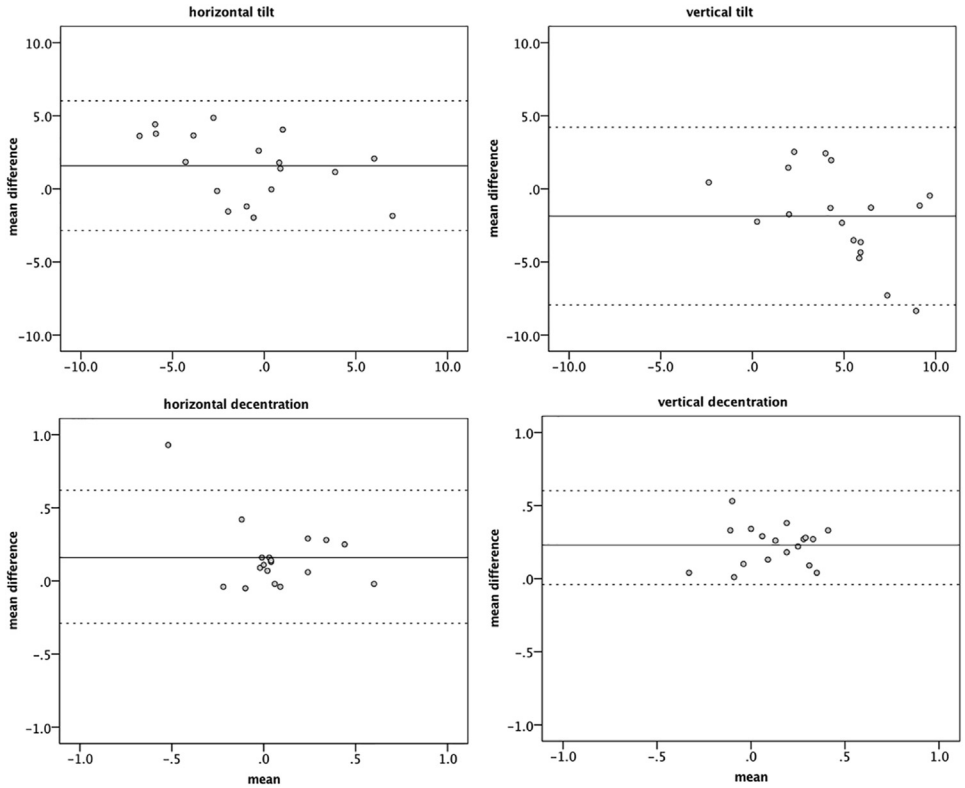

Figure 8. Bland-Altman plots for horizontal tilt, vertical tilt, horizontal decentration, and vertical decentration in substudy 2.

in 14 cases (78%) and 17 cases (94%), respectively. For horizontal and vertical IOL decentration, direction of the measurements was congruent in 10 cases (56%) and 13 cases (72%), respectively.

Computational Model

Table 1 shows the results of the simulation using the model eye. Figure 9 shows the simulated LOAs and HOAs.

DISCUSSION

The aim of this study was to assess the feasibility and short-term reproducibility of 2 Purkinje meters. Concerning feasibility, the Spanish meter performed significantly better than the German meter. For the German meter, only 66% of measurements were successful in substudy 1. To ascertain that the number of unsuccessful measurements was not caused by improper use of the Purkinje meter systems,

Table 1. The results of ocular wavefront simulation using the model eye by Liou and Brennan.[28]

					Simulated Aberrations (μm)			
Image*	*y*-Tilt (°)	*x*-Tilt (°)	*x*-Shift (mm)	*y*-Shift (mm)	Z(1,1)	Z(−1,1)	Z(0,2)	Z(2,2)
a	−1.15	—	—	—	−0.208	0.000	−0.005	0.112
b	−2.23	—	—	—	−0.254	0.000	0.047	0.153
c	−4.35	—	—	—	−0.348	0.000	0.167	0.250
d	−9.2	—	—	—	−0.581	0.000	0.543	0.561
e	−11.36	—	—	—	−0.696	0.000	0.762	0.746
f	−37.8	—	—	—	−3.827	0.000	8.554	8.325
g	−4.89	—	—	—	−0.373	0.000	0.202	0.279
h	—	7.57	—	—	−0.161	−0.321	0.089	−0.045
i	−4.89	7.57	—	—	−0.381	−0.331	0.351	0.160
j	—	—	0.07	—	−0.150	0.000	−0.053	0.079
k	—	—	0.08	—	−0.148	0.000	−0.053	0.079
l	—	—	0.44	—	−0.118	0.000	−0.067	0.099
m	—	—	0.74	—	−0.120	0.000	−0.091	0.110
n	—	—	0.85	—	−0.127	0.000	−0.100	0.115
o	—	—	4.31	—	—	—	—	—
p	—	—	0.30	—	−0.126	0.000	−0.059	0.093
q	—	—	—	0.35	−0.162	0.056	−0.069	0.084
r	—	—	0.30	0.35	−0.131	0.049	−0.073	0.104

Z = Zernike
*Letters correspond to letters of images in Figure 9

the inventers of both systems attended all measurements in substudy 2. The inventors of both systems were asked to observe the examiners and guide them, if necessary. In a few cases, they also repeated the measurements themselves if the examiners did not obtain a successful measurement. However, despite this change in measurement setup in substudy 2, 38% of eyes were still not measurable with the German meter, whereas all eyes could be measured in both substudies with the Spanish meter.

Using Purkinje reflexes for the analysis of IOL alignment has advantages. It is a noncontact technique, not dependent on pupil dilation, clinically feasible, and achieves fast results.

Nishi et al.[14] showed that the Spanish meter is a reliable instrument to measure IOL tilt and decentration even in extreme cases. Intraexaminer and interexaminer reproducibility of IOL decentration and tilt measurements was high with the Spanish meter. Even in cases with insufficient pupil dilation or clinically manifest IOL decentration and tilt, the reproducibility of measurements was good.

As mentioned earlier, the German meter has been shown to measure tilt of the crystalline lens in healthy eyes[24,25] and pseudophakic eyes,[26,27] and measurements were shown to be reproducible over time. In a clinical study by Mester et al.,[27] IOL tilt and decentration measured with the German meter were lower than the same values measured with the German meter in our study and similar to the values measured with the Spanish meter; however, Mester et al. did not mention problems with the clinical feasibility of the German meter.

We compared the systems and found differences concerning using them in a clinical setting. The Spanish meter has a fixed chinrest and an LED fixation target to allow for repeatable measurements. The system is aligned in all 3 planes with a joystick, equivalent to most models used for many ophthalmic imaging devices. A possible advantage of the German meter is that the device consists of a compact video camera and a laptop computer; this makes the system portable. It might be why, in our hands, the German meter system was more challenging to align because the recording camera was mounted on a rotatable stick, which could be varied in multiple directions. In addition, this system uses only a single LED, whereas the Spanish meter uses a semicircular array of LEDs. The single-spot Purkinje reflexes induced by the German meter make estimation of the optimum focusing of the camera difficult. Another problem is that the single-spot reflexes are small and symmetrical, which in some cases made identification of the Purkinje reflexes I, III, and IV almost impossible, in particular when the reflexes were superimposed on each other. This might be an explanation for some of the unsuccessful measurements with the German meter. However, one third of the measurements with this device could not be used for analysis, even when the measurements were performed by the inventor (F.S.).

To our knowledge, there are no actual data concerning the comparability of the 2 Purkinje meters used in this study. However, the clinical feasibility results were similar in the 2 substudies. Despite the presence of the inventor of the Purkinje German meter during the measurements in substudy 2, the number of successful scans did not increase.

Both inventors were asked to analyze the data obtained with their respective device during our measurements, which could be a source of error. Although the inventor of the German meter did analyze the image data, the number of successful scans did not increase, which might indicate that the influence of the experience of the examiner during image acquisition and evaluation might not be as relevant as one might think.

Table 1. (Cont.)

Simulated Aberrations (μm)									
Z(−2,2)	Z(1,3)	Z(−1,3)	Z(3,3)	Z(−3,3)	Z(0,4)	Z(2,4)	Z(−2,4)	Z(4,4)	Z(−4,4)
0.000	−0.076	0.000	0.000	0.000	0.040	0.001	0.000	0.000	0.000
0.000	−0.093	0.000	−0.001	0.000	0.041	0.001	0.000	0.000	0.000
0.000	−0.126	0.000	−0.002	0.000	0.041	0.002	0.000	0.000	0.000
0.000	−0.210	0.000	−0.008	0.000	0.043	0.003	0.000	0.000	0.000
0.000	−0.252	0.000	−0.012	0.000	0.044	0.004	0.000	0.000	0.000
0.000	−1.419	0.000	−0.493	0.000	0.128	0.098	0.000	0.041	0.000
0.000	−0.135	0.000	−0.002	0.000	0.041	0.002	0.000	0.000	0.000
0.236	−0.059	−0.115	0.002	0.000	0.041	0.000	0.001	0.000	0.000
0.400	−0.138	−0.119	0.003	−0.004	0.042	0.001	0.002	0.000	0.000
0.000	−0.056	0.000	−0.001	0.000	0.041	0.001	0.000	0.000	0.000
0.000	−0.055	0.000	−0.001	0.000	0.041	0.001	0.000	0.000	0.000
0.000	−0.046	0.000	−0.004	0.000	0.046	0.004	0.000	0.000	0.000
0.000	−0.048	0.000	−0.010	0.000	0.051	0.008	0.000	0.000	0.000
0.000	−0.051	0.000	−0.013	0.000	0.053	0.009	0.000	0.000	0.000
—	—	—	—	—	—	—	—	—	—
0.000	−0.049	0.000	−0.003	0.000	0.044	0.003	0.000	0.000	0.000
0.029	−0.060	0.018	0.001	−0.001	0.041	0.000	0.002	0.000	0.000
0.014	−0.050	0.015	−0.001	−0.004	0.045	0.002	0.003	0.000	0.000

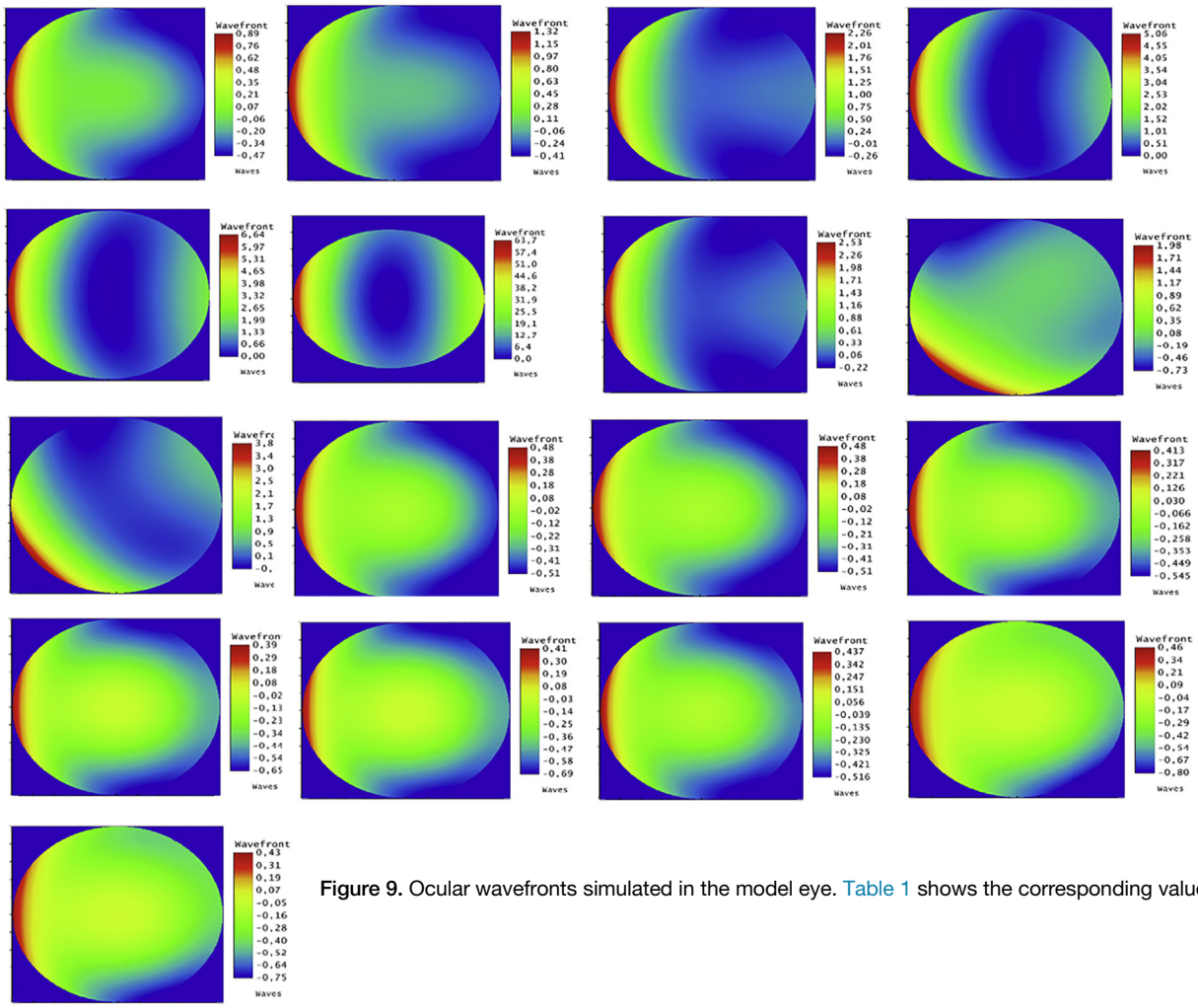

Figure 9. Ocular wavefronts simulated in the model eye. Table 1 shows the corresponding values.

Concerning IOL tilt measurements, the German meter measured significantly higher tilt values than the Spanish meter. The congruence between the devices concerning the direction of IOL tilt was better for the vertical measurements than for the horizontal measurements. The IOL decentration values tended to be higher with the German meter, although the differences were not statistically significant. Despite these results in our pseudophakic patients, the German meter has been shown to measure lens tilt and decentration reliably and with good repeatabilty.[24,25] Repeatability with the Spanish meter had a relatively low influence on HOAs. In contrast, repeatability of the German meter would have resulted in significant HOAs, resulting in reduced visual quality. However, because 7 degrees of tilt and 0.4 mm of decentration can have a significant influence,[3] we would consider a repeatability of 1.4 degrees and 0.08 mm (20% of the relevant influence) to be acceptable.

In conclusion, the Spanish meter had better clinical feasibility in pseudophakic eyes than the German meter. Despite the supervision of a highly experienced specialist during measurements, the percentage of unsuccessful scans with the German meter was relatively high. In addition, the German device measured significantly higher tilt values than the Spanish meter. Data published with these Purkinje meters should not be directly compared because of the differences found in this study.

WHAT WAS KNOWN

- Several techniques to assess IOL tilt and decentration lack accuracy and objectivity.
- Using the Purkinje reflexes to measure IOL alignment yields repeatable and reproducible results.

WHAT THIS PAPER ADDS

- The clinical feasibility of the Spanish Purkinje meter system was better than that of the German Purkinje meter.
- In pseudophakic eyes, the German Purkinje meter measured significantly higher IOL tilt and decentration values than the Spanish Purkinje meter.

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