Refractive and Visual Outcome of Misaligned Toric Intraocular Lens After Operative Realignment

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• PURPOSE: The study was performed to evaluate the refractive and visual outcome of patients with misaligned toric intraocular lenses (IOLs) after operative realignment, with and without back-calculation of the toric axis after implantation of the IOL.

• DESIGN: Institutional, retrospective case-control study.

• METHODS: This is a retrospective case series of 39 patients who underwent a second operation to realign a misaligned toric IOL from August 2013 to December 2019 at the Department of Ophthalmology, Goethe University, Frankfurt, Germany. Ideal toric axis was calculated using the back-calculator astigmatismfix.com.

• RESULTS: The study consists of 39 treated eyes (20 [51%] right eyes). The toric IOLs showed a postoperative misalignment of 25.69 ± 26.06°. Postrotational, uncorrected distance visual acuity (UDVA) improved from 0.39 ± 0.29 logMAR to 0.27 ± 0.18 logMAR. Refractive outcome showed a reduction of residual sphere and cylinder. The postoperative UDVA when performing alignment to the preoperative calculated axis (51%) was 0.24 ± 0.16 logMAR with a cylinder of 0.90 ± 0.90 diopter (D). In the group with alignment to a back-calculated axis (49%), the UDVA was 0.32 ± 0.20 logMAR with a cylinder of 0.76 ± 0.72 D. High cylinder power IOLs (≥2 D) showed a higher decrease in residual cylinder when back-calculation was performed than low cylinder power IOLs (< 2 D) (27% vs 9%). The mean spherical equivalent prediction error of the back-calculator was 0.54 ± 0.55 D.

• CONCLUSION: Realignment of misaligned toric IOLs improves visual acuity and reduces residual refractive errors. Especially for high cylinder power IOLs, better refractive outcome can be seen when performing a back-calculation before realignment. (Am J Ophthalmol 2021;224:150–157. © 2020 Published by Elsevier Inc.)

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TORIC INTRAOCULAR LENSES (IOLS) HAVE BEEN developed to improve unaided visual acuity in patients with astigmatism while performing lens exchange. This is of great importance because almost half of the candidates for cataract surgery have an astigmatism of at least 1.0 D.[1]

The correct alignment of toric IOLs in the right axis is the determining factor to achieve satisfactory outcome by decreasing astigmatism. Owing to widely improved preoperative calculation and precise implantation of the IOLs, postoperative rotation represents the main remaining problem.[2] Mencucci and associates show a mean rotation of 2.66 ± 1.53° after 3 months,[3] which results in a loss of approximately 9% of the power.[4] Depending on preoperative astigmatism, residual refractive astigmatism ranged from 0.00 to 2.25 D with a mean of 1.89 D after implantation of toric IOL.[5,6]

When looking at visual acuity, every 1 D of residual cylinder reduces uncorrected distance visual acuity (UDVA) by approximately 0.16 logMAR.[7]

To treat disruptive residual astigmatism, a surgical realignment of the IOL can be performed. Studies show a requirement of realignment in 0.65% to 7.41% of the cases.[8–15] When performing repositioning surgery, the toric IOL can be aligned to the originally calculated axis or to a newly determined axis. Performing a back-calculation postoperatively may be beneficial in 90% of the cases to identify the optimal axis, even if the IOL is on the axis.[5] The website astigmatismfix.com (Ocular Surgical Data LLC, Sioux Falls, South Dakota, USA) provides a back-calculator to determine the optimal axis and to predict the postrotational refraction based on current position and cylinder power of the IOL.[16]

To this date, there has been no large-scale clinical investigation of the outcome using a back-calculator. The purpose of this study is to investigate the refractive and clinical outcome of realignment surgery and to compare the alignment to the initially planned axis with the alignment to an axis determined by back-calculation.

METHODS

THIS RETROSPECTIVE CASE SERIES INCLUDES 39 EYES OF 39 patients who underwent femtolaser-assisted lens exchange

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TABLE 1. Study Sample Characteristics	
Variable	Value, n (%) or Mean ± SD
Sex	
Male	20 (51.28)
Female	19 (48.72)
Eye	
Right	20 (51.28)
Left	19 (48.72)
Mean age (years) ± SD	62.03 ± 12.52
Surgery	
Cataract	29 (74.36)
Refractive	10 (25.64)
IOL haptic	
C-haptic	27 (69.23)
Plate-haptic	12 (30.77)
IOL model	
AcrySof SN (Alcon, USA)	5 (13)
AcrySof IQ PanOptix (TFN, USA)	8 (21)
Rayner T-flex toric (Rayner, UK)	6 (15)
TECNIS AMO Symfony (J&J Vision Care, Inc.)	9 (23)
AT LISA tri MP (Carl Zeiss Meditec, Germany)	8 (21)
AT LARA MP (Carl Zeiss Meditec, Germany)	3 (8)
IOL power (SE, D) ± SD	18.46 ± 7.74
Axial length (mm)	24.78 ± 2.73
Anterior chamber depth (mm)	3.21 ± .36
White-to-white (mm)	12.03 ± .46
Lens thickness (mm) by IOL-Master (21/39 eyes)	4.46 ± 0.47
Time span to realignment surgery (d)	86.54 ± 157.99

IOL = intraocular lens, SE= spherical equivalent.

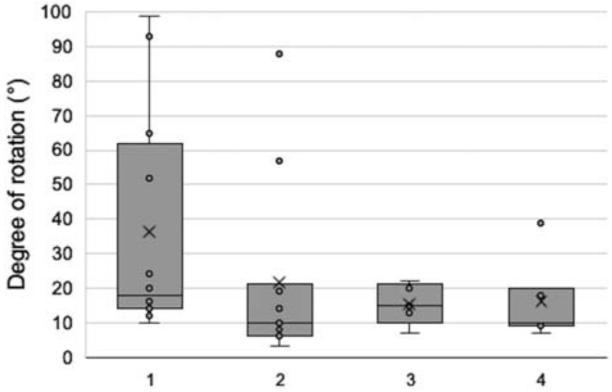

FIGURE 1. Degree of postoperative rotation by haptic of intraocular lens. 1 = C haptic clockwise; 2 = C haptic counterclockwise; 3 = Plate haptic clockwise; 4 = Plate haptic counterclockwise.

between August 2013 and December 2019. All operations were performed at the Department of Ophthalmology at the Goethe University Frankfurt by T.K. The study was conducted with approval of the local ethics committee and in accordance with the Declaration of Helsinki.

Patients with femtolaser-assisted lens exchange due to cataract or for refractive surgery and implantation of a toric IOL were enrolled when having undergone a second operation to realign a misaligned toric IOL. Exclusion criteria was dislocated IOL.

Owing to the institutional study design, examination methods and surgical procedures are standardized, and indication for realignment was decided by the same surgeon. Preoperatively, patients underwent standard ophthalmologic examination, including subjective refraction performed by an optometrist. IOL calculation was performed using Barrett formula (manufacturer-specific calculators) based on optical biometric measurements (IOL Master 500/700; Carl Zeiss Meditec, Jena, Germany). Lens exchange was performed femtolaser-assisted (LenSx; Alcon, Fort Worth, Texas, USA) using the built-in marking of alignment axis.

Postoperatively, patients underwent ophthalmologic examination on Days 1, 7, and 30, including subjective refraction and assessment of IOL alignment by retroillumination at a slit-lamp in mydriasis on Day 7. Indication of realignment was based on the judgment of the surgeon assuming improvement of uncorrected visual acuity with repositioning and in consent with the patient. Realignment surgery was conducted using the Verion digital marker of the LenSx. Neither additional limbal relaxing incision nor astigmatic keratotomy was performed. Moreover, no capsular tension ring was implanted. Retrospectively, the optimal axis was recalculated using the online back-calculator astigmatismfix.com (Ocular Surgical Data LLC) for all patients.

• **STATISTICAL ANALYSIS:** The data were statistically analyzed using SPSS Statistics (version 26; IBM Corp, Armonk, New York, USA). Descriptive statistics included mean, standard deviation, median, maximum, and minimum. To test for normal distribution, Kolmogorov-Smirnov test was executed. For normally distributed variables, dependent and independent *t* tests were applied, whereas Mann-Whitney *U* test and Wilcoxon test were applied for variables that were not normally distributed. Variance analysis was performed with ANCOVA testing. Linear regression was used to explore effects between variables. *P* values below .05 were considered significant.

A subgroup analysis was performed by dividing the study sample into IOL cylinder power <2 D and ≥ 2 D and subdividing these groups into groups with alignment to the originally planned axis and groups with alignment to a newly determined axis by back-calculation.

TABLE 2. Refractive and Visual Outcome After Implantation and Realignment

	Preoperative	Prerotational	Postrotational	Group 1	Group 2
Misalignment (degrees) ± SD	—	25.69 ± 26.06	7.32 ± 12.57	8.00 ± 16.91	6.53 ± 3.89
Corneal sphere (D) ± SD	−1.45 ± 5.55	0.86 ± 1.56	0.28 ± 0.87	0.41 ± 1.03	0.05 ± 0.54
Corneal cylinder (D) ± SD	−2.16 ± 2.34	−1.87 ± 2.28	−0.83 ± 0.81	−0.90 0± 0.90	−0.76 ± 0.72
Vector analysis (D) ± SD	–	From 0.61 ± 2.17 to 0.24 ± 2.08	From 0.24 ± 2.08 to 0.22 ± 0.79	From 0.44 ± 0.79 to 0.19 ± 0.53	From 0.19 ± 1.18 to 0.05 ± 0.50
UDVA (logMAR) ± SD	–	0.39 ± 0.29	0.27 ± 0.18	0.24 ± 0.16	0.32 ± 0.20
BCVA (logMAR) ± SD	0.28 ± 0.22	0.15 ± 0.14	0.14 ± 0.14	0.11 ± 0.12	0.18 ± 0.15

BCVA = best corrected visual acuity, UDVA = uncorrected distance visual acuity.
Group 1: postrotational, conventional group without back-calculation. Group 2: postrotational, group with back-calculation.

Furthermore, the prediction error (predicted refraction by back-calculator–postrotational refraction) and percentage of eyes within ±0.25, ±0.5, ±0.75, and ±1.0 D were calculated.

RESULTS

THIS STUDY INCLUDES 39 EYES (20 [51%] RIGHT EYES) OF 39 PAtients who underwent repositioning surgery due to significant misalignment out of a total of 1209 implanted toric IOLs (3%) from August 2013 to December 2019. Table 1 shows the characteristics of the study sample. After implantation of the toric IOL, the best-corrected visual acuity (BCVA) improved from 0.28 ± 0.22 logMAR (20/40) to 0.15 ± 0.14 logMAR (20/32) and uncorrected distance visual acuity (UDVA) was 0.39 ± 0.29 logMAR (20/50). Residual cylinder was −1.87 ± 2.28 D. Vector analysis showed a decrease from 0.61 ± 2.17 D to 0.24±2.08 D postoperatively. On Day 7, the measured axes showed a misalignment of the IOL by 25.69 ± 26.06°. Based on the smallest angle, 17 (44%) IOLs rotated clockwise (30.12 ± 28.95°), whereas 22 eyes (56%) rotated counterclockwise (22.27 ± 23.72°) (P = .138, Mann-Whitney U). Separated by haptic, more IOLs with a c-haptic rotated counterclockwise (56%) than clockwise (44%). Five (42%) IOLs with plate-haptic rotated clockwise and 7 (58%) counterclockwise. The degree of rotation by haptic is shown in Figure 1. A linear regression model indicated there was no significant effect of the axial length (24.78 ± 2.73 mm; P = .704), anterior chamber depth (3.21 ± 0.36 mm; P = .875), white-to-white (12.03 ± 0.46 mm; P = .721), and natural lens thickness (4.46 ± 0.47 mm [21/39 eyes], by IOL-Master; P = .109) on the degree of rotation of the IOL.

Repositioning surgery was performed after 86.54 ± 157.99 days. Outcomes are summarized in Table 2 and demonstrated in Figures 2-4. In all eyes, BCVA remained unchanged at 0.14 ± 0.14 logMAR (20/32), whereas UDVA improved significantly from 0.39 ± 0.29 logMAR (20/50) to 0.27 ± 0.18 logMAR (20/40) (P = .001, Wilcoxon). The postrotational spherical equivalent (SE) was within ±2.25 D in all eyes with a decreased residual cylinder from −1.87 ± 2.28 D to −0.83 ± 0.81 D (P < .001, Wilcoxon) and decreased residual sphere from 0.86 ± 1.56 D to 0.28 ± 0.87 D (P = .009; Wilcoxon). Vector analysis showed a decrease from 0.24±2.08 D to 0.22±0.79 D. Misalignment was significantly reduced from 25.69 ± 26.06° to 7.32 ± 12.57° (P < .001; Wilcoxon). Preoperative type of astigmatism (with/against the rule/oblique) had no impact on UDVA or on cylinder (P = .806; P = .511, ANCOVA). No effect between the time of the operation and the visual or refractive outcome (UDVA; BCVA; cylinder) could be found (P = .586; P = .532; P = .555, linear regression).

In 20 cases (51%), the toric IOL was realigned to the preoperatively determined axis, which required a rotation of 31.25 ± 30.11° (Group 1). In the remaining 19 (49%) cases, a back-calculation (with astigmatismfix.com) was performed before realignment surgery to determine the optimal axis (Group 2). In this group, the difference of the current axis to the calculated axis was 33.58 ± 37.29°. Back-calculation was reperformed for Group 1 and showed a difference of 18.95 ± 29.84° from the actually targeted axis at the second operation. Table 2 shows the different postrotational outcomes regarding BCVA, UDVA, and vector analysis, and Figure 5 demonstrates residual cylinders. There was no significant difference in the visual and refractive outcome (UDVA; BCVA; cylinder) between the 2 groups (P = .778; P = .654; P = .437, ANCOVA).

To analyze the outcome for IOLs with a high cylinder power of ≥2.0 D, a subgroup analysis was performed as described in the methods. All results regarding the subgroup analysis are summarized in Table 3. Postrotational

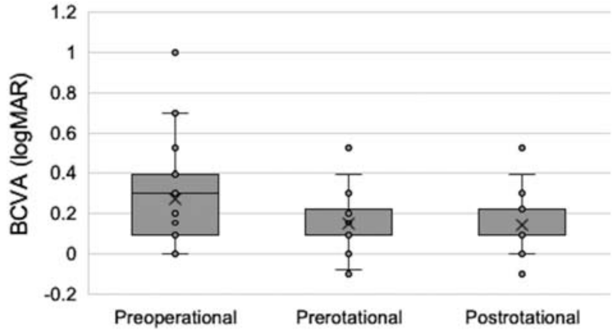

FIGURE 2. Change in best-corrected visual acuity (BCVA, logMAR).

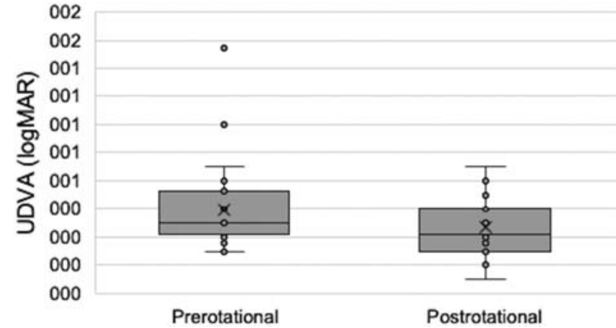

FIGURE 3. Change in uncorrected distance visual acuity (UDVA, logMAR).

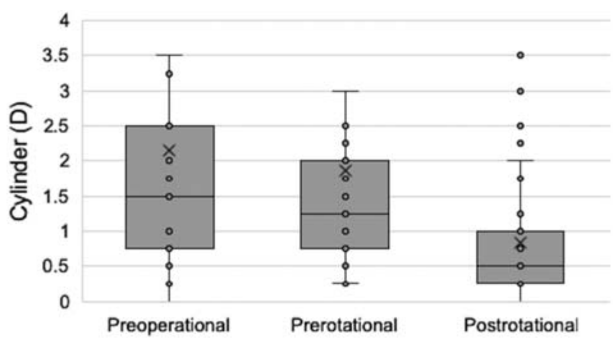

FIGURE 4. Change in cylinder (D) (Enlarged section for better visualization).

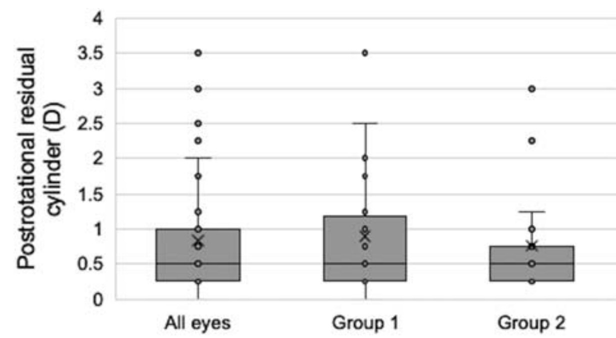

FIGURE 5. Postrotational residual cylinder (D) split in groups regarding back-calculation. Group 1: All eyes without back-calculation; Group 2: All eyes with back-calculation.

cylinder was lower in low cylinder power IOLs ($P = .293$, ANCOVA). Comparing conventional realignment to realignment to a back-calculated axis, residual cylinder in eyes with low cylinder power IOLs was -0.53 ± 0.39 D and -0.48 ± 0.22 D, respectively ($P = .067$, ANCOVA); in eyes with high cylinder power IOLs, the residual cylinder was -1.15 ± 1.06 D and -0.84 ± 0.65 D, respectively ($P = .846$, ANCOVA). The refractive outcome regarding the residual cylinder split in subgroups comparing low and high IOL cylinder power are demonstrated in Figure 6.

Postrotational UDVA in all low cylinder power IOLs was 0.21 ± 0.18 logMAR, whereas UDVA in high cylinder power IOLs was slightly worse at 0.32 ± 0.18 logMAR ($P = .220$, ANCOVA). Vector analysis in low cylinder power IOLs showed an increase without back-calculation (increase of 0.14 ± 0.31 D) and a decrease with back-calculation (decrease of 0.06 ± 0.50 D). For high cylinder power IOLs, both methods showed a decrease in the vector analysis.

In the group with high cylinder power IOLs without back-calculation, 4 cases showed residual cylinder of ≥1.0 D. In 3 of these 4 eyes, postrotational misalignment was $<5°$, albeit with a residual cylinder of -2.0, -3.5, and -1.0 D, respectively. The axes calculated by a back-calculator deviate by 9, 37, and 47° from the intended axes. In the group with high cylinder power IOLs with back-calculation, 2 cases showed a residual cylinder of -2.25 and -1.25 D; in both eyes, postrotational misalignment was $>5°$. The first case showed a misalignment of 8° with an IOL cylinder power of 6 D; the second case showed a misalignment of 10° with an IOL cylinder power of 5.5 D. Table 4 summarizes the referred cases.

In a final step, the prediction error was evaluated. In Group 1 without back-calculation, the mean absolute prediction error of the residual sphere was 0.82 ± 0.91 D, and in Group 2 with back-calculation, 0.46 ± 0.56 D. The mean absolute prediction error of the residual cylinder was 0.46 ± 0.56 D and 0.42 ± 0.31 D, respectively. The mean absolute prediction error of the spherical equivalent was 0.74 ± 0.89 D for Group 1 and 0.48 ± 0.53 D for Group 2. The percentage of eyes in a particular range of residual sphere and cylinder is shown in Figure 7.

DISCUSSION

THIS STUDY ANALYZES THE REFRACTIVE AND VISUAL outcome after realignment of a misaligned toric IOL with

TABLE 3. Refractive and Visual Outcome of Subgroup Analysis

	IOL Cylinder Power <2 D (18 eyes)	Group A (8 eyes)	Group B (10 eyes)	IOL Cylinder Power ≥2 D (20 eyes)	Group C (12 eyes)	Group D (8 eyes)
Prerotational misalignment (degrees) ± SD	27.28 ± 26.24	27.00 ± 28.90	27.50 ± 25.51	24.95 ± 27.01	34.67 ± 31.43	10.38 ± 4.78
Prerotational sphere (D) ± SD	0.40 ± 0.77	0.00 ± 0.35	0.73 ± 0.87	1.23 ± 1.99	1.46 ± 2.50	0.88 ± 0.87
Postrotational sphere (D) ± SD	0.14 ± 0.46	0.13 ± 0.46	0.15 ± 0.47	0.38 ± 1.07	0.60 ± 1.27	0.31 ± 0.60
Prerotational cylinder (D) ± SD	–1.08 ± 0.68	–0.78 ± 0.49	–1.33 ± 0.73	–2.34 ± 2.84	–2.56 ± 3.55	–2.00 ± 1.36
Postrotational cylinder (D) ± SD	–0.50 ± 0.30	–0.53 ± 0.39	–0.48 ± 0.22	–1.03 ± 0.91	–1.15 ± 1.06	–0.84 ± 0.65
Vector analysis (D) ± SD	from 0.02 ± 0.59 to 0.12 ± 0.27	from 0.06 ± 0.24 to 0.08 ± 0.20	from 0.08 ± 0.53 to 0.06 ± 0.18	from 0.37 ± 1.81 to 0.14 ± 0.63	from 0.18 ± 0.71 to 0.05 ± 0.46	from 0.11 ± 0.75 to 0.06 ± 0.33
Postrotational UDVA (logMAR) ± SD	0.21 ± 0.18	0.16 ± 0.13	0.25 ± 0.21	0.32 ± 0.18	0.29 ± 0.17	0.36 ± 0.20
Postrotational BCVA (logMAR) ± SD	0.14 ± 0.16	0.61 ± 0.05	0.20 ± 0.19	0.15 ± 0.13	0.14 ± 0.14	0.16 ± 0.10

BCVA = best corrected visual acuity, IOL = intraocular lens, UDVA = uncorrected distance visual acuity.

Group A: IOL toric power <2 D without back-calculation. Group B: IOL toric power <2 D with back-calculation. Group C: IOL toric power ≥2 D without back-calculation. Group D: IOL toric power ≥2 D with back-calculation.

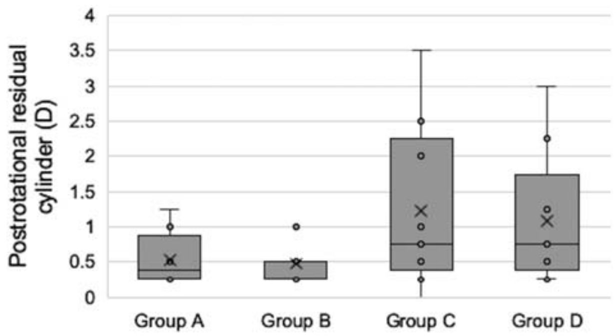

FIGURE 6. Postrotational residual cylinder (D) split in groups regarding IOL cylinder power and back-calculation. Group A: IOL toric power < 2 D without back-calculation; Group B: IOL toric power < 2 D with back-calculation; Group C: IOL toric power ≥2 D without back-calculation; Group D: IOL toric power ≥2 D with back-calculation.

comparison of realignment with and without back-calculation. Realignment surgery corrects misaligned toric IOLs while simultaneously correcting surgically induced changes in corneal structure. Prior studies have shown an incidence of realignment surgery of 0.65% to 7.41%,[8–15] which agrees with the incidence of this study of 3.23%.

Outcomes after realignment surgery have been investigated by Oshika and associates[10] in a retrospective, multicenter case series in Japan. In all cases, the toric IOLs were realigned to the axis planned at the time of cataract surgery. They measured a residual misalignment after realignment of 8.8 ± 9.7° at 7 weeks, which is slightly higher than the present residual alignment of 7.32 ± 12.57°. The residual cylinder was again slightly higher at 1.1 ± 0.8 D compared to the outcome of this study at −0.83 ± 0.81 D for all eyes and at −0.9 ± 0.90 D for the conventional group (Group 1). Better refractive outcome after realignment when being performed between 1 and 3 weeks after initial operation could not be confirmed in the present study. The high range of days between the operations and the much later timing of second surgery has to be taken into consideration.

To the authors' knowledge, refractive and visual outcomes after realignment to a newly determined axis by a back-calculator have not been studied yet. The back-calculator astigmatismfix.com (Ocular Surgical Data LLC)[16] uses vector analysis and proposes an optimal alignment axis while also predicting the postrotational refraction based on current position and cylinder power of the IOL. In this study, astigmatismfix.com showed consensus with measured outcomes and an especially low prediction error for the residual cylinder. A benchmark suggested by Gale and associates for refractive outcome after cataract surgery implies that 85% of patients should achieve a spherical equivalent within ±1.0 D of the predicted outcome.[17] When applying this benchmark to the present study, however, the results of astigmatismfix.com were slightly below the benchmark (79% of all eyes, 84% of the back-calculation group).

Retrospective evaluation of input data of the back-calculator astigmatismfix.com stated that performing a realignment based on the results of the back-calculator is likely to be beneficial in 90% of the cases, even in the 30% being at the originally calculated axis, because of inaccurate or fluctuating keratometry, posterior corneal curvature, surgically induced astigmatism, or differences between the axes of astigmatism at different optical zones.[5,18] The mean residual astigmatism of all cases input into the back-calculator was at 1.89 D, which conforms with the postoperative residual cylinder of this study of −1.87 ± 2.28 D. A median expected reduction of 54% was proposed.[5] In the present study, the back-calculation group showed a reduction of the mean by 60%.

The comparison of low (<2 D) and high (≥2 D) IOL cylinder power showed less postoperative rotation of the IOL and higher residual astigmatism in high cylinder power IOLs. The refractive and visual outcome after realignment was better in eyes with IOLs with low cylinder power than with high cylinder power, showing a residual astigmatism of ≤0.75 D in both alignment to the original axis and alignment to the axis determined by back-calculation. Berdahl and associates showed similar results in their study evaluating input data of the back-calculator astigmatismfix.com. They found that a low IOL cylinder power of <1.5 D was significantly associated with a higher chance of the residual cylinder being <0.5 D after realignment.[19]

In the subgroup analysis, there was a considerably higher decrease in the vector after alignment with back-calculation. Although for low cylinder power IOLs, back-calculation did not have a positive impact on vector decrease, the group with high cylinder power IOLs showed a decrease both with and without back-calculation. When looking at the residual cylinder as shown in Figure 6, all cylinder power IOLs showed a lower residual cylinder after alignment with back-calculation; for high cylinder power IOLs, there was a higher difference between both methods (27% vs 9%), which implies a high advantage of using a back-calculator especially for this subgroup.

Study limitations include the retrospective study design, with indication and timing of realignment not being standardized. To this date, there is no guideline covering realignment surgery. Because of commencement of usage of the back-calculator in 2017 in the reviewed department, there is an additional chronologic distribution of patients without and with back-calculation. Preferably, patients could have been randomly assigned to either realignment to the initial axis or realignment to a back-calculated axis.

TABLE 4. Referred Cases in Subgroup With High Cylinder Power IOL (≥2 D) and With Residual Cylinder ≥1 D

	Residual Cylinder (D)	Misalignment (degrees)	Toric Power of the IOL (D)	Suggested Difference in Alignment by Back-Calculator (degrees) (Residual Cylinder Predicted [D])
Group C				
Patient 1	−2.5	19	6.0	100 (0.1)
Patient 2	−2.0	5	4.5	9 (1.9)
Patient 3	−3.5	2	6.0	37 (3.66)
Patient 4	−1.0	2	2.25	47 (0.13)
	Residual Cylinder (D)	Misalignment (degrees)	Toric Power of the IOL (D)	Calculated Residual Error Due to Misalignment (D)
Group D				
Patient 1	−2.25	8	6.0	1.58
Patient 2	−1.25	10	5.5	1.82

IOL = intraocular lens.

Group C: postrotational, subgroup (IOL toric power ≥2 D) without back-calculation. Group D: postrotational, subgroup (IOL toric power ≥2 D) with back-calculation.

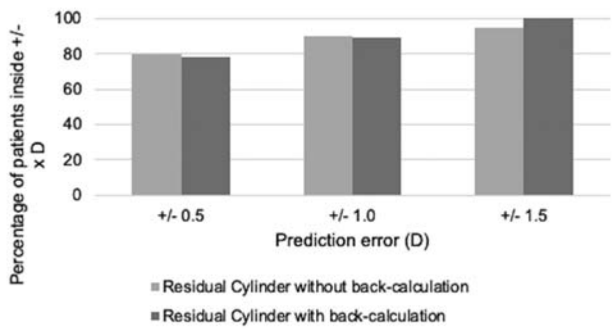

FIGURE 7. Percentage of patients within ±*x* D of prediction error.

Future prospective randomized investigation of refractive and visual outcomes, and evaluation of the back-calculator would be of great interest to achieve a better understanding of realignment surgery and to develop guidelines for realignment management. However, the number of patients that need to be included would be very high as a clinically significant misalignment of a toric lens is a relatively rare incident. Another option would be to put more emphasis and expand functionality of international registries like the EUREQUO. Through data input of many surgeons, a larger sample size could be generated, increasing the validity of similar studies.

In conclusion, realignment of misaligned toric IOLs improves visual acuity and reduces residual refractive errors, especially residual cylinder. Performing a back-calculation before realignment leads to better refractive outcome. This benefit could particularly be shown for high cylinder power IOLs.

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