# Precision and refractive predictability of a new nomogram for femtosecond laser-assisted corneal arcuate incisions

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#### ABSTRACT.

*Purpose:* Validating a new nomogram for low to moderate astigmatism (0.75 D to 2.5 D) correction with epithelium- and Bowman-penetrating femtosecond laser-assisted arcuate incisions.

*Methodology:* Prospective, interventional case series at the Augen- und Laserklinik, Castrop-Rauxel, Germany. Cataract patients with low to moderate corneal astigmatism were treated with femtosecond laser-assisted arcuate incisions. Patients with previous refractive corneal treatment were excluded. Outcome assessment was based on manifest refraction, astigmatic vector analysis and visual acuity.

*Results:* The study analysed 43 eyes of 33 patients after three months and 35 eyes of 27 patients after 12 months. After 12 months, 100% of all eyes treated had  $\leq$ 1.0 D and 97%  $\leq$ 0.5 D of subjective residual astigmatism. Mean residual astigmatism was 0.27 D. 90% of all eyes were within one line of difference between UDVA and CDVA. SEQ Mean Absolute Error was 0.26 D and SEQ. Mean error was  $-0.08 \pm 0.32$  D. CI was  $0.98 \pm 0.2$  D, and Index of Success,  $0.20 \pm 0.18$  D.

*Conclusion:* The Castrop nomogram showed results that are comparable to or better than results presented in the literature for existing nomograms. Our results for astigmatic reduction are comparable to published results for TIOL implantation. It seems to be a predictable and safe measure to reduce manifest astigmatism.

Key words: arcuate incisions – astigmatism – Castrop nomogram – corneal incisions – femtosecond laser – keratotomy

#### Acta Ophthalmol. 2021: 99: e1297-e1306

doi: 10.1111/aos.14837

### Introduction

With the newer generation of cataract patients, growing expectations of good visual results and spectacle independence are establishing new benchmarks for cataract surgery.

In order to achieve the best possible results regarding uncorrected visual acuity, a cataract surgeon has to address the correction of corneal astigmatism. Astigmatism has been shown to considerably compromise visual results in patients after multifocal lens implantation (Wolffsohn et al. 2011). For monofocal intraocular lens (IOL) implantation, a residual astigmatism of 1.0 D was shown to also have a negative impact on uncorrected visual acuity (Watanabe et al. 2013). The EUREQUO database showed that more than 30% of all pseudophakic patients suffer from a residual astigmatism of more than 1.0 D (Lundström et al. 2018), confirming the results of previous studies (Hoffmann & Hütz 2010; Khan & Muhtaseb 2011). Whereas management of preoperative corneal astigmatism of more than 0.75 D has been shown to be beneficial (Buscacio et al. 2016), the degree of preoperative corneal astigmatism that needs to be addressed is a topic of discussion (Kessel et al. 2016).

There are several ways to address corneal astigmatism: Toric intraocular lens (TIOL) implantation, refractive laser procedures and corneal incisions.

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Between these, TIOL implantation is the most frequently used option that can be used to address even high amounts of astigmatism. A possible drawback is the risk of misalignment, either from surgically induced astigmatism (SIA) and/or lens misalignment or rotation. Excimer laser refractive procedures are expensive and require a second procedure. While the same goes for a femtosecond laser, corneal incisions may be combined with (femtosecond laser-assisted) cataract surgery and may serve as good alternative for IOLs that are not available with torus or situations when a TIOL may be contraindicated or difficult to do (compromised zonules, small pupil, pseudoexfoliation syndrome, etc.). Furthermore, they can be used subsequently to cataract surgery for fine-tuning of refractive cylinder. The use of femtosecond laser technology makes the use of corneal incisions more appealing, as precisely planned and executed cuts allow a higher predictability of the results. Possible drawbacks include a weakening of the cornea and dysphotopsia, especially with smaller optical zones.

While limbus-near incision nomograms exist (limbal relaxing incision (LRI): Donnenfeld, Nichamin, Gills), they do not translate perfectly onto arcuate incision results, have an undefined optical zone and are coarse with few and large possible steps between corrections. Existing nomograms for arcuate keratotomy are designed for smaller optical zones and higher correction (Lindstrom, ARC-T, Thornton).

Therefore, feeling the need for a reproducible correction of frequently observed astigmatism between 0.75 D and 2.5 D, a new femtosecond laserbased nomogram for femtosecond laserassisted arcuate incisions (FSAI) was developed by modifying the Oshika nomogram, as it reported a slight undercorrection (Oshika et al. 1998). In this study, we evaluated the outcome of epithelium- and Bowman-penetrating FSAI in patients with simultaneous intraocular lens implantation as an alternative to TIOL implantation in order to evaluate the dose-effect relationship of the newly developed nomogram.

# Methods

#### Study design

This investor initiated study is a prospective, consecutive case series.

As an open-label study, it is performed by a single surgeon on a single site. It enrols 43 eyes from 33 consecutive patients receiving combined femtosecond laser-assisted phacoemulsification and FSAI while implanting aspheric non-toric intraocular lenses in the Augen- und Laserklinik, Castrop-Rauxel, Germany, from March 2013 to January 2014.

Four IOL designs were used, including the Alcon SN60AT (Alcon Laboratories, Inc., Fort Worth, TX), the AMO ZCB00 (Abbott Medical Optics, Santa Ana, CA, USA), the Carl Zeiss CT Asphina 404 (Carl Zeiss Meditec, Jena, Germany) and the Hoya AF-1 iMics 1 (Hoya Corp., Tokyo, Japan).

The local ethics committee (Ethikkommission der Westfälischen Wilhelms-Universität Münster und der Arztekammer Westfalen Lippe) approved the protocol for this study, and any data collection went in accordance with ethical standards of the Helsinki Declaration of 1964 and its current revisions. The study follows good clinical practice guidelines. Written informed consent was obtained from all patients prior to their inclusion for the study.

Inclusion criteria were a corneal astigmatism between 0.5 and 2.5 D. Exclusion criteria were eyes with irregular astigmatism, keratoconus and previous corneal refractive treatment.

Patients underwent an ophthalmic examination including slitlamp biomicroscopy, funduscopy, UDVA and CDVA examination, wavefront analysis, keratometry and topography/tomography (Using Lenstar (Haag-Streit AG, Koeniz, Switzerland), Tomey TMS-5 and TMS-5 'real astigmatism' (Tomey Corp., Nagoya, Japan) and iTrace (Tracey Technology, Houston, Texas, USA). Subjective manifest refraction was performed by the same optometrist at a lane length of 6 m using Landolt C optotypes according to DIN/EN/ISO 8596.

Postoperative examinations were scheduled for the first day, as well as one week, one month and three months after surgery. A 12-month examination was added as an amendment.

#### Surgical technique

The new nomogram was derived from Oshika et al. (1998) and adjusted by

adding a correction for age dependency (Table 1).

First assumptions for age dependency correction were set at -0.75%per year under 70 years, and +0.75% per year over 70 years. The optical zone was kept at 8.5 mm to avoid overfitting in later modifications of the nomogram. After completing the first procedures, the results were reviewed performing vector analysis (as described in the section statistical analysis). A new nomogram was derived, containing only two variables: age (years) and arc length (degrees). Outcomes of this nomogram were evaluated, and further fine-tuning was applied, resulting in the final version of the nomogram that was used for this study.

Analogous to TIOL calculation, the astigmatic vector (magnitude and meridian) was chosen as mean vector of Lenstar keratometry and Tomey TMS-5 'real astigmatism' (including the posterior curvature; Hoffmann et al. 2013). SIA<sub>incision</sub> from the cataract surgery main incision was not considered for the preoperative measures, as we learned from a previous cohort that the effect is rather negligible (Hoffmann et al. 2011). Postoperatively, manifest refraction was taken as benchmark value, as recommended by Alpins et al. (2012).

Alignment was secured via limbal markings, and surgery was performed under topical anaesthesia by the same experienced surgeon (P.C.H.).

All 43 FSAI were carried out as symmetric 'open' incisions using a TechnolasVictus SW 2.7 (Bausch & Lomb Inc, Dornach, Germany) in the context of a combined phacoemulsification and arcuate keratotomy while implanting an aspheric non-toric lens.

After application of a proprietary Victus suction ring, symmetric paired arcuate keratotomies were placed on the edge of the optical zone, which was chosen to be 8.5 mm. The self-sealing main limbal incision for phacoemulsification was performed with a 2.2-mm double-bevelled steel blade at the limbus of the temporal cornea, independent from location of the steep axis.

The depth of the keratotomies was derived from TMS-5 pachymetry measurements and set to 80% of the corneal thickness measured at 4.25 mm peripheral to the corneal apex. The side-cut angle was set at 90

Table 1. Castrop nomogram.

Effect $[D] = -2.4699 + 0.0610 * arclength[°] + 0.0155 * age[years]$																					
Effect (D) Age (years)	0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.2	2.3	2.4	2.5
40	39	40	42	43	45	47	48	50	52	53	55	57	58	60							
45	37	39	41	42	44	45	47	49	50	52	54	55	57	59	60						
50	36	38	39	41	43	44	46	47	49	51	52	54	56	57	59						
55	35	36	38	40	41	43	45	46	48	49	51	53	54	56	58	59					
60	33	35	37	38	40	42	43	45	47	48	50	51	53	55	56	58	60				
65	32	34	35	37	39	40	42	44	45	47	49	50	52	53	55	57	58	60			
70	31	33	34	36	37	39	41	42	44	46	47	49	51	52	54	55	57	59	60		
75	30	31	33	35	36	38	39	41	43	44	46	48	49	51	53	54	56	57	59		
80		30	32	33	35	37	38	40	41	43	45	46	48	50	51	53	55	56	58	59	
85			30	32	34	35	37	39	40	42	43	45	47	48	50	52	53	55	57	58	60
90				31	32	34	36	37	39	41	42	44	45	47	49	50	52	54	55	57	59

Final version of the nomogram. The operator has to consider the patients age (years) in the left column and the desired effect (D) from the top row. This results in the required arc length (°) for the paired arcuate incisions.

degrees. Both cuts had the same arc length, which was chosen between 30 and 60 degrees depending on the target induced astigmatism (TIA) of the arcuate incisions and the age of the patient (Table 1). Parameters used were laser pulse energy of 1.2 µJ, horizontal spacing 5 µm, vertical spacing 2 µm. After completion of these steps, the suction ring was removed, the patient was transferred to the sterile field, the phacoemulsification performed and the keratotomies manually opened with a dedicated conic hook. Postoperatively, all patients received prednisolone acetate for 4 weeks.

#### Statistical analysis

Statistical analysis was conducted by using the Statistical Package for the Social Sciences (SPSS) software version 24.0 (SPSS Inc., Chicago, IL, USA).

Baseline characteristics were summarized. Data were tested for normality.

Statistical analysis and presentation of corneal and refractive astigmatic outcomes based on corneal topography/tomography measurements before and after surgery, as well as manifest refraction after surgery were performed using recommendations presented by Abulafia et al. (2018) and by using standardized graphs for reporting the outcomes of refractive surgery (Reinstein et al. 2017). Accordingly, vector changes were analysed using Hotelling's  $T^2$ .

When needed, a conversion of subjective refraction to the corneal plane was applied (Abulafia et al. 2015).

Vector analysis to determine SIA was performed using the Holladay

method in plus cylinder format (Holladay et al. 2001). Double angle plots were created using the Abulafia double angle plot tool (Abulafia et al. 2018). p < 0.05 was considered as statistically significant. To address possible bias from bilateral eye inclusion, success parameters were compared with results from unilateral eye inclusion (randomly chosen), and in case of similar results, it was examined if the similarity of the values is not only observed for the whole study population but also after individual comparisons of all pairs using a two-way mixed-model intraclass correlation coefficient (ICC) with average measures selection and absolute agreement definition. Effect size was calculated according to Cohen's classification. Based on the primary study goal (60% of eyes with  $\leq 0.75$  D of refractive residual astigmatism (RRA) after three months), a sample size of  $43 \le n \le 50$  eyes was calculated for  $\alpha = 0.05$  and  $1-\beta = 0.8$ (power level).

# Results

#### Demographic data

The study analysed 43 eyes from 33 patients. Mean patient age was 69 years. After a complete three month follow-up, 35 eyes (18 right eyes, 17 left eyes) from 27 patients (13 females, 14 males) were available for the 12-month visit. For the 12-month amendment, one patient was lost due to retinal detachment, the others due to non-compliance for unknown reasons.

#### Non-vector outcomes (Astigmatic)

Pre-operatively, the magnitude of corneal astigmatism ranged between 1D and 2D in 88% of all eyes, mean value was  $1.45 \pm 0.34$  D, and median value 1.46 D.

Main aim of the study was to achieve 60% of eyes with ≤0.75 D of RRA after three months. This study goal was met, as 98 % of eyes achieved ≤0.75 D of RRA after three months (Table 2). Additionally, a 12-month amendment visit showed 100% of the eves achieved  $\leq 0.75$  D and 97% of the eyes achieved ≤0.5 D of RRA. The difference between mean preoperative corneal astigmatism and mean postoperative manifest astigmatism (at one, three and 12 months) was statistically significant (p < .001) and the difference between one and 12 months was significant (p = 0.035), while the difference between one and three months (p > 0.999) and three and 12 months (p = 0.147) was not.

If not stated otherwise, all figures display results for the 12 months of visit as it represents the furthest point in time.

#### Vector analysis outcomes (Astigmatic)

The goal and raison d'être of any nomogram is of course its accuracy. A Correction Index (CI) (calculated as the ratio of SIA to TIA) of 1.0 is considered a perfect result. We observed a slight undercorrection with a mean CI of  $0.92 \pm 0.21$  and  $0.98 \pm 0.20$  (Table 2). The TIA vs SIA scatterplot mirrored these results providing a gradient of  $R^2 = 0.96$  after

	1 month post-	op	3 months post	-op	12 months post-op			
Variable	Mean [SD]	Median [IQR]	Mean [SD]	Median [IQR]	Mean [SD]	Median [IQR]		
Corneal astigmatism* [D]	0.65 [0.40]	0.62 [0.50]	0.51 [0.25]	0.50 [0.31]	0.55 [0.35]	0.50 [0.38]		
Manifest astigmatism [D]	0.39 [0.25]	0.38 [0.48]	0.40 [0.27]	0.50 [0.25]	0.27 [0.23]	0.25 [0.5]		
TIA [D]	1.45 [0.34]	1.46 [0.51]	1.45 [0.34]	1.46 [0.50]	1.43 [0.34]	1.40 [0.47]		
SIA [D]	1.36 [0.46]	1.35 [0.71]	1.33 [0.48]	1.21 [0.67]	1.39 [0.42]	1.26 [0.77]		
Difference vector	0.39 [0.25]	0.38 [0.25]	0.40 [0.27]	0.50 [0.25]	0.27 [0.23]	0.25 [0.5]		
Correction Index	0.94 [0.22]	0.93 [0.32]	0.92 [0.21]	0.94 [0.23]	0.98 [0.20]	1.00 [0.27]		
Flattening effect	1.29 [0.53]	1.34 [0.82]	1.29 [0.48]	1.14 [0.74]	1.37 [0.43]	1.22 [0.77]		
Index of success	0.29 [0.23]	0.26 [0.27]	0.28 [0.18]	0.30 [0.27]	0.20 [0.18]	0.20 [0.34]		

\* Corneal astigmatism measured as mean vector TMS-5 'real astigmatism' and Lenstar without PCA.

12 months. Accordingly, mean TIA (1.45  $\pm$  0.34 D) was higher than mean SIA (1.39  $\pm$  0.42 D) (Table 2). The Index of success calculated as the ratio of the difference vector (DV) to TIA had a mean magnitude of 0.20  $\pm$  0.18. The refractive astigmatism angle of error (AE) had an arithmetic mean of 0.97  $\pm$  5.62 and an absolute mean of 3.49  $\pm$  4.48.

The mean DV was  $0.27 \pm 0.23$  D, which is reflected in the postoperative double angle plot (Fig. 1). The mean preoperative vector of all eyes with a complete dataset by the 12 month visit is slightly lower than for the entire population (1.43 D versus 1.45 D). Centroid values are  $0.72 \pm 1.30$  D preoperatively and  $0.04 \pm 0.36$  D postoperatively. Representing the mean astigmatism vector, the centroid moved closer to zero while both 95% confidence ellipses narrowed.

The astigmatic vector can be chosen from different modalities. We chose to perform vector calculations with values from two devices. To confirm this course of action, an analysis of the different modalities for corneal measurement was undertaken postoperatively. Each device was compared to the pseudophakic manifest refraction. The vector difference between both measurements was taken as a predictor for accuracy-the smaller the vector, the higher the accuracy. Double angle plots are shown for all available values, hence for 42 eyes one month after surgery, for 43 eyes three months after surgery and for 35 eyes 12 months after surgery (Fig. 2).

#### Further outcomes

Biometric accuracy was assessed: the mean manifest refraction spherical

equivalent (SEQ) 12 months after surgery was  $0.01 \pm 0.25$  D for eyes with emmetropic target refraction (Table 3), mean sphere  $-0.22 \pm 0.87$  D and mean cylinder  $-0.27 \pm 0.23$  D. 89% of eves were within a SEO of  $\pm 0.5$  D and 100% were within  $\pm 1.0$  D of the intended target SEQ (Fig. 3D). SEQ prediction error, as defined by the difference between attempted and achieved manifest refraction (spherical equivalent), resulted in  $-0.08 \pm 0.32$ D. The scattergram (Fig. 3e) shows a slight undercorrection with a gradient of  $R^2 = 0.87$  at 12 months postoperatively. SEQ mean absolute prediction error was 0.26 D, median absolute error 0.21 D. SEQ and defocus equivalent (DEQ) at one and 12 months significantly were not different (p = 0.129; p = 0.076). A difference of one line or less between UDVA and CDVA was observed in 90 % of all subjects (Fig. 3B) that received treatment with an emmetropic target refraction (29 eyes).

Postoperative UDVA and CDVA are presented in Fig. 3. Cataract related, 66% of the eyes gained more than three lines (CDVA) after the combined phacoemulsification and keratotomy procedure (Fig. 3C).

#### Bilateral eye inclusion bias

Success parameters (CI, Index of Success, DV, MAE, medAE) were analysed regarding bias from bilateral eye inclusion. After 12 months, differences between bilateral (n = 35) und unilateral (n = 27) inclusion for mean DV ( $0.27 \pm 0.23$  versus  $0.27 \pm 0.22$ ), median DV (0.25 for both), mean CI ( $0.98 \pm 0.2$  versus  $0.97 \pm 0.19$ ) and median CI (1.0 for both), mean index of success ( $0.20 \pm 0.18$  for both),

median index of success (0.2 for both), SEQ MAE (0.26 versus 0.24) and SEQ medAE (0.21 versus 0.20) were marginal. The intraclass correlation efficient was 1.0 for all tested parameters.

## Discussion

Although toric IOLs are widely accepted and cover a wide range of astigmatism, there are certain situations when correcting the corneal astigmatism at a corneal level is advantageous. In order to be a viable alternative to TIOL implantation, FSAI have to fulfil some basic preconditions. Using a femtosecond laser, any confounding influence of manual imprecisions to the keratotomies can be widely reduced. The Castrop nomogram is specifically designed for FSAI. Therefore, it does not compete with LRI nomograms such as Donnenfeld. As opposed to Donnenfeld, it has a fixed optical zone and incision depth and allows a continuous dosing. While FSAI share some problems with TIOLs, they have certain advantages and disadvantages in other areas.

Most importantly, FSAI are judged by their accuracy of reducing astigmatism, as they can serve to reduce corneal astigmatism in phakic or pseudophakic eyes. The main aim of this non-comparative study was to reproduce and confirm the accuracy of the newly developed Castrop nomogram. This aim was surpassed, as 98% of eyes were within ≤0.75 D of RRA three months after surgery. The magnitude of our correction was excellent, as we noted only a slight undercorrection, observing a CI of  $0.92 \pm 0.21$  D after three months and  $0.98 \pm 0.2$  D after 12 months. This may be seen as a consequence of our choice of



**Fig. 1.** Double angle plots of astigmatic vectors are displayed. Preoperative astigmatism measurements are based on mean vector calculation between TMS-5 and Lenstar values. Postoperative values and SIA values are displayed for the manifest refraction (upper row), which was taken as benchmark value for this study. Exploratively, results for mean vector calculation between TMS-5 and Lenstar are displayed in the second row, but were not considered in the creation of the nomogram and are therefore not considered as marker for success of the nomogram. Columns A and B show the preoperative and postoperative astigmatism of all eyes available at the 12 months of visit. Column C shows the SIA. Column D displays the postoperative astigmatism prediction error. As the predicted postoperative astigmatism was 0 in all cases, columns B and D are identical in this study with the notable difference that columns A-C display 1.0 D of astigmatism per ring while column D displays 0.5 D of astigmatism per ring. The black squares display the centroids, the larger ellipses display the 95% confidence ellipse of the whole dataset, while the smaller ellipses around the black squares display the 95% confidence ellipse of the centroids.

astigmatism measurement and a slight underrepresentation of posterior corneal astigmatism, which will be discussed later on. To set our results into perspective, after two months and two years, Chan et al. observed a higher DV (0.87 and 0.74 D to 0.4 and 0.27 D) and a lower CI (0.86 and 0.85 to 0.92 and 0.98) than we did after three and 12 months respectively (Chan et al. 2015; Chan et al. 2016). The IOS (0.62 and 0.51 to 0.28 and 0.20) was favourable in our study. Only 33% of eyes accomplished a postoperative astigmatism of 0.5 D, while the mean postoperative astigmatism was  $0.87 \pm 0.56$  D (97% and  $0.27 \pm 0.23$ D in our study; Chan et al. 2015). Rückl et al. (2013) report a higher variance in their results, achieving astigmatism postoperative of а

 $0.33\pm0.42$  D, a DV of 0.69  $\pm$  0.45 D and CI of  $1.0 \pm 0.44$ . Hirnschall et al. presented results comparing TIOLs and LRI, achieving a postoperative refractive cylinder of 0.62  $\pm$  0.38 D for TIOLs and 0.8  $\pm$  0.58 D for LRI (Hirnschall et al. 2014a). 52% (TIOLs) and 40% (LRI) of eyes achieved a residual refractive astigmatism of  $\leq 0.5D$ , while 96% and 84% could be kept below 1.0 D. We achieved very comparable numbers with our TIOL implantation (Hoffmann et al. 2011). Mean DV was 0.26 (Hoffmann et al. 2013), which compares pretty well to this study. Venter et al. reported a residual refractive cylinder of  $0.55 \pm 0.40$  D after intrastromal femtosecond laser-assisted arcuate incisions (IFSAI) in a mixed group of patients with and without previous refractive cornea surgery (Venter et al. 2013). Roberts et al. compared LRI and FSAI and found better results in eyes with FSAI, reporting postoperative refractive cylinder with 20% to 42% of eyes with cylinder below 0.5 D and 44% to 74% of eyes with postoperative cylinder below 1.0 D, showing mean residual astigmatism of  $0.89\,\pm\,0.54~$  D and  $~1.17\,\pm\,0.69~$  D (Roberts et al. 2018). Lüdeke et al. (2019) reported 83.2% of eyes with ≤0.5D of residual astigmatism. Baharozian et al. (2017) reported on variable success, depending on the orientation of preoperative astigmatism. They reported a mean CI of 1.01 (ATR), 0.95 (OBL) and 0.53 (WTR). The postoperative residual refractive astigmatism resulted in 0.5  $\pm$  0.4 D. Blehm and Potvin (2017) used the Woodcock



**Fig. 2.** Postoperative corneal astigmatism analysis. The mean vector between Lenstar and TMS-5 'real astigmatism' was calculated. Statistic mean posterior corneal astigmatism can be added to the calculation. Each ring represents 0.5 D of Astigmatism. The black square represents the centroid. The small ellipse represents the 95% confidence ellipse of the centroid. The large ellipse represents the 95% confidence ellipse of the dataset.

nomogram on patients with a mean refractive cylinder of  $1.35 \pm 0.3$  D and achieved a reduction of refractive cylinder of  $1.21 \pm 0.42$  D.

In our study, the addition of FSAI did not negatively impact the IOL predictability of cataract surgery. IOL predictability has come a long way and shows accurate results regarding SEQ predictability (Connell & Kane 2019). Newer studies report MAE of 0.33 to 0.38 for regular IOL implantation

(Connell & Kane 2019). In previous studies, our group reported outcomes for TIOL implantation (Hoffmann et al. 2011, 2013). MAE for TIOLs was 0.27 D (Hoffmann et al. 2013), which was even surpassed in this study ( $0.26 \pm 0.19$  D).

The median DEQ of TIOL implantation (0.75 D) is worse to the 0.25 D observed in this study using the Castrop nomogram, although a much higher amount of astigmatism was corrected with the TIOLs (Hoffmann et al. 2011). Results seem stable, and changes from one to 12 months after surgery in SEQ and DEQ were not significant (p = 0.129; p = 0.076).

Chan et al. presented another FSAI nomogram for low and moderate astigmatism (Chan et al. 2015). MAE is not reported, but since the mean SEQ was -1.16 D after two months, our results match very well to that (three months:  $-0.32 \pm 0.9$  D; 12 months

#### Table 3. Visual acuity and refraction.

	Pre-operativ	rely	1 month pos	st-op	3 months po	ost-op	12 months post-op		
Parameter	Mean [SD]	Median [IQR]	Mean [SD]	Median [IQR]	Mean [SD]	Median [IQR]	Mean [SD]	Median [IQR]	
UDVA [logMAR]	0.84 [0.50]	0.80 [0.70]	0.17 [0.27]	0.10 [0.20]	0.14 [0.27]	0.1 [0.20]	0.13 [0.30]	0 [0.20]	
CDVA [logMAR]	0.30 [0.14]	0.30 [0.08]	-0.03 [0.07]	0 [0.10]	-0.05 [0.09]	0 [0.10]	-0.04 [0.10]	-0.10 [0.19]	
SEQ* [D]	-1.76 [3.12]	-1.63 [4.81]	-0.02 [0.25]	-0.13 [0.50]	0.04 [0.38]	0 [0.38]	0.01 [0.25]	0 [0.44]	
DEQ* [D]	3.58 [2.19]	3 [0.08]	0.42 [0.16]	0.5 [0.25]	0.44 [0.23]	0.5 [0.25]	0.32 [0.24]	0.25 [0.25]	
Absolute Prediction Error [D]	_	_	0.22	0.18	0.29	0.28	0.26	0.21	
Prediction Error [D]	-	-	-0.04 [0.27]	-0.07 [0.37]	-0.08 [0.35]	-0.09 [0.5]	-0.08 [0.32]	-0.12 [0.45]	
Cylinder:									
Eyes $\le 0.5 \text{ D} [\%]$	0		81		79		97		
Eyes $\leq 0.75 \text{ D} [\%]$	0		98		98		100		
Eyes $\leq 1.0 \text{ D} [\%]$	11		100		100		100		
SEQ:									
Eyes ± 0.5 D [%]	12		93		91		89		
Eyes ± 1.0 D [%]	16		100		98		100		

Absolute prediction Error = SEQ mean absolute error; DEQ = Defocus equivalent; Prediction Error = SEQ mean error; SEQ = Spherical equivalent.

\* For SEQ and DEQ only eyes with emmetropic target refraction were counted; for Prediction Error and Absolute Prediction Error all eyes were counted.

 $-0.36 \pm 0.85$  D). In patients with plano target refraction, our mean SEQ turned out even better with  $0.01 \pm 0.25$  D. Rückl et al. report outcomes unfavourable to ours due to high scattering  $(-0.41 \pm 1.71$  D) using IFSAI (Rückl et al. 2013). Interesting and comparable results were reported by Lüdeke et al. who performed FSAI in multifocal IOL patients three months after lens exchange and observed no changes in SEQ  $(0.07 \pm 0.38$  D to  $0.05 \pm 0.35$  D; Lüdeke et al. 2019).

Another shared problem is the selection of the appropriate measure where the correction should be based on. The accuracy of this data source is crucial for the success of FSAI. Differences between preoperative corneal measurement techniques were shown as the biggest contributor to miscalculations of astigmatic correction (Hirnschall et al. 2014b). Our study group was able to show promising results for TIOL implantation using a combination of Lenstar keratometry and topography/tomography, the same principles were also applied to this study (Hoffmann et al. 2013). Looking at double angle plots of the difference vector between postoperative RRA and measured corneal astigmatism (Fig. 2), mean vectors with statistical PCA taken into account seemed to provide the most accurate results. These results

are slightly worse than our results in a previous study (Hoffmann et al. 2011).

Simple keratometry of the anterior corneal astigmatism leads to systematic offset (overcorrection of with-the-rule astigmatism (WTR), undercorrection of against-the-rule astigmatism (ATR), shift in oblique axis; Koch et al. 2012; Preussner et al. 2015), which led to the invention of nomograms accounting for posterior astigmatism (Koch et al. 2012; Koch et al. 2013; Abulafia et al. 2015; Reitblat et al. 2016). Still, 5% outliers >0.5 D cannot be fully accounted for by nomograms (Preussner et al. 2015; Ueno et al. 2015). Baharozian et al. (2017) worked these ideas into their nomogram for FSAI and added a variable for axis orientation in keratometer readings.

On top of that, corneal astigmatism is known to change over time that has to be considered for surgery planning (Hayashi et al. 2011). Taking the mean vector of TMS-5 'real astigmatism' and Lenstar, a slight error in PCA will remain unaccounted for. Our CI of 0.98 might be a precursor of this system deviation, as this means that WTR is slightly overcorrected and ATR slightly undercorrected. In part, this is caused by asymmetrical aberrations due to IOL tilt that appears as slight ATR astigmatism in manifest refraction (Langenbucher et al. 2020). Vector addition of statistic PCA might further reduce this source of error. Blehm and Potvin (2017) presented another solution to circumvent this problem: performing the FSAI subsequent to cataract surgery astigmatic correction could be based on the refractive residual cylinder. Nonetheless, basing the correction on the cylinder of refraction poses a factor of uncertainty. Manifest refraction was shown to be a high contributor to miscalculations of astigmatic correction (Grein et al. 2014; Hirnschall et al. 2014b), but is still recommended as benchmark value (Alpins et al. 2012).

Additionally, this eliminates the need to predict any personal SIA from cataract incisions, which can be troublesome because it typically shows a larger variation (Arthur et al. 2016). Our nomogram does not take SIA into account, as an earlier study showed that mean/median SIA was around 0.08D (Hoffmann et al. 2011). As already mentioned above, the problem is mainly the spread rather than the mean value, further factors such as irregular components of corneal astigmatism, IOL aberrations and tolerances of subjective refraction come into play and are hard to distinguish from corneal SIA. Our SD was reported to be 0.41 D, which is close



Fig. 3. Standardized graphs for reporting outcomes of refractive surgery.

to the limits of repeatability with common devices (Visser et al. 2012). Therefore, we deem it negligible and consider our nomogram applicable for concomitant cataract surgery for surgeons with comparable SIA results.

Nonetheless, not dividing the effect of SIA from the effect of the AIs poses a limitation to this study. In a clinical setting, AIs and cataract surgery are hardly separable; therefore, the limitation is shared with similar recent studies. Comparable studies provide either descriptions of their posterior limbal astigmatism-neutral cataract incisions (Schwarzenbacher et al. 2020), their 2.75-mm uniplanar clear corneal incisions (Day et al. 2016), their varying incisions sizes and personal SIA values for different surgeons that went into preoperative calculations (Baharozian et al. 2017), or less precise descriptions of their corneal incisions (Rani et al. 2020; Wortz et al. 2020), while others used one penetrating AI as clear corneal incision for the cataract surgery with a symmetric nonpenetrating AI (Chan et al. 2015). Another general limitation of this kind of studies is the accuracy of the measurement of corneal astigmatism. Hirnschall et al found preoperative measurement of the cornea as the main error source (27% for 3 D cylinder) in toric IOL implantation (Hirnschall et al. 2020). Yet, in an earlier study, Hoffmann et al were able to show that averaging TMS 5 or CASIA values with Lenstar keratometry as performed in this study led to the best predictive precision and best reduction in measurement noise (Hoffmann et al. 2014). The reproducibility of the residual refraction cylinder varies, but SD can be as low as 0.3 D (Grein et al. 2014). Finally, another limitation is the inclusion of bilateral eye data, although we were able to show that unilateral inclusion results do not differ significantly from bilateral results. Overall, the Castrop nomogram showed promising results regardpostoperative ing refractive astigmatism and CI when using a mixture of keratometry and topography/tomography as an indicator of astigmatism. The Vienna work group used the same nomogram in conjunction with the Ziemer Laser and CASIA2 OCT and yielded very similar results up to one year postoperatively (Schwarzenbacher et al. 2020). Postoperative refractive results in cases of low

and moderate corneal astigmatism between 0.75 D and 2.50 D are on par with reported results of TIOL implantation and are at least similar if not favourable to published results of existing nomograms for arcuate incisions in low to moderate corneal astigmatism. Long-term results on the stability of cylinder and SEQ will be interesting for our understanding of this uncomplicated alternative to TIOL implantation or mean for a postoperative correction of manifest refractive astigmatism.

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Received on November 1st, 2020. Accepted on February 12th, 2021.

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reading and language editing our article. This study was author initiated. Some material presented in this manuscript was provided by Bausch & Lomb Technolas. The authors received no financial support for the research, authorship, and/or publication of this article. No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article. Therefore, Dr. Hoffmann did not get financial support from Bausch & Lomb Technolas for the conduct of the study; personal fees from Alcon, personal fees from Bausch & Lomb, personal fees from Johnson & Johnson and personal fees from Carl Zeiss Meditec AG were received outside the submitted work. He has no consulting function in any of the aforementioned companies. There are no further conflicts of interest.