ARTICLE

Correction of astigmatism with small-incision lenticule extraction: Impact of against-the-rule and with-the-rule astigmatism

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Purpose: To determine the influence of against-the-rule (ATR) and with-the-rule (WTR) astigmatism on the outcomes of small-incision lenticule extraction for myopic astigmatism.

Setting: University eye clinic, Aarhus, Denmark.

Design: Retrospective case series.

Methods: One eye of each patient had small-incision lenticule extraction for astigmatism of 1.00 diopter (D) or more. Surgery was performed with a Visumax femtosecond laser. Subjective refraction and Scheimpflug tomography (Pentacam HR) were performed preoperatively and 3 months postoperatively. Cylinder data were evaluated by vector analysis and correlation analyses. Multiple linear regression was used to predict magnitude of error from age, sex, left or right eye, target-induced astigmatism (TIA), subjective ATR/WTR astigmatism, cap diameter, cap thickness, incision width, and back-surface astigmatism.

Results: The study enrolled 829 patients (505 women; median age 37 years). The mean preoperative subjective cylinder was 1.76 D ± 0.86 (SD). Overall, 66% and 95% of patients achieved a refractive cylinder within ±0.50 D or ±1.00 D, respectively. Astigmatism was WTR in 73% of eyes and ATR astigmatism in 16% of eyes. The linear regression model significantly predicted the magnitude of error (R^2 = 0.23, P < .001), with TIA contributing −0.15 D per attempted diopter and subjective ATR astigmatism contributing a constant 0.32 D (both P < .001). No other parameters had a significant impact on the outcome.

Conclusions: Almost 25% of the variation after small-incision lenticule extraction for myopic astigmatism might be explained by the size of the attempted cylinder correction and ATR/WTR astigmatism. Incorporating these parameters in preoperative planning might produce more consistent results in high cylinder corrections.

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Small-incision lenticule extraction (SMILE, Carl Zeiss Meditec AG) has become accepted as an effective means of correcting myopic astigmatism with a high safety profile and a good clinical outcome.[1–6] However, undercorrection of high cylinders has been reported, with an average undercorrection of approximately 10% to 15% depending on the size of the attempted astigmatic correction.[1,2]

In most patients seeking treatment for refractive errors, with-the-rule (WTR) astigmatism predominates due to the age of the population.[7] Still, it remains to be determined whether the axis of the preoperative cylinder influences the outcome of astigmatic small-incision lenticule extraction.

In the present study, vector analysis was used to evaluate the outcome after small-incision lenticule extraction in WTR or against-the-rule (ATR) astigmatism. Furthermore, the impact of back-surface astigmatism on the postoperative outcome was evaluated.

PATIENTS AND METHODS

Patients treated with small-incision lenticule extraction for myopic astigmatism at the Department of Ophthalmology, Aarhus University Hospital, Aarhus, Denmark, between January 2011 and June 2017 were evaluated. All patients who attended the 3-month control and had a preoperative cylinder of 1.0 diopter (D) or more, were included in the study. The study was conducted in agreement with the tenets of the Declaration of Helsinki and was considered a quality-control study, and according to Danish Law, ethical approval was not needed. Informed consent was obtained from all patients before the procedure.

Ocular examinations were performed by highly trained optometrists before and 3 months after surgery. The preoperative and postoperative examinations included uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA),

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manifest refraction, and high-resolution Scheimpflug tomography (Pentacam HR, Oculus). Only healthy patients 18 years or older with a stable preoperative refraction and no ocular pathology were considered for surgery.

Surgical Technique

Surgery was performed using topical anesthesia of 2 drops of oxybuprocaine hydrochloride 0.4% (Novesine 0.4%). Small-incision lenticule extraction was performed using a 500 kHz Visumax (Carl Zeiss Meditec AG) femtosecond laser as previously detailed.[2] Cap thickness ranged from 100 to 130 μm, cap diameter from 7.3 to 8.0 mm, and lenticule diameter from 6.0 to 7.0 mm with a transition zone of 0.0 to 0.1 mm. The laser cut energy index varied between 25 and 34 and the spot spacing between 2.5 μm and 4.5 μm. Lenticule dissection was performed with a blunt spatula, and the lenticule was extracted through a 30-degree to 60-degree incision (approximately 1.9 to 3.8 mm incision) at 12 o'clock. Postoperative treatment comprised of tobramycin–dexamethasone eyedrops (Tobradex) or chloramphenicol–fluorometholone eyedrops 4 times a day tapered over 2 weeks.

Statistical and Data Analysis

One eye of each patient was randomly included in the study. Analyses were performed using Excel for Mac software (version 16.9, Microsoft Corp.), Graphpad Prism (6.0, Graphpad, Inc.), and Stata 15 (Statacorp LLC).

Refractive outcomes were analyzed and presented based on the methods of Reinstein et al.[8] when relevant. Data were stratified according to the preoperative subjective cylinder axis; WTR astigmatism was described as a positive cylinder between 60 degrees and 120 degrees and ATR astigmatism, as a positive cylinder between 0 degree and 30 degrees or between 150 degrees and 180 degrees. Oblique cylinders were not considered. Astigmatic corrections were evaluated with vector analysis and included the determination of the target-induced astigmatism (TIA), surgically induced astigmatism (SIA), difference vector, magnitude of error, and correction index as described by Alpins.[9]

Back-surface astigmatism and axis were measured using the high-resolution Scheimpflug tomography device from posterior simulated keratometry (K) values. The K values were derived from curvature maps at a sagittal angle of 15 degrees (equivalent to ∼3.0 mm diameter) using refractive indices of 1.376 for the cornea and 1.336 for the aqueous.

Statistical tests included the Fisher exact test, chi-square test, unpaired *t* test, Pearson correlation, and linear regression analysis. Multiple linear regression was used to predict the influence on magnitude of error of sex (M/F), eye (left/right), ATR/WTR astigmatism, age, TIA, incision length, cap diameter, cap thickness, and back-surface astigmatism. Only variables with a significant bivariate correlation (continuous variables) or a significant Fisher exact test (dichotomous variables) were included in the analysis. The variance inflation factor was used to test for multicollinearity. For correlation analyses, cylinders with axes between 90 degrees and 180 degrees were reflected through the 90-degree meridian.

RESULTS

The study enrolled 829 patients (505 women) with a mean age of 37.7 years ± 9.1 (SD) (range 18 to 60 years). The WTR group comprised 605 patients (376 women) with a mean age of 37.5 years ± 9.0 (SD) (range 19 to 60 years). The ATR group comprised 131 patients (71 women) with a mean age of 37.8 years ± 9.0 (SD) (range 19 to 57 years).

Tables 1 shows the preoperative and 3-month postoperative characteristics of all patients. Table 2 shows the preoperative and perioperative parameters stratified by WTR and ATR cylinder axis. Table 3 shows the postoperative visual outcomes stratified by the magnitude and axis (WTR or ATR) of the preoperative cylinder.

Efficacy and Safety

The target refraction in 529 eyes was plano. In these patients, the mean UDVA 3 months after surgery was 0.06 ± 0.14 logarithm of the minimum angle of resolution (logMAR) (range −0.30 to 0.70 logMAR). The UDVA was 20/20 or better in 283 eyes (50%) (Figure 1, *A*) and within 1 line of the preoperative CDVA in 434 eyes (77%) (Figure 1, *B*). Sixteen eyes (1.9%) had a loss of 2 or more lines of CDVA, whereas 19 eyes (2.2%) gained 2 or more lines (Figure 1, *C*). The postoperative UDVA and CDVA had no correlation with the magnitude of or the axis of the intended cylinder correction (both $r^2 < 0.01$).

Predictability

Spherical Equivalent Refraction Three months after surgery, a strong correlation was observed between achieved and attempted spherical equivalent (SE) refraction ($r^2 = 0.94$, Figure 1, *D*). 625 eyes (75%) and 777 eyes (94%) achieved a postoperative refraction within ±0.50 and ±1.00 D of the target, respectively (Figure 1, *E*). The mean postoperative error in SE refraction (achieved – attempted) was −0.20 ± 0.50 D and was neither correlated with the magnitude nor axis of the intended cylinder correction ($r^2 = 0.02$ and $r^2 < 0.01$, respectively) (Figure 1, *F*).

Astigmatism Overall, 545 eyes (66%) and 782 eyes (95%) achieved a refractive cylinder within ±0.50 D or ±1.00 D, respectively (Figure 1, *G*). For all attempted cylinder corrections, a higher proportion of patients with ATR than WTR had a postoperative cylinder below 0.50 D or 1.00 D (Table 3). Significantly more patients with more than 3.00 D of ATR astigmatism than patients with more than 3.00 D of WTR astigmatism achieved a postoperative cylinder within ±0.50 D ($P < .005$) (Table 3).

Table 1. Preoperative and 3-month postoperative characteristics of all 829 patients.

Parameter	Preoperative Mean ± SD	Preoperative Range	Postoperative Mean ± SD	Postoperative Range
Sphere (D)	−6.29 ± 2.41	−12.75, 0.00	−0.10 ± 0.58	−3.25, 2.25
Cylinder (D)	−1.76 ± 0.86	−5.00, −1.00	−0.50 ± 0.38	−2.00, 0.00
SE refraction (D)	−7.10 ± 2.20	−13.25, −1.00	−0.20 ± 0.50	−3.63, 1.75

SE = spherical equivalent