

OUTCOMES OF TRIFOCAL TORIC LENS IMPLANTATION IN CATARACT PATIENTS

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SUMMARY

Aim: The aim of our study was to evaluate the outcome of cataract surgeries with implantation of intraocular trifocal toric lens, and to study the accuracy of astigmatism correction, lens rotational stability, and safety of the procedures.

Patients and Methods: Our study comprised 22 eyes of 16 patients who underwent unilateral or bilateral implantation of AT LISA tri toric 939MP, or its implantation in combination with AT LISA tri 839MP. Mean patient age was 58 ± 11 years (39 to 75 years). Mean follow-up was 5 months. Evaluated parameters were preoperative and postoperative decimal corrected (CDVA) and uncorrected (UDVA) distance visual acuity. Uncorrected near (UNVA) and intermediate (UIVA) visual acuity was obtained with Jaeger optotypes. Furthermore, we studied manifest refraction, amount of corneal astigmatism, implanted lens position, and potential complications. Using two types of questionnaires we surveyed patients on their subjective satisfaction with vision.

Results: Spherical equivalent changed from preoperative -1.32 ± 4.05 D (-9.25 to 4.00 D) to postoperative -0.23 ± 0.21 D (-0.75 to 0.00 D). Preoperative corneal astigmatism was -1.97 ± 0.76 D (-4.02 to -1.01 D), manifest astigmatism was -1.70 ± 1.26 D. After the surgery, manifest astigmatism significantly improved to -0.34 ± 0.37 D ($p < 0.001$). Mean monocular UDVA increased from 0.26 ± 0.18 (0.05 to 0.60) to postoperative 0.88 ± 0.13 (0.60 to 1.00) ($p < 0.001$). CDVA also improved significantly, from 0.57 ± 0.24 to a final value of 1.02 ± 0.07 ($p < 0.001$). Mean postoperative monocular UNVA was Jaeger 1-2, UIVA corresponded to Jaeger 3-4.

No serious complications were recorded. Based on the outcome of questionnaires, all patients are satisfied with their vision and they are independent of spectacles.

Conclusion: In the present study we have obtained very good functional outcomes of vision at far, near and intermediate in cataract patients after trifocal AT LISA tri toric lens implantation. Also, total astigmatism in studied eyes was substantially reduced. The treatment led to a high subjective satisfaction of patients and to their independence of spectacles.

Key words: trifocal toric intraocular lens, cataract, astigmatism, refractive outcomes, patient subjective satisfaction

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INTRODUCTION

Cataract surgery is the most frequently performed surgical procedure in ophthalmology, and worldwide is one of the most common surgical procedures of all. An active lifestyle brings with it strenuous demands on vision, in which in addition to refractive error and presbyopia, quality of vision may be impaired in later life by the presence of cataracts.

Currently a suitable method for treating cataracts, and at the same time for correction of presbyopia and refractive error appears to be the implantation of a trifocal intraocular lens; in patients with a high degree of astigmatism implantation of its toric variant. An example is the trifocal toric intraocular lens AT LISA tri toric 939MP (Carl Zeiss Meditec AG) (fig. 1, 2). The first short-term results of implantation of this type of intraocular lens in patients following cataract surgery were published only recently (11, 12). In patients following refractive lens exchange (RLE) (6, 15, 16) or in a combined group (5, 9, 17) the results have so far been presented in the form of lectures at international ophthalmological congresses or as contributions summarising the first experiences with implantation (1).

In addition to the functional results, however, it is important also to evaluate subjective patient satisfaction in order

to verify whether it is appropriate to implant this type of diffractive lens in patients with cataract and with higher astigmatism. Even despite the problem-free course of the operation and the excellent refractive outcomes, patient satisfaction with vision may also be influenced by individual postoperative adaptation to the implanted lens (7).

For this reason, in our cross-sectional study we observed the functional outcomes of postoperative vision, rotational stability of the lens, effectiveness and safety of the procedure and subjective patient satisfaction.

PATIENTS AND METHOD

The study included 16 patients (22 eyes), who during the years 2013 and 2014 underwent cataract surgery with implantation of a trifocal toric lens of the type plate-haptic design AT LISA tri toric 939MP (Carl Zeiss Meditec AG) at the Lexum European Eye Clinic in Prague. The average age of the patients (6 women and 10 men) at the time of surgery was 58 ± 11 years (39 to 75 years). The observation period was on average 5 months.

The indication criterion for treating astigmatism was a value of 0.5 D cyl or more (according to IOL Master). As a rule, within the range of the values 0.5 to 1.5 D cyl a limbal relaxa-

tion incision (LRI) was performed, in the case of higher values a toric lens was implanted. However, the decision was also influenced by the angle of astigmatism, the stability of the lachrymal film and the level of astigmatism in the other eye. Due to worse tolerance of residual astigmatism, at variance with the rule priority was given to the toric variant of the intraocular lens, which also has higher effectiveness of correction in the case of this type of astigmatism. Similarly, implantation of a toric lens was selected for eyes with deteriorated quality and stability of the lachrymal film in order to ensure that no further disruption occurred due to limbal relaxation incisions (LRI). For patients with astigmatism above 1.5 D in one eye and around 1.0 D in the other, a toric intraocular lens was preferred in both eyes for the sake of symmetry and preservation of the same surgical technique.

Examination of patient

Before surgery a complete ocular examination, measurement of decimal uncorrected (UVA) and best corrected (BCVA) visual acuity and instrumental measurements for evaluating the suitability for indication for surgery and the selection of an intraocular lens were performed on all the patients. Biometry and corneal astigmatism were measured using the instrument IOL Master 500 (Carl Zeiss Meditec AG), keratometry was obtained on the basis of measurement using an OCULUS keratograph (OCULUS Optikgeräte GmbH). Intraocu-



Fig. 1 Trifocal toric lens AT LISA tri toric 939MP (Carl Zeiss Meditec AG)



Fig. 2 Trifocal toric lens AT LISA tri toric 939MP (Carl Zeiss Meditec AG)

lar pressure was measured using a tonometer NIDEK NT-2000 (NIDEK CO., LTD.).

To calculate the strength of the intraocular lens we used data from the IOL Master instrument (and upon accordance of keratometry with the corneal keratograph). After entering into a Z-CALC online calculator (Carl Zeiss Meditec AG), a lens strength was selected that led to the smallest possible residual refractive deviation.

Surgical technique

Uncomplicated cataract surgery was performed on all patients. The surgical procedure incorporated local instillation anaesthesia, 2.2 mm wide input corneal incision with one paracentesis, capsulorhexy with a size of 5.0 mm, phacoemulsification (Alcon INFINITI / CONSTELLATION Vision System), implantation of a toric lens into the sac using a BLUEMIXS 180 injector (Carl Zeiss Meditec AG) and its positioning into the axis of astigmatism.

The trifocal toric lens AT LISA tri toric 939M/MP (Carl Zeiss Meditec AG) with diffraction optics has an addition of +3.33 D for near vision and +1.66 D to middle distance. It is produced from hydrophilic acrylate with a hydrophobic surface treatment and enables the correction of astigmatism up to 4.0 D (in the case of the preloaded version; AT LISA tri toric 939MP) or up to 12.0 D cyl (in the case of the non-preloaded version; AT LISA tri toric 939M). The trifocal toric lenses in our cohort were implanted bilaterally, unilaterally (due to the presence of a cataract in only 1 eye) or in combination with the non-toric variant AT LISA tri 839MP. The values of refractive power of the implanted lenses were within the range of 15.50 to 28.00 spherical and from 1.00 to 5.00 cylindrical dioptre.

Postoperative examinations

Postoperative follow-up examinations took place 1 day, 1 week, 1 month and 3 months after the procedure, and further according to the recommendation of the attending physician. All were examined according to the standard procedure for patients following cataract surgery.

During the postoperative follow-up examinations decimal uncorrected and best corrected distance visual acuity was observed using Snellen's optotypes. Jaeger tables were used for measurement of near and middle distance vision. Visual acuity was evaluated both monocularly and binocularly.

For the eyes in our cohort, the position of the implanted lens in mydriasis was also determined using a ray on a slit lamp.

Subjective patient satisfaction

We determined patient satisfaction with vision after the procedure and patients' independence of glasses correction using two questionnaires. The first questionnaire (non-standardised) contained 22 questions with 5 sub-questions relating to patient satisfaction with distance, middle and near vision. The majority of answers were in the form of a 3 point scale, with the possibility of one response. We also determined satisfaction with vision in twilight, when driving a motor vehicle and during regular activities (work with computer, reading various types of printed materials and texts, watching television and

sport). We also asked about the presence of photic phenomena (dispersion and rings around lights). At the end we asked patients to evaluate their overall satisfaction after surgery. The second questionnaire was focused on satisfaction with near vision. This was a standardised Near Activity Vision Questionnaire (NAVQ) (2). The questionnaire contained 10 questions determining the patient's complaints (in connection with vision) during reading a small text, labels and price tags, letters, during writing and reading their own writing, during work with computer and mobile telephone, observing close objects (e.g. when playing cards) etc. The questionnaire was evaluated with the help of an NAVQ score on a scale of 0-100 logits (0 = best evaluation, 100 = worst evaluation).

Data processing

For the data analysis and creation of standard graphs the Datagraph-med program was used (version 4.10; Ingenieurbüro Pieger GmbH, Wendelstein, Germany). The statistical analyses were performed in the STATISTICA program (version 12.7, Dell Software Inc., Aliso Viejo, CA, USA). The normality of the data was tested using a Shapiro-Wilk test. A Wilcoxon non-parametric test was used for testing the differences between preoperative and postoperative values of the studied variables, in the case of comparison of the values of intraocular pressure a pair t-test was used. A p-value lower than 0.05 was considered statistically significant.

RESULTS

The original refractive error of the 22 eyes included in the study cohort was hypermetropia in 14 eyes and myopia in 2 eyes, 6 eyes were originally emmetropic. However, pronounced myopisation occurred in several eyes due to the influence of cataract. Six patients underwent bilateral implantation of an AT LISA tri toric 939MP lens, 4 patients had the toric variant of AT LISA implanted in one eye and three patients the non-toric variant, and 6 patients underwent unilateral implantation of the toric variant.

The preoperative and postoperative average values and range of the observed parameters are summarised in table 1.

The spherical equivalent changed from preoperative values of -1.32 ± 4.05 D (-9.25 to 4.00 D) to -0.23 ± 0.21 D (-0.75 to 0.00 D). After surgery 91% of eyes were within the range of ± 0.5 D and 100% of eyes within the range of ± 1.0 D spherical equivalent (graph 1).

Preoperative astigmatism measured using the IOL Master instrument was -1.97 ± 0.76 D (-4.02 to -1.01 D). Preoperative manifest astigmatism was -1.70 ± 1.26 D, after surgery it significantly improved to the value of 0.34 ± 0.37 D ($p < 0.001$). After surgery 91% of eyes had a cylindrical deviation between 0.0 and 0.5 D (graph 2).

In the studied cohort of eyes there was a statistically significant improvement of monocular BCVA from 0.57 ± 0.24 (0.05 to 0.70) to the result value of 1.02 ± 0.07 (0.90 to 1.20) ($p < 0.001$). After the procedure 91% of eyes gained 1 or more rows of BCVA, 82% gained 2 or more rows. There was no loss of rows of BCVA in any of the patients (graph 3).

Average monocular UVA for distance vision increased from

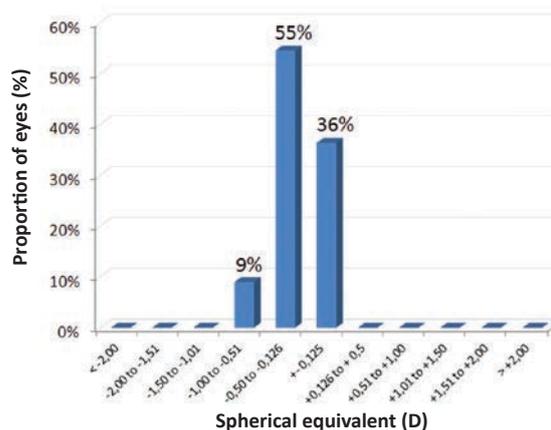
the preoperative value of 0.26 ± 0.18 (0.05 to 0.60) to the postoperative value of 0.88 ± 0.13 (0.60 to 1.00) ($p < 0.001$). After the procedure 71% of eyes had monocular UVA better than 0.9 and 100% of eyes had vision better than 0.5 (graph 4).

Average monocular uncorrected visual acuity for near vision was J1-2 after the procedure, for middle distance vision it corresponded to J3-4 (graph 5).

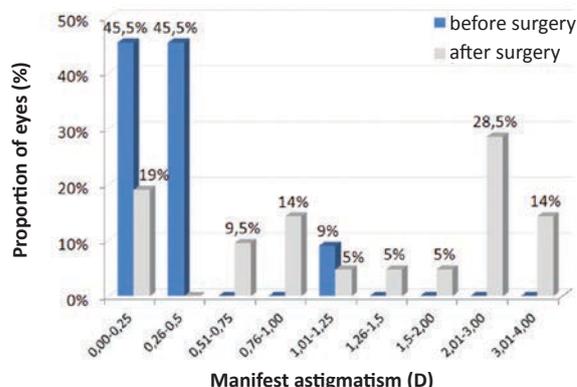
Complications

In the postoperative period it was necessary to reposition the lens in 1 patient due to rotation of the lens. On the first day after the procedure we determined a shift of the implanted lens from the planned axis by 89 degrees. The lens was repositioned, but on the next day we again observed a shift by 66 degrees. Upon the second repositioning of the toric lens a distension ring was concurrently applied. During the course of the further observation period its position was stable. The toric lens in the second eye of this patient remained in the correct position after surgery. In a further 6 eyes a deviation was measured from the planned axis within the range of 2 to 10 degrees, but repositioning of the lens was not necessary in these eyes due to good visual acuity.

Nd: YAG capsulotomy for opacification of the posterior lens



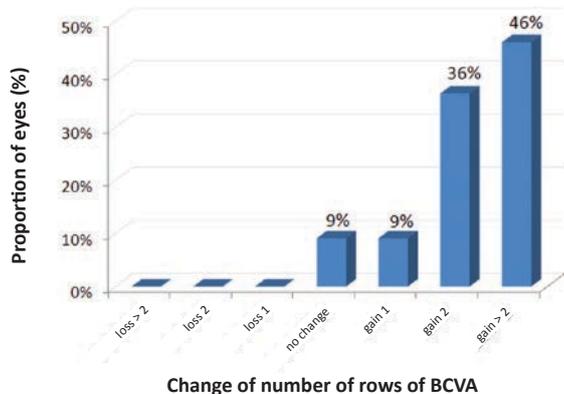
Graph 1 Postoperative spherical equivalent (D) in studied cohort of eyes following cataract surgery with implantation of a trifocal toric intracocular lens AT LISA tri toric 939 MP



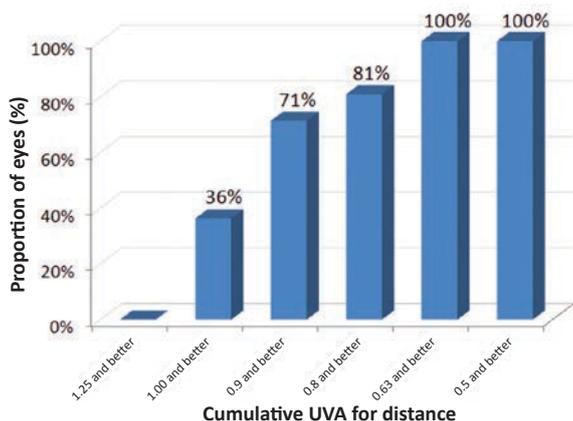
Graph 2 Manifest astigmatism (D) before and after surgery

capsule and reduction of visual acuity on average by 2 rows was performed in 3 eyes at an interval of 4, 5 and 10 months after the procedure.

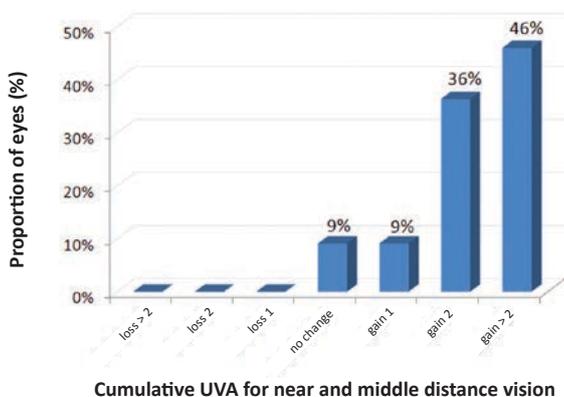
Laser additional correction using photorefractive keratectomy (PRK) was performed in 2 eyes. In the case of the first patient, who had a postoperative spherical deviation,



Graph 3 Change of number of rows of best corrected visual acuity (BCVA) expressing safety of procedure



Graph 4 Cumulative monocular uncorrected visual acuity (UVA) for distance vision after procedure



Graph 5 Cumulative monocular uncorrected visual acuity (UVA) for near and middle distance vision in studied cohort of eyes after procedure

the calculation was performed on the basis of measurement of immersion biometry due to opacity of the cataract, which could have influenced the precision in the calculation of the strength of the lens. The reason for additional correction in the second patient was residual astigmatism. No serious complications were observed.

Satisfaction

The non-standardised questionnaire was completed by 15 patients. 80% of patients were fully satisfied with distance vision, 20% were partially satisfied, none of the patients were dissatisfied. In total 87% of patients were fully satisfied with vision when driving a motor vehicle and 13% of patients were partially satisfied. The patients stated that they wore glasses for driving only exceptionally (87% of patients never, 13% of patients occasionally). All the respondents were satisfied with near vision (93% of patients fully satisfied, 7% partially) and with middle distance vision, e.g. upon work with a computer (93% fully satisfied, 7% partially). The patients are able to read a telephone directory, train timetable or map without glasses (93% fully capable, 7% partially), a menu, newspaper, price list and to write a text message on a mobile telephone (all fully capable), to see a television screen well (93% fully capable, 7% partially) and during sport (93% fully capable, 7% partially).

Perception of disruptive phenomena was stated by 87% of patients. Most frequently these are perceived in twilight (62%) and darkness (69%), less in artificial light (23%) and daylight (8%). Car headlights and dispersion of lights caused some patients complaints (13% of patients had no complaints, 80% slight complaints, 7% complaints, 0% marked complaints). However, 80% of patients do not consider dispersion of lights limiting, 20% consider it slightly limiting, none of the patients consider it markedly limiting.

After the procedure all patients were satisfied with their vision (90% of patients fully satisfied, 10% of patients rather satisfied, no patients dissatisfied) and would recommend the same procedure to close friends or family (90% definitely yes, 10% rather yes). None of the patients were dependent upon glasses correction after surgery. The standardised NAVQ questionnaire focusing on near and middle distance vision was completed by 14 patients, the average NAVQ score was 15.75 ± 10.69 logits (0.00 to 33.30 logits)

DISCUSSION

In our study cataract surgery brought an improvement of best corrected visual acuity, in which more than 82% of patients gained 2 or more rows, and none of the patients recorded the loss of a row. Implantation of a trifocal toric lens also led to a marked reduction of astigmatism and thereby to an overall improvement of uncorrected visual acuity.

Good results of this method are also confirmed by the study conducted by Kretz et al. (11). Average monocular postoperative UVA for distance vision in their study cohort was 0.13 logMAR (~ 0.7-0.8 decimally), whereas in our cohort we measured an average value of 0.88. Average monocular postoperative BCVA for distance vision 0.00 logMAR (~ 1.00 decimally), in their study corresponded to value measured in

Table 1 Average preoperative and postoperative values with ranges of observed variables. Statistically significant differences of these variables before and after the procedure are indicated with a star

	Before procedure		After procedure		<i>p</i> -value
	average ± SD	(min. to max.)	average ± SD	(min. to max.)	
Sphere (D)	-0.46 ± 4.06	(-8.75 to 5.25)	-0.06 ± 0.24	(-0.75 to 0.50)	0.825
Astigmatism (D)	-1.70 ± 1.26	(-4.00 to 0.00)	-0.34 ± 0.37	(-1.25 to 0.00)	<0.001*
Spherical equivalent (D)	-1.32 ± 4.05	(-9.25 to 4.00)	-0.23 ± 0.21	(-0.75 to 0.00)	0.754
UVA (decimal)	0.26 ± 0.18	(0.05 to 0.60)	0.88 ± 0.13	(0.60 to 1.00)	<0.001*
BCVA (decimal)	0.57 ± 0.24	(0.05 to 0.70)	1.02 ± 0.07	(0.90 to 1.20)	<0.001*
IOP (mm Hg)	16.41 ± 2.51	(10.30 to 20.00)	15.00 ± 1.71	(12.00 to 18.00)	0.022*

Note: UVA – uncorrected visual acuity for distance vision, BCVA – best corrected visual acuity for distance vision, IOP – intra-ocular pressure

our study. Average monocular postoperative UVA for centre was better in comparison with our results (0.08 logMAR ~ J2), whereas UVA for near vision was slightly worse (0.13 logMAR ~ J2-3).

Fabian (8) also observed patients following cataract surgery with implantation of an AT LISA tri toric lens. The author states that all 40 patients included in the study had BCVA of 1.0 or better after the procedure, and their minimum near vision corresponded to J3. Average UVA is not stated in the abstract, but in all patients was 0.40 or better (8). The results presented by the authors Monterio et al. (15) demonstrated that refractive lens exchange (RLE) with implantation of an AT LISA tri toric lens in 40 eyes brought average postoperative monocular UVA for distance vision of 0.94, for middle distance of 0.94 and for near vision of 0.75; none of the patients lost a row of BCVA or more (15). In our previous study of the results of implantation of this lens in the first 5 patients (8 eyes) after RLE (16), average postoperative monocular UVA was 0.89, UVA for near vision corresponded to J1-2 and UVA for middle distance vision was J3-4. Manifest astigmatism was reduced from the preoperative value of -1.13 ± 0.53 D to the postoperative value of -0.31 ± 0.41 D (16).

A suitable equivalent could be the toric lens FineVision toric POD FT (PhysIOL), which is (similarly to the AT LISA tri toric 939MP) trifocal, whereas however no studies have been published dealing with the refractive outcomes of this intraocular lens. However, the results of our study are comparable with the results of implantation of non-toric trifocal lenses such as the AT LISA tri 839MP (Carl Zeiss Meditec AG) (13) and FineVision Micro F (PhysIOL) (3, 20). Although uncorrected vision acuity was on average lower by one row in comparison with the results of the AT LISA tri 839MP (13), in comparison with the studies on the implantation of a FineVision Micro F lens conducted by the authors Cochener et al. (3) and Vryghem and Heireman (20), the values measured in our study cohort were virtually identical. Uncorrected visual acuity was in fact 2 rows better than stated by Sheppard etc. (18). Another indisputable advantage of the implantation of the intraocular lens AT LISA tri toric is its possible combination with a non-toric variant in the case of different values of astigmatism of the first and second eye and the wide range of dioptres and cylinders.

One of the aims of implantation of this lens is to resolve astigmatism. In our study cohort we achieved a statistically significant reduction from a preoperative average value of -1.70 ± 1.26 D to -0.34 ± 0.37 D. These results are comparable with the values achieved for a trifocal toric lens in the study conducted by the authors Kretz et al. (11), where astigmatism was reduced from -1.21 ± 1.01 D to postoperative -0.40 ± 0.31 D, and in the study by Mojzis et al. (12), where astigmatism was reduced from -1.80 ± 1.65 to the value of -0.35 ± 0.27 D. A similar result was also achieved in the case of multifocal toric lenses, e.g. Lentis Mplus toric (Occulantis GmbH) (19) and AT LISA toric 909M (Carl Zeiss Meditec AG) (14).

In the case of all types of toric lenses, the precise calculation of the intraocular lens is more complex than for non-toric lenses. The final result thus depends not only on the precisions of measurement before surgery, but also on the surgically indicated astigmatism and the healing of the eye after the procedure. The actual placing of the implanted lens in the sac then depends on a number of factors which cannot be exactly measured or predicted. It is possible to assume that in some eyes the sac may not be entirely symmetrical, which may lead to partial decentration of the lens, and in the case of a smaller eye to its front-to-back misalignment. All these and more factors (neuroadaptation, angle kappa, optical aberration of higher orders etc.), including the correct position of the axis of the lens may then have an influence on the final refractive deviation and remain the subject of examination and professional discussions (4, 10).

The stability of toric intraocular lenses in the eye is of key importance primarily in the case of higher cylindrical defects, where rotation of the lens may substantially reduce the patient's postoperative vision. Even despite the ideal position of the lens in the eye, the precision of the correction of the cylindrical defect may, in addition to the above-stated factors, be linked also to the interval of the individual gradations in the cylindrical correction of the given lens. In the case of the AT LISA tri toric 939M/MP lens the interval of the gradations is 0.5 cylindrical dioptres. The precision of the procedure should therefore be increased if the lens was available in gradations of 0.25 cylindrical dioptres.

Due to the refractive deviation in 2 eyes in the studied group, laser correction using PRK was required, and in 1 eye

repeated rotation of the lens was performed with subsequent application of a distension ring. No serious complications were recorded during surgery or in the postoperative period.

From the patient's perspective above all subjective satisfaction with postoperative vision is of fundamental importance. With the help of a standardised questionnaire we determined that the patients were very satisfied with vision at all three key distances, and did not consider secondary light phenomena to be disruptive. The average score on the Near Activity Vision Questionnaire corresponded to the values determined in patients with multifocal lenses (2, 18) and the results of this standardised questionnaire confirmed high patient satisfaction with near and middle distance vision.

Despite the fact that the short-term results of the implantation of this trifocal toric lens are highly promising, it will be

of fundamental importance to observe the patients further and evaluate the benefit and stability of this procedure over a longer time interval.

CONCLUSION

In patients with cataract and a high degree of astigmatism we achieved a marked reduction of overall astigmatism through the implantation of a trifocal toric lens, which indicates the high effectiveness of this method. From the results it ensues that there is a marked reduction of uncorrected and corrected visual acuity for distance vision, which together with very good visual acuity for near and middle distance vision contributes to high subjective patient satisfaction and independence of wearing glasses.

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