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Perception of Trifocal IOL Performance in Young Adults with High Astigmatism and Hyperopia and its Improvement Using Small Incision Lenticule Extraction

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ABSTRACT

Background: Hyperopia is a kind of refractive error in which incoming light is focused behind, instead of on, the retina wall due to insufficient accommodation by the lens. It is likely affected by ethnicity, geography, and a family history of hyperopia or accommodative esotropia and is categorized as low (≤ 2.00D), moderate (2.00–4.00 D), and high (> 4.00D). Beyond hyperopia refractive error, patients may have poor accommodative function or visual perceptual skills. **Objective**: This study aimed to present the latest approaches to planning trifocal intraocular lens (IOL) and toric trifocal IOL implantation for residual refractive errors in young adults with high astigmatism and hyperopia and increase the patients' best visual outcome and satisfaction using Small Incision Lenticule Extraction (SMILE) after implantation. **Methods**: Eighty eyes of 40 consecutive patients who underwent refractive lensectomy were included in this retrospective study. It included patients aged 20–45 years seeking spectacle independence with pre-operative high spherical hypermetropia of 4D or higher and astigmatism of 3D or higher. Patients' treatment status was categorized as trifocal IOL (n=40) and toric trifocal IOL (n=40).The mean patient follow-up time was six months after IOL implantation. First, we assessed visual acuity and satisfaction for both groups and then examined laser vision correction results of patients who were dissatisfied after IOL implantation (trifocal IOL group) and underwent SMILE surgery to increase satisfaction level. **Results:** There were no statistically significant differences between trifocal IOL and toric trifocal IOL for near (UNVA), intermediate (UIVA), and distance (UDVA) uncorrected visual acuity. Comparisons related to patient satisfaction six months after IOL implantation were statistically significant for using a computer and night driving. In the trifocal IOL group, compared to pre-operative values, sphere and cylinder at six months were significantly improved. **Conclusion:** In young adults, toric trifocal and trifocal IOL provided sufficient results in visual acuity; however, patients were dissatisfied after implantation. This study reported patient satisfaction levels, including quality of life and life without glasses by using Small Incision Lenticule Extraction (SMILE) surgery.

Keywords: SMILE, pseudophaka, trifocal IOL, toric trifocal IOL.

1. BACKGROUND

Hyperopia is a kind of refractive error in which incoming light is focused behind, instead of on, the retina wall due to insufficient accommodation by the lens. It is likely affected by ethnicity (1), geography (2), and a family history of hyperopia or accommodative esotropia (3-5) and is categorized as low (≤ 2.00D), moderate (2.00–4.00 D), and high (> 4.00D). Beyond hyperopia refractive error, patients may have poor accommodative function or visual perceptual skills (6). The current treatment for hyperopia is excimer laser ablation (LASIK or PRK) for low or moderate levels and refractive lens exchange (RLE) for high hyperopia. They are sequential methods of treating large and complex refractive errors and shown to be effective for hyperopia. Intraocular lenses (IOLs) used for RLE, multifocal, trifocal, and toric trifocal have become a vital part of managing aphakia and presbyopia following refractive lensectomy (7). These have allowed surgeons to correct both distances, near

and distance, using multifocal (IOLs); near, intermediate, and distance using trifocal (IOLs) and toric trifocal (IOL), which have been shown to be effective and safe in patients with hyperopia, astigmatism, and cataract (8-12).

Young patients with considerably high hyperopia comprise a challenging population for treatment after phakic IOL implantation is ruled out due to a shallow anterior chamber. In young adulthood hyperopia, there is still considerable uncertainty whether in the presence of or despite optical correction young adults become dissatisfied after IOL implantation. The main reasons for this were post-operative blurred vision and the need for spectacles, especially in the intermediate range (13). Woodward et al. and de Vries et al. evaluated the reasons for blurred vision and presented posterior capsule opacification (PCO), ametropia, dry eye syndrome, and wavefront anomalies as the possible reasons (14, 15).

We need to understand the progression and consequences of hyperopia for the treatment of refractive error. Only then can evidence-based guidelines for refractive correction be provided to clinicians for systematic management of these patients.

2. OBJECTIVE

This study aimed to present the latest approaches to planning trifocal (IOLs) implantation for residual refractive errors after surgery and using Small Incision Lenticule Extraction (SMILE) to increase the best visual outcome and satisfaction of patients leading to better acceptance of trifocal (IOLs) implantations and stimulate further discussion and sight.

3. MATERIAL AND METHODS

Study Population

Eighty eyes of 40 patients who underwent refractive lensectomy in the Department of Ophthalmology, Eye Hospital, Prishtina, Kosova, between June 2018 and June 2019, were included in this retrospective study. It included patients aged 20–45 years seeking spectacle independence with pre-operative high spherical hypermetropia of 4D or higher and astigmatism of 3D or higher. Some patients had amblyopia or strabismus (accommodative esotropia) suitable for refractive lens exchange. We excluded patients with a history of glaucoma, retinal detachment, corneal disease, irregular corneal astigmatism, abnormal iris, macular degeneration, advanced retinopathy, neuro-ophthalmic disease, cataract, keratoconus, ocular inflammation, or ocular surgery. Patients' treatment status was categorized as trifocal IOL and toric trifocal IOL. The trifocal IOL category included patients who underwent implantation of type AT LISA TRI 839MP (Carl Zeiss Meditec, Jena, Germany) followed by SMILE surgery six months later to increase satisfaction. The toric trifocal IOL category included patients who underwent implantation of type AT LISA TRI TORIC 939MP. At the baseline, patients in the trifocal IOL category did not want toric trifocal implantations and preferred trifocal IOL. They were informed that after trifocal implantations they might require retreatment for residual astigmatism via ReLex SMILE treatments. The second group was also informed that after toric trifocal implantations,in case of residual diopter, retreatments via ReLex SMILE could be performed.

The study was approved by the national research ethics committee of the Ministry of Health, Kosovo, and the protocol was registered at clinicaltrials.gov (Clinical trial Reg: NCT04468022).

Written informed consent for all patient information to be published was obtained from each patient. Information about trifocal IOL and toric trifocal IOL implantation plus ReLEx SMILE was provided to each patient.

Pre- and Postoperative Assessments

A complete ocular examination, including slit-lamp examination, Goldman applanation tonometry, measurement of uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest refraction, keratometry, biometry (IOL Master v.4.3, Carl Zeiss Meditec, Jena, Germany), corneal topography (ATLAS, Carl Zeiss Meditec, Dublin, USA), and fundoscopy, was conducted before the surgical procedure. Data obtained from the IOL Master and keratometry were used to corroborate the Atlas 9000. The sphere was calculated using SRK-T, Haigis, Hoffer Q, and Holladay formulas through obtained biometric data from the IOL Master, such as axial length, white-to-white, and anterior chamber depth.We used the Hoffer Q formula to evaluate high hyperopia. Toric IOL calculations were made using the keratometric data from the Zeiss ATLAS 9000 and IOL Master and z-calc. A postoperative evaluation was performed on the 1st day, 1st week, 1st month, 3rd month, and 6th month after the eye surgery. After complete stability of the eyes, uncorrected and corrected visual acuity for distance were assessed. Visual acuity was assessed for uncorrected near (40 cm) distances, intermediate (80 cm) distances, and far (5m) distances to simulate natural daily life activities. The IOL status was assessed to look for any posterior capsular opacity (PCO) or malposition of the lens. First, visual acuity was measured with ETDRS charts using the Sloan family of 5x5 letters as optotypes under photopic conditions using room illumination of 85 cd/m2. Subsequently, measures were converted into LogMAR. Refraction was assessed in terms of diopter for sphere and cylinder.

Questionnaire was administered at the 6-month post-operative follow-up to all patients. It was related to patients' assessment of vision and vision difficulties associated with daily activities such as reading, using a computer, or night driving in the postoperative period. Both toric trifocal IOL and trifocal IOL cases were given questionnaires to assess the following: reading or using mobile phones for distance activities; using a computer for intermediate activities; vision at night driving or night outdoor activities for distance activities. The purpose was to evaluate patient satisfaction and the quality of life. Each question was scored between 0 to 5, where zero presented worst and five presented the best score. Later, grades were converted into 60–100 (20). The trifocal implanted eyes (40) required a laser vision correction procedure using the SMILE technique to treat residual refractive errors, while toric trifocal implanted eyes did not require retreatment.

Surgical Techniques

An experienced surgeon performed all surgeries using a standard sutureless phacoemulsification technique. Topical

anesthesia was administered, and then pharmacological mydriasis was induced using a combination of tropicamide and phenylephrine in all cases. According to the position of the pre-op highest K value of the patient, a mean clear corneal micro-incision of 2.2 mm was made using a surgical knife. A paracentesis was made 60 to 80 degrees, clockwise from the main incision, and the anterior chamber was filled with an ophthalmic viscoelastic (OVD) after phacoemulsification/lensectomy and removal of the clear lens. The IOL was implanted through the main incision using the BLUEMIXS 180 injector (Carl Zeiss Meditec, Jena, Germany) for trifocal IOL and VISCOJECTTM BIO injector for toric trifocal IOL, and then the OVD was removed.

Carl ZEISS VisuMax Femtosecond laser (500 kHz frequency) was used to treat residual refractive errors with the SMILE technique after IOL implantation. First, topical anesthesia drops were applied to the cornea. A low vacuum was used on the cornea after docking the curved cone. Next, an intrastromal lenticule with a 6.5 mm diameter and a 15-micron minimum thickness at the edge was created with the femtosecond laser (140 nJ spot energy) in a shape with the desired refractive correction on the cornea. The lenticule was opened for reachability, dissected manually using Mallosa 1297 spoon type spatula, and removed using forceps. Postoperative pharmacologic treatment was performed with a combination of antibiotics and steroidal anti-inflammatory drops five times a day for a month.

Statistical analysis

SPSS 21.0 (IBM Corp. Armonk, NY) program was used to analyze all data. The distribution of data was tested by the Shapiro-Wilk test. As descriptive statistics, mean ± standard deviation or median (minimum-maximum) were used for quantitative data, and frequency and percentage were used for qualitative data. As the data did not show normal distribution, the Wilcoxon Signed Ranks Test was used to analyze the dependent variables and the Mann-Whitney U test to analyze the independent variables. The significance level was determined as $\alpha = 0.05$.

4. RESULTS

Of 40 patients included in the study, 18 (45.0%) were women, 22 (55.0%) were men, 40 (50.0%) eyes were right, and 40 (50.0%) were left-sided. The overall mean age was 31.18±7.34. Patients were divided into two main groups: Toric trifocal IOL (n=40) and trifocal IOL (n=40) cases. The groups were similar in terms of age (p=0.787), gender (p=0.500), IOL Power (p=0.950), and at the baseline UNVA (p=0.224), UIVA (p=0.161), UDVA (p=0.144), respectively.

Visual Acuity

The preoperative and postoperative 1st day, 1st week, 1st month, 3rd month, and 6th month values of near (UNVA), intermediate (UIVA), and distance uncorrected visual acuity (UDVA) are presented in Table 1 and Figure 1-3 for both study groups. Compared to preoperative values, UNVA at the 1st month was significantly improved (pre-op 0.64±0.03 LogMAR; post-op at one month 0.38±0.25 LogMAR, p<0.001); and UNVA at three months (0.35±0.30 LogMAR, p<0.001) and six months (0.25±0.31 LogMAR, p<0.001) significantly improved according to pre-operative values for trifocal IOL UNVA.

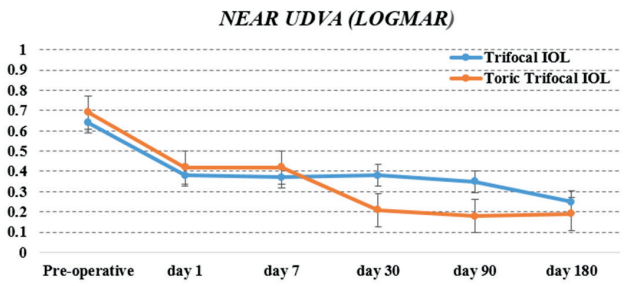

Figure 1.Average UNVA (LogMAR) for both study groups
UNVA significantly improved during the 6-month post-operation period in Trifocal IOL and Toric Trifocal IOL patients.

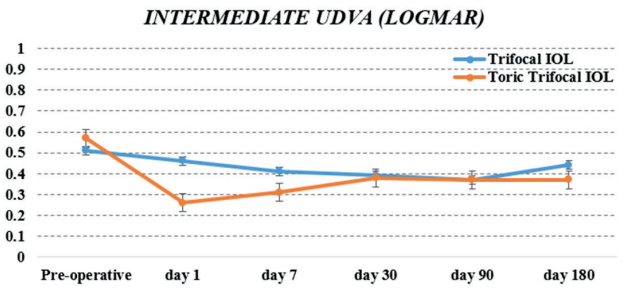

Figure 2. Average UIVA (LogMAR) for both study groups
UIVA significantly improved during the 6-month post-operation period in Trifocal IOL and Toric Trifocal IOL patients.

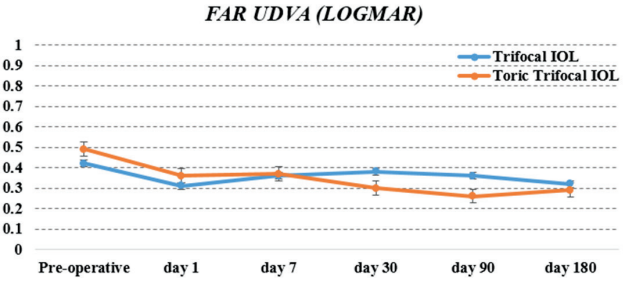

Figure 3. Average UDVA (LogMAR) in both study groups
UDVA significantly improved during the 6-month post-operation period in Trifocal IOL and Toric Trifocal IOL patients.

In the toric trifocal IOL group, compared to pre-operative values, UNVA at 1st month was significantly improved (pre-op 0.69±0.04 LogMAR; post-op at one month 0.21±0.29 LogMAR, p<0.001); UNVA at three months (0.18±0.28 LogMAR p<0.001) and six months (0.19±0.28 LogMAR, p<0.001) significantly improved according to pre-operative values such as trifocal IOL group. In both toric trifocal IOL and trifocal IOL groups, UIVA and UDVA values improved compared to preoperative values, respectively, such as UNVA.

Questionnaire Results

The questions were related to patients' assessment of vision and vision difficulties associated with daily activities such as reading, using a computer, and night driving in the post-operative 6th month. Per the questionnaire results for patient satisfaction, the quality of reading for trifocal IOL mean was 66.75±1.31, and toric trifocal IOL mean was 68.00±1.09, without a statistically significant difference (p=0.254). For the quality of using a computer, the trifocal IOL mean was 64.25 ± 0.94, while toric trifocal IOL mean was 67.5 ± 1.06, showing a statistically significant difference

		PREOPERATIVE	1 DAY	1 WEEK	1 MONTH	3 MONTHS	6 MONTHS
TRIFOCAL IOL	NEAR UDVA						
	Mean±SD	0.64±0.03	0.38±0.20	0.37±0.22	0.38±0.25	0.35±0.30	0.25±0.31
	Median(Min-Max)	0.70(0.20-0.90)	0.50 (0.00-0.70)	0.40 (0.00-0.80)	0.50 (0.10-0.80)	0.40 (0.00-0.80)	0.10 (0.00-0.80)
	p (preoperative)		<0.001*	<0.001*	<0.001*	<0.001*	<0.001*
	p (previous)			0.477	0.854	0.418	0.106
	INTERMEDIATE UDVA						
	Mean±SD	0.51±0.19	0.46±0.23	0.41±0,24	0.39±0.23	0.37±0.24	0.44±0.29
	Median(Min-Max)	0.50 (0.10-0.80)	0.50 (0.00-0.70)	0.50 (0.00-0.70)	0.40 (0.00-0.70)	0.40 (0.10-0.80)	0.50 (0.00-0.80)
	p (preoperative)		0.320	0.069	0.077	0.017*	0.207
	p (previous)			0.027*	0.324	0.178	0.306
	FAR UDVA						
	Mean±SD	0.42±0.21	0.31±0.29	0.36±0.28	0.38±0.24	0.36±0.24	0.32±0.25
	Median(Min-Max)	0.40 (0.10-0.80)	0.40 (0.00-0.70)	0.50 (0.00-0.70)	0.50 (0.00-0.70)	0.40 (0.00-0.70)	0.40 (0.00-0.80)
	p (preoperative)		0.003*	0.129	0.336	0.339	0.096
	p (previous)			0.543	0.633	0.443	0.115
TORIC TRIFOCAL IOL	NEAR UDVA						
	Mean±SD	0.69±0.04	0.42±0.32	0.42±0.33	0.21±0.29	0.18±0.28	0.19±0.28
	Median(Min-Max)	0.75 (0.2-1.00)	0.50 (0.00-0.80)	0.50 (0.00-0.80)	0.10 (0.00-0.80)	0.10 (0.00-0.80)	0.10 (0.00-0.80)
	p (preoperative)		<0.001*	<0.001*	<0.001*	<0.001*	<0.001*
	p (previous)			0.733	<0.001*	0.278	0.317
	INTERMEDIATE UDVA						
	Mean±SD	0.57±0.25	0.26±0.22	0.31±0.26	0.38±0.29	0.37±0.31	0.37±0.32
	Median(Min-Max)	0.60 (0.10-0.90)	0.10 (0.00-0.80)	0.10 (0.00-0.80)	0.40 (0.00-0.80)	0.50 (0.00-0.80)	0.40 (0.00-0.80)
	p (preoperative)		<0.001*	<0.001*	0.006*	0.006*	0.004*
	p (previous)			0.1307	0.183	0.691	0.990
	FAR UDVA						
	Mean±SD	0.49±0.25	0.36±0.24	0.37±0.27	0.30±0.25	0.26±0.25	0.29±0.28
	Median(Min-Max)	0.60 (0.10-0.90)	0.50 (0.10-0.80)	0.50 (0.10-0.80)	0.30 (0.00-0.80)	0.10 (0.00-0.80)	0.10 (0.00-0.80)
	p (preoperative)		0.042*	0.049*	0.005*	0.096	0.008*
	p (previous)			0.669	0.070	0.260	0.063

Table 1. Uncorrected distance visual acuity (UDVA (LogMAR)) change according to the study groups. Each cell reports mean±SD or n. of subjects with a characteristic. *p<0.05

	PREOPERATIVE		POST OPERATIVE (6 MONTH)		P Value
	Mean±SD	Median(Min-Max)	Mean±SD	Median(Min-Max)	
Sphere (D)	-6.04±1.61	-5.87 (-3.50-10.00)	-0.53±0.45	-0.50 (-1.50-0.75)	<0.001*
Cylinder (D)	-2.38±0.39	-2.25 (-1.75-3.25)	-1.69±0.43	-1.75 (-3.00-(-1.00))	<0.001*
Angle	89.32±24.08	92.50 (20.00-136.00)	116.87±43.76	115.00 (40.00-180.00)	0.005*

Table 2. Uncorrected vision acuity (UDVA) before and after application of ReLEx SMILE in Trifocal IOL group patients. Each cell reports mean±SD or n. of subjects with a characteristic. *p<0.05

(p=0.023) between groups. For night driving, the trifocal IOL mean was 63.75 ± 0.93, and toric trifocal mean was IOL 68.5 ± 1.11, and there was a statistically significant difference (p<0.001).

SMILE Surgery Results

The time between the trifocal IOL implantation and SMILE range was six months. Patients in the toric trifocal IOL group did not require laser vision correction using SMILE.Potential refractive reasons for patients' dissatisfaction were reading, using a computer, and night driving. The preoperative and postoperative 6th month values of sphere, cylinderand angleare presented in Table 2. Compared to pre-operative values, sphere at six months was significantly improved (pre-op -6.04±1.61D; post-op at six months -0.53±0.45D; p<0.001). Further, compared to pre-operative values, the cylinder at six months was significantly improved (pre-op -2.38±10.39D; post-op at six months -1.69±0.43D; p<0.001).

5. DISCUSSION

In this study, first, we assessed the visual outcomes of trifocal and toric trifocal IOL platforms. Second, we evaluated the results of young patients who underwent SMILE surgery for residual refractive errors to increase the best visual outcome and satisfaction. To our knowledge, this is the first attempt to provide SMILE surgery as a solution for residual refractive correction after trifocal IOL implantation.

We found that it can be an effective solution to fix the problem. Our findings document that there was no difference between visual outcomes of trifocal IOL and toric trifocal IOL, which is consistent with other studies (16-27).

Many studies have extensively investigated the discrepancies between monofocal and multifocal implantation (7, 9, 10, 18, 28-32). However, discrepancies between trifocal and toric trifocal implantation are not well investigated (8, 20, 21, 32-34). Khandelwal et al. and Leyland and Zinicola showed that monofocal and multifocal lens implantation increased patient satisfaction (7, 10). Multifocal IOL, com-

pared to standard IOL, results in better uncorrected near vision (35). Multifocal and monofocal IOLs had a significant percentage of patient complaints about the low quality of vision, halos, and glare. Moreover, they did not provide intermediate distance (36). Newer diffractive lenses such as trifocal IOL and toric trifocal IOL give better near vision and quality of vision outcomes than refractive lenses (28). Although the main aim of IOL implantation is emmetropia for surgeons, in patients with high astigmatism, residual refractive errors may be present after implantation. They may have a significant role in visual function in terms of patient satisfaction related to a decrease in visual quality and dry eye symptoms.

Some studies showed that approximately 88% of patients were satisfied after multifocal (trifocal) IOLs implants (37, 38), while Maurino et al. found that only 74–80% of their patients were satisfied (39). To increase patient satisfaction, some studies suggest that laser vision correction has been proposed after multifocal IOL implantation (40-42). In our study, patients with trifocal implantation had lower satisfaction than those who had toric trifocal implantation. Therefore, they underwent SMILE surgery to increase their satisfaction level. We selected laser vision correction by SMILE technique because of its advantage of no flap, fewer dry eye symptoms, and lower risk for epithelial growth. Furthermore, most eyes with trifocal implantation (100%) suffered from ametropia with astigmatism greater than 0.50D, followed by myopia and hyperopia. We preferred the threshold of astigmatism as 0.50D because McNeely et al. presented that refractive astigmatism greater than that significantly decreased UDVA after a multifocal IOL implantation, however, there was no impact on uncorrected near visual acuity (43).

The results demonstrated that patients were satisfied with the post-operative visual outcomes. Our results on laser vision correction of refractive errors after multifocal IOL implantation, especially the effective correction of astigmatism, were consistent with other studies (22, 37, 39, 40, 43-47). Residual refractive errors after trifocal implantation can have a significant role in visual function and patient satisfaction, including decreased visual quality and dry eye symptoms. Knowing the visual phenomenon of trifocal lenses, such as glare, halos, and night vision problems, that is significantly worsened by previous refractive errors (hyperopia and high astigmatism) and contrast sensitivity, cataract surgeons should take all precautions to prevent it.

Limitation of the study

The limitations of this study are that interventions with patients with refractory anomalies depends on their choice and desire, while patients with cataracts are forced to choose such an intervention.

6. CONCLUSION

Our study demonstrated that both the non-toric and toric versions of the trifocal IOL obtained and provide an excellent functional vision for patients, with good distance, intermediate and near uncorrected visual acuity for high hyperopia and high hyperopic astigmatism. Especially, toric trifocal IOLs were highly effective for patients with high astigmatism. SMILE technique was effective, safe, and comfortable for both pseudophakic patients and surgeons. Even though toric trifocal and trifocal IOLs provide sufficient results for the best visual acuity, the SMILE surgery may address issues such as quality of life, patient satisfaction, and life without glasses. In pseudophakic patients with residual refraction, the ReLex SMILE method may be the best option. Furthermore, it can be an alternative treatment to LASIK as there is no flap, there are fewer dry eye symptoms, and a lower risk for epithelial ingrowth.

Abbreviations:

IOL: Intraocular lens
SMILE: Small Incision Lenticule Extraction
RLE: Refractive lens exchange
LASIK: Laser-assisted in-situ keratomileusis
PRK: Photorefractive keratectomy
UDVA: Uncorrected distance visual acuity
CDVA: Corrected distance visual acuity
PCO: Posterior capsule opacification
OVD: Ophthalmic viscoelastic

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