

Clinical and Self-Reported Outcomes after Multifocal Intraocular Lens Implantation of Patients with Stable Keratoconus

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Research Article

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Abstract

Background: Multifocal intraocular lens (IOL) implantation is generally not considered in patients with keratoconus; however, it may provide good optical results in selected patients with stage I and II keratoconus based on two case reports.

Aims: To evaluate patient satisfaction and clinical outcomes in this patient population.

Methods: This is a retrospective single-center, non-interventional, non-comparison study. All patients with frank keratoconus who had undergone a trifocal IOL implantation between 2016 and 2019 were invited to participate in this study (18 eyes of 9 patients). Postoperatively, refractive outcomes, contrast sensitivity, and ocular aberrations were recorded. A questionnaire was used for determining patient satisfaction and their quality of life. The mean follow-up time was 31.22 ± 6.38 months.

Results: Postoperatively the patients' uncorrected distance visual acuity improved from 1.13 ± 0.93 to 0.10 ± 0.17 ($p < 0.001$), corrected distance visual acuity went from 0.10 ± 0.11 to 0.05 ± 0.09 ($p = 0.19$), mean refractive spherical equivalent changed from -4.34 ± 4.31 to 0.05 ± 0.51 D ($p < 0.001$), and manifest astigmatism from 2.44 ± 1.92 to 0.88 ± 1.81 D ($p = 0.017$). A target refraction of less than ± 0.50 D was achieved in 17 eyes (94%) and one eye exhibited a hyperopic MRSE of $+2.0$ D. Three eyes (17%) lost 1 line of best corrected visual acuity and no patient lost two or more lines. The patients were independent of glasses in 78% for all distances.

Conclusions: A trifocal IOL currently gives relatively good, predictable results with most patients feeling satisfied with the results of spectacle independence for all distances.

Background

The advancing technology of multifocal IOLs is able to allow spectacle independence with great levels of patient satisfaction in those without astigmatism or in patients with regular astigmatism [1]. The main problem in keratoconus patients is unreliable biometric measurements [2–5]. The irregular astigmatism in keratoconus might not be fully corrected using multifocal toric IOLs and the residual astigmatism may affect the visual outcomes [6, 7]. A cornea with keratoconus is aberrated and a further increase in high order aberrations due to multifocal lens implantation could result in further visual dysfunction for the patient. That is why generally a multifocal IOL implantation is not considered in this population. To date, two studies on patients with keratoconus and multifocal IOL implantation were published [8, 9]. Montano et al. (2014) described good results in one patient with forme-fruste and one with frank keratoconus with residual refraction within 0.5 D in both cases after a trifocal IOL implantation [8]. Doroodgar et al. (2017) performed a prospective study on 10 eyes with stable keratoconus and a toric trifocal IOL [9]. Both studies showed good optical performances and refractive results [8, 9].

There are very few studies regarding phacoemulsification in eyes with keratoconus with most being limited to individual case reports or small case series. This is especially true for patients that had a

trifocal IOL implanted. The aim of this study is to objectively and subjectively evaluate visual results on patients that underwent phacoemulsification with a trifocal IOL implantation with a comprehensive eye examination, biometry, tomography, auto-refractometry, aberrometry, contrast sensitivity testing, and a questionnaire focusing on the need for visual aids and their quality of life.

Methods

This retrospective single-center non-interventional case series included all patients with keratoconus that underwent phacoemulsification with trifocal IOL implantation due to a cataract or a refractive lens exchange, in a private ophthalmic practice setting between 2016 and 2019.

The study was approved by the National Medical Ethics Committee, Ministry of health following the tenets of the Declaration of Helsinki, Oviedo Convention and the National Medical Ethics Codex.

A written informed consent was obtained from all patients.

Patients with stable frank keratoconus that underwent phacoemulsification with a trifocal IOL implantation between 2016 and 2019 were identified, reviewed and invited to participate in this study. The exclusion criteria were a declined cooperation to participate in the study and additional later surgery including IOL exchange but not Nd:YAG capsulotomy. There were no additional exclusion criteria required since the patients had no glaucoma with visual field defects, macular or other changes apart from keratoconus that would influence visual performance. The diagnosis of keratoconus was supported by topographic and tomographic data using Pentacam HR (Oculus Optikgeräte GmbH) and a comprehensive eye examination.

All patients who agreed to participate in the study had a comprehensive eye examination, aberrometry (WaveLight Analyzer II), corneal topography and tomography (Pentacam HR, Oculus Optikgeräte GmbH), biometry (IOL Master 700, Carl Zeiss Meditec AG), OCT of the maculae and optic disk, electronic refractometry, contrast sensibility testing (Sinewave test, Topcon CC-100), monocular and binocular visual acuity at a distance at 3 m, intermediate at 60 cm and near at 40 cm with and without correction. The distances used were the reference distances of the implanted trifocal IOLs determined by the manufacturer. Contrast sensitivity was evaluated by CC-100 Topcon LCD monocularly and binocularly under photopic conditions (luminance of the chart 85 cd/m²) using gray-scale sine-wave gratings. No refractive correction was used with the viewing eye.

Patient satisfaction and quality of life were quantified using a scaled questionnaire with the help of reference photos. The questionnaire included 22 questions regarding the dependence on and the frequency of spectacle or contact lens use, driving capabilities, ocular side effects (glare, halos, starburst, blur) and the overall satisfaction with their vision after surgery.

Available preoperative data included uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest refraction, biometry (IOL Master V. 4.08, Carl Zeiss Meditec AG) and corneal tomography (Pentacam HR, Oculus Optikgeräte GmbH).

All surgeries were executed by a single expert ophthalmic surgeon (MK). Preoperatively the reference marks for IOL axis were done with a patient in a standing position under a slit lamp using an ink marker. A routine small incision cataract surgery or a refractive lens exchange with a temporal 2.5mm clear corneal incision under topical anesthesia and in the bag IOL implantation were done. At the conclusion of the surgery an intracameral antibiotic was applied. There were no intra- or postoperative complications.

Two types of intraocular lenses were used: non-preloaded AT Lisa for 16 eyes (89%) and Pod FT for 2 eyes (11%). Both IOLs are acrylic hydrophilic IOLs with an optic diameter of 6,0 mm. The IOL power formula calculation was made by using the industry based online calculator ZCalc for patients implanted with the AT Lisa. Abulafa-Koch and Barrett II Universal Formula were used for patients implanted with POD FT IOL. Keratometric values for the calculation were taken from the IOL Master V. 4.08 (Carl Zeiss Meditec AG). The mean SE of the IOLs was 15.01 ± 6.90 Dsph (range from 1.25 to 25.5) and astigmatism 3.25 ± 2.78 Dcyl (range from 0 to 8.5). Sixteen eyes (89%) had a toric IOL implanted and 2 eyes (11%) had a non-toric IOL due to low central astigmatism and a mid-peripheral cone.

Statistical Analysis

The statistical analysis was divided into two parts. In the first phase a descriptive analysis was done on all available data from the patients recruited for this study. A univariate analysis was done for key attributes connected to surgery and preoperative UDVA, CDVA, MRSE and astigmatism. The second part of the analysis included the latter attributes and compared them to the postoperative ones. We wanted to see whether the differences were significant. The data distribution of attributes was tested using the Kolmogorov-Smirnov and Shapiro-Wilk tests. From these tests we could see that a normal distribution was seen only in MRSE and astigmatism before surgery, otherwise the data was not normally distributed. The Welch's and Brown-Forsythe tests showed significant differences in mean values of UDVA, MRSE and astigmatism before and after surgery. A parametric analysis was not possible so the Wilcoxon test was used which confirmed the significant changes from the previously mentioned test.

Results

This study was comprised of 18 eyes of 9 patients with stable, frank keratoconus. Of 12 patients identified with having keratoconus that underwent phacoemulsification with trifocal IOL implantation between 2016 and 2019, 2 patients did not respond to the invitation and 1 patient was not invited due to an IOL exchange procedure which he had because of intolerable ocular side effects. There were 9 patients willing and eligible to participate in this study and were included in the analysis. There were 6 women (67%) and 3 men (33%), mean age was 55.89 ± 8.89 years of age (range 40 to 71). Mean follow up time was 31.22 ± 6.38 months (range 23 to 42). Ten eyes (56%) underwent cataract surgery and 8 (44%) had a refractive lens exchange. Preoperative data is shown in Table 1.

All patients had frank keratoconus of which stage I was identified in 8 eyes (44%), stage II in 7 eyes (39%) and stage III in 3 eyes (17%) using the Amsler-Krumeich classification. Four eyes (22%) had previous CXL.

Refractive And Visual Outcomes

The data analysis showed postoperative binocular UDVA 0.02 ± 0.07 logMAR (range 0.22 to 0.00). An improvement was seen in monocular mean UDVA from 1.13 ± 0.93 to 0.10 ± 0.17 logMAR ($p \leq 0.01$), CDVA from 0.10 ± 0.11 to 0.05 ± 0.9 ($p = 0.198$), MRSE from -4.34 ± 4.31 to 0.05 ± 0.51 ($p \leq 0.01$) and manifest astigmatism from 2.44 ± 1.92 to 0.88 ± 1.81 D ($p \leq 0.05$). The study showed a statistically important improvement in UDVA, MRSE and astigmatism and a non-significant improvement in CDVA using the Welch's and Brown-Forsythe test. Postoperative visual outcomes are shown in Table 2.

Improvement in UDVA was seen in 17 eyes (94%), CDVA in 8 eyes (44%), MRSE in 14 eyes (78%) and astigmatism also in 14 eyes (78%), which is graphically presented in Fig. 1. Target refraction of less than ± 0.50 D was achieved in 17 eyes (94%), one eye exhibited a hyperopic MRSE. Three eyes (17%) lost 1 line of CDVA and no eye lost 2 or more lines. The eyes that lost 1 line of CDVA had stage I, II and III keratoconus, one eye each. The overall safety index of the procedure, which is the ratio of mean postoperative to mean preoperative CDVA at final visit, was 1.09.

Biometry And Tomography

Postoperative biometry showed that eyes had an AL of 24.99 ± 2.09 mm (range 21.12 to 27.68) and total spherical equivalent 44.78 ± 1.89 (range 42.93 to 50.62). Anterior chamber depth (ACD) changed from 3.71 ± 0.4 to 4.9 ± 0.47 mm (latter range 4.25 to 5.59). Tomography showed a mean K2 of 45.57 ± 2.44 (range 43.3 to 53.3), Kmax 48.13 ± 3.52 (range 44.0 to 56.6), overall astigmatism 1.96 ± 1.52 (range 0.4 to 5.0) and ARTmax value of 226.5 ± 87.72 (range 91.0 to 464.0).

There was no significant change between pre- and postoperative AL, K1, K2, Kmax, overall corneal astigmatism and ARTmax values.

Contrast Sensitivity

The test was done using four spatial frequencies 3, 6, 12 and 18 cyc/deg. Mean monocular values of Log_{10} contrast sensitivity for these spatial frequencies were 1.95 ± 0.27 , 1.99 ± 0.36 , 1.33 ± 0.45 and 1.08 ± 0.35 , respectively. Mean binocular values were 2.05 ± 0.10 , 2.14 ± 0.18 , 1.45 ± 0.41 and 1.22 ± 0.48 , respectively. The results are shown in Fig. 2.

Ocular Aberrometry

The ocular wave-front aberrations were analyzed for a 4 mm diameter circular area, the data for the 6 mm diameter were not available for all patients. The analysis showed that the degree of aberrations was

highly dependent of the pupil size. The mean root-mean-square (RMS) of coma, trefoil and spherical aberration were $0.39 \pm 0.29 \mu\text{m}$ (range 0.10 to 1.27), $0.2 \pm 0.13 \mu\text{m}$ (range 0.05 to 0.44) and $0.10 \pm 0.09 \mu\text{m}$ (0.01 to 0.3), respectively. The mean total higher order aberrations (HOA) were $0.64 \pm 0.49 \mu\text{m}$ (range 0.16 to 2.06). The results are shown in Fig. 3.

Patient-reported Outcomes And Satisfaction

The questionnaire results showed that independence of glasses was present in 7 out of 9 patients (78%). One patient (11%) needed glasses for reading, 1 (11%) used glasses most of the time for all distances and 1 (11%) used glasses sometimes for reading and very rarely for intermediate distance. The patients had very little problems driving with a mean score of $1,86 \pm 0,90$ (range 1 to 3) on a scale from 1 to 5 with 5 meaning they could not drive due to severe eye problems. Night driving problems reached a score of 2.29 ± 1.10 (range 1 to 5). One patient (11%) did not drive a car and another (11%) drove a car only during daytime due to other reasons. Whether patients' sight caused them trouble in everyday life on a scale from 0 to 5, with 5 causing severe problems, a score of $1.33 \pm 1,0$ (range 0 to 3) was reached.

All patients exhibited glare, halos and starburst. Blurred vision was present in all patients but one (89%). An analog scale from 0 to 5 was used to assess the intensity, frequency and the level of disturbance of ocular side effects, with 0 meaning the patient had no problems and 5 meaning very severe/intense/constant problems. The overall intensity of ocular side effects was 2.56 ± 1.32 , frequency 2.81 ± 1.6 and level of disturbance 2.39 ± 1.48 .

Five out of 9 patients (55,5%) were very happy with the outcome defined by the score 4 and 5 out of 5 with a mean score of 3.44 ± 1.13 (range 0 to 5). The quality of life improvement after surgery reached a score of 4.0 ± 0.71 (range 3 to 5). When asked whether they would refer a friend or family member to undergo surgery if they were in a similar situation, 7 (78%) said yes and two (22%) were undetermined. Details on the questionnaire results can be found in Table 3.

Table 1
Patient Demographics

	Mean \pm SD	Range	
		Minimum	Maximum
No. of eyes	18		
Female : male	2:1 (6:3)		
Age (years)	55.89 \pm 8.89	40	71
Follow up time (months)	31.22 \pm 6.38	23	42
UDVA (logMAR)	1.13 \pm 0.93	2.30	0,,0
CDVA(logMAR)	0.10 \pm 0.11	0.30	0.00
MRSE	-4.34 \pm 4.31	-11.50	1.50
Manifest Astigmatism	2.44 \pm 1.92	0.00	-7.00
K1	43.61 \pm 1.75	41.40	48.00
K2	45.64 \pm 2.30	43.50	52.40
Kmax	48.13 \pm 3.52	44.00	56.60
ARTmax	234.67 \pm 109.80	98.00	510.00
Keratoconus Stage (A-K)	1.72 \pm 0.75	1	3
AL (mm)	25.01 \pm 2.07	21.17	27.74
ACD (mm)	3.71 \pm 0.40	3.10	4.43
AL = axial lenght, ACD = anterior chamber depth			

Table 2
Postoperative visual outcomes (logMAR)

	Mean ± SD	Range		95% Confidence Interval of the mean	
		Minimum	Maximum	Lower	Upper
Monocular					
UDVA	0.10 ± 0.17	0.70	0.00	0.18	0.01
UIVA	0.43 ± 0.18	1.0	0.30	0.52	0.34
UNVA	0.23 ± 0.17	0.70	0.00	0.32	0.15
CDVA	0.05 ± 0.09	0.30	0.00	0.10	0.01
CIVA	0.28 ± 0.16	0.70	0.10	0.36	0.20
CNVA	0.19 ± 0.17	0.60	0.00	0.27	0.11
Binocular					
UDVA	0.02 ± 0.07	0.22	0.00	0.08	-0.03
UIVA	0.31 ± 0.08	0.48	0.18	0.37	0.25
UNVA	0.11 ± 0.12	0.30	0.00	0.20	0.02
CDVA	0.02 ± 0.05	0.15	0.00	0.06	-0.02
CIVA	0.16 ± 0.13	0.40	0.00	0.26	0.06
CNVA	0.05 ± 0.10	0.30	0.00	0.13	-0.02
MRSE (D)	0.05 ± 0.51	-0.50	2.00	-0.20	0.30
Astigmatism (D)	-0.88 ± 1.81	0.00	-8.00	0.02	-1.77

Table 3
Questionnaire analysis

	Mean ± SD	Range	
		Minimum	Maximum
Overall ocular side effects			
Intensity	2.56 ± 1.32	0	5
Frequency	2.81 ± 1.60	0	5
Disturbance level	2.39 ± 1.48	0	5
Day-time driving problems	1.86 ± 0.90	0	3
Night-time driving problems	2.29 ± 1.11	0	4
Overall visual problems in everyday life	1.33 ± 1.0	0	3
Overall satisfaction with current vision	3.44 ± 1.13	1	5
Improvement in quality of life after surgery	4.00 ± 0.71	3	5
Ocular Side Effects include blurred vision, glare, halos and starburst			

We calculated the Pearson correlation coefficients of all attributes and discovered that anterior chamber depth was the single most important variable connected with the intensity ($p \leq 0.01$), frequency ($p \leq 0.05$) and the disturbance level ($p \leq 0.01$) of glare, intensity ($p \leq 0.05$) and disturbance level ($p \leq 0.05$) of halos and disturbance level ($p \leq 0.01$) of starburst. The correlation was inverse meaning that patients with a deeper ACD had fewer ocular side effects. Patients with a better preoperative uncorrected distance visual acuity exhibited intense and disturbing glare ($p \leq 0.05$) and starburst ($p \leq 0.05$). A higher preoperative spherical equivalent was associated with the intensity and frequency of blurred vision ($p \leq 0.05$). A higher K2 was associated with a worse outcome including CDVA and UDVA ($p \leq 0.01$). Interestingly self-reported satisfaction with the visual outcomes had no statistically significant correlations with any objective or other subjective outcomes including postoperative MRSE, CDVA, UDVA, HOA and contrast sensitivity.

Discussion

Data analysis showed an improved UDVA from 1.13 ± 0.93 to 0.10 ± 0.17 ($p \leq 0.001$), CDVA from 0.10 ± 0.11 to 0.05 ± 0.09 ($p = 0.19$), MRSE from -4.34 ± 4.31 to 0.05 ± 0.51 D ($p \leq 0.001$), and manifest astigmatism from 2.44 ± 1.92 to 0.88 ± 1.81 D ($p = 0.017$). Target refraction of less than ± 0.50 D was achieved in 17 eyes (94%) and one eye exhibited a hyperopic MRSE of +2.0 D. This is quite high when comparing results published by Savini et al. (2019) where a refractive error within ± 0.50 D was achieved in 62%, 31%, and 14% of eyes with stage I, II or III keratoconus where a monofocal IOL was implanted [6]. In our study, three eyes (17%) lost one line of CDVA. No eye lost two or more lines of CDVA. Ocular aberrometry and contrast sensitivity testing showed acceptable results [10]. The mean total HOA RMS was higher than in those reported by Carballo-Alvarez et al. (2015) who conducted a study on healthy

eyes after a trifocal diffractive intraocular lens implantation [11]. The results of contrast sensitivity testing are close to the ones investigated by Montes-Mico et al. (2004) and Carballo-Alvarez et al. (2015) in a population of patients with healthy eyes implanted with a multifocal IOL [11, 12].

The analysis of the questionnaire showed a high degree of independence from glasses (78%). Patients were mostly satisfied with the outcome with a mean score of 3.44 ± 1.13 on a scale of 0 to 5, with 5 being very happy. All patients reported an improvement in the quality of life with a mean score of 4.00 ± 0.71 (range 3 to 5) even though all exhibited some degree of ocular side effects. The anterior chamber depth seemed to be the single most important variable associated with halos, starburst, and glare, where patients with a deeper chamber had less ocular side effects. A better preoperative uncorrected distance visual acuity was associated with glare and starburst. Interestingly, the self-reported satisfaction with the visual outcomes had no statistically significant correlations with any of the variables.

The visual and refractive results of the present study are comparable with a case report published by Montano et al. (2014) and a study on 10 eyes by Doroodgar et al. (2017) which also showed good refractive results and optical performances [8, 9]. The patients in our study had similar refractive results but with better contrast sensitivity. Ocular aberrations could not be compared between studies. Lisa et al. (2018) performed a sequential Ferrara-type ICRS and an extended range of vision IOL implantation which provided an improvement in UDVA and CDVA of patients with keratoconus stages I to III and cataract [13]. Due to the specifics of this latter study we could not make a comparison between them.

Even though this study is currently the largest available study in its field, it has a number of limitations. It is a retrospective, single-center study conducted on a small population sample. Also, the questionnaire was developed internally, within our center and was not validated.

This study shows that despite being a controversial procedure in patients with corneal ectasia, a trifocal IOL implantation may be a reasonable option in selected patients with stable and mild keratoconus. Our study demonstrated a high degree of spectacle independence, a self-reported improvement in the quality of life, and significant improvements in UDVA, MRSE, and astigmatism in most patients with stable and mild keratoconus. Given the small sample size it is not possible to reliably define which patients would benefit from the trifocal IOL technology, and which would not. An IOL exchange procedure should be presented as an option in case of ocular side effects before surgery. Additional research is much needed on the subject, especially on determining which are the criteria one has to take into account when considering using trifocal IOL in this population.

Abbreviations

IOL = intraocular lens, OCT = optical coherence tomography, UDVA = uncorrected distance visual acuity, CDVA = corrected distance visual acuity, SE = spherical equivalent, MRSE = mean refractive spherical equivalent, ACD = anterior chamber depth, HOA = high order aberrations, RMS = root-mean-square, CXL = corneal collagen cross-linking

Declarations

Funding: There is no private or public support for this study.

Conflicts of interest/Competing interests: All authors declare that they have no conflict of interest, financial or proprietary.

Availability of data and material: All data generated or analysed during this study are included in this article.

Code availability: NA

Authors' contributions: All authors had substantial contributions, have read and approved the final manuscript.

Ethics approval: The study was approved by the National Medical Ethics Committee, Ministry of Health, Republic of Slovenia following the tenets of the Declaration of Helsinki, Oviedo Convention and the National Medical Ethics Codex.

Consent to participate: A written informed consent was obtained from all patients.

Consent for publication: A written informed consent was obtained from all patients.

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Figures

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Figure 1

A Uncorrected and corrected distance visual acuity; B Difference between UDVA and CDVA; C Postoperative spherical equivalent refractive accuracy; D Postoperative refractive astigmatism.

Image not available with this version

Figure 2

The figure illustrates contrast sensitivity in the patient population under photopic conditions. The shaded area represents the highest 75% of the scores. The test score ranges are indicated by Maximum and Minimum. Median score for the cohort with 95% confidence intervals is shown by the solid line.

Image not available with this version

Figure 3

The figure illustrates mean RMS values of ocular aberrations in the patient population for a 4mm diameter circular area.