

Original Article

Outcomes after bilateral implantation of AcrySof IQ PanOptix trifocal intraocular lens: a prospective interventional study

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ABSTRACT

Background: Implantation of multifocal intraocular lenses (IOLs) is becoming increasingly popular for the treatment of visual demands at various distances in patients undergoing phacoemulsification cataract surgery. We aimed to assess the visual performance and rates of photic phenomena, posterior capsule opacification (PCO), and spectacle independence in patients with bilateral implantation of the AcrySof® IQ PanOptix® multifocal IOL model TFNT00 at one and six months postoperatively.

Methods: This prospective interventional cohort study included adult patients who underwent uneventful phacoemulsification cataract surgery with bilateral implantation of AcrySof® IQ PanOptix® IOL. Uncorrected and corrected visual acuities at far, intermediate, and near distances were measured preoperatively and at the one- and six-month postoperative follow-up examinations. The rates of photic phenomena, postoperative need for near and distance spectacles, and PCO were also recorded.

Results: We included 164 eyes of 82 patients with a male-to-female ratio of 38 (46.3%) to 44 (53.7%) and a mean (standard deviation [SD]) age of 52.37 (7.62) years. There were statistically significant improvements in the visual acuities of both eyes across all distances at the one- and six-month follow-up examinations compared to the preoperative values (all P < 0.001), except for corrected near visual acuity in the right eye (P > 0.05) at six-month. We also detected significant postoperative improvements in visual acuities of both eyes across all distances at the six-month follow-up compared to values at the one-month follow-up (all P < 0.05), except for corrected near visual acuity in the right eye (P > 0.05). The photic phenomenon was reported by 12 (14.6%) of the 82 patients at the six-month postoperative follow-up. Five (6.1%) and eight (9.8%) of the 82 patients reported using spectacles for distance and near, respectively. Additionally, PCO developed in 19 (11.6%) of the 164 included eyes, although it was not clinically significant at six months.

Conclusions: The AcrySof® IQ PanOptix® IOL model TFNT00 is recommended for use, given its excellent performance in all ranges of vision, a high rate of spectacle independence, and a good safety profile. Future comparative studies with longer follow-up periods are warranted to verify superiority of its performance over that of other available multifocal IOLs.

KEYWORDS

presbyopias, cataracts, cataract extractions, phacoemulsifications, visual acuities, multifocal intraocular lens, optical phenomenon, entoptic phenomenon

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INTRODUCTION

After surgical treatment of cataracts using monofocal intraocular lenses (IOLs), the use of corrective glasses is usually required during the postoperative period to improve intermediate and near vision [1]. However, most patients seek spectacle independence at all distances after cataract surgery [2]. Various multifocal IOLs have been developed to overcome these problems. Most IOLs have been proven beneficial in terms of distance and near vision; however, some patients may still require glasses for intermediate vision [1]. The invention of trifocal IOLs with three focal points may reduce the need to improve intermediate vision during the postoperative period. However, there are drawbacks associated with multifocal IOLs, including reduced contrast sensitivity, halos, and increased photic phenomena [2, 3].

Many technological improvements occurred during the development of trifocal IOLs, which were first introduced between 2010 and 2012 [1,4]. There are several differences between these IOLs in terms of optical quality and light distribution behavior [5]. The intermediate focal point was 80 cm in the first-generation IOLs. The recommended length was adjusted according to the average arm length. Accordingly, the optimum length has been estimated at approximately 60-70 cm for a person of average height [1,2,4,6-8]. This adjustment may increase the acuity of intermediate vision, and consequently, patient satisfaction [2,3].

The AcrySof® IQ PanOptix® IOL model TFNT00, which was introduced to the market in Europe in 2015 [4], has certain advantages regarding the intermediate focal length [2, 3]. In contrast to its near and distance focal points, which are similar to those of other conventional trifocal IOLs, its intermediate focal length is 60 cm [9, 10]. Better visual acuity from near (40 cm) to intermediate (60 cm) distances in patients with these IOLs has been reported [2, 4, 8, 11]. These lenses may provide a more comfortable and extended range of intermediate vision [12].

The clinical safety and efficacy of PanOptix IOLs have been studied in different countries, including South Korea and India, using different body morphometrics [1, 2]. Similarly, other studies have addressed the outcomes of cataract surgery performed using this type of IOL in the Turkish population [13-15].

In light of this background, we aimed to reassess the visual performance, spectacle independence, and rates of photic phenomena and posterior capsule opacification (PCO) in patients with bilateral implantation of the PanOptix IOL.

METHODS

This prospective interventional cohort study recruited the eyes of adult patients who underwent uneventful phacoemulsification cataract surgery with bilateral implantation of trifocal IOLs (AcrySof® IQ PanOptix® IOL model TFNT00, Alcon Laboratories, Inc., Fort Worth, TX, USA) between January 2019 and January 2020 at the tertiary referral center of Akdeniz University, Faculty of Medicine, Department of Ophthalmology, Antalya, Turkey. This study was approved by the Akdeniz University Clinical Research Ethics Committee (approval code: 09.09.2020/690). This study was conducted in accordance with the principles outlined in the Declaration of Helsinki. All patients provided written informed consent after their briefing on the study protocol.

This study consecutively included all patients aged ≥ 18 years who underwent uneventful phacoemulsification with bilateral implantation of the AcrySof® IQ PanOptix® IOL. The exclusion criteria were (1) any pathologies of the ocular surface, choroid, retina, or optic nerve, (2) clinically significant ectatic diseases of the cornea (keratoconus, keratoglobus, or pellucid marginal degeneration), (3) amblyopia, (4) neurological or psychological diseases leading to cooperation concerns, (5) previous eye surgery, (6) zonular fiber weakness in more than one quadrant, (7) mature or traumatic cataracts preventing retinal examination, (8) corneal astigmatism > 0.75 diopter, (9) any intraoperative complications impacting surgical success, (10) postoperative complications other than PCO, (11) irregular follow-up examinations during the six postoperative months, and (12) unwillingness to participate.

All eligible patients underwent complete ophthalmologic examinations before surgery and at the one-and six-month postoperative follow-ups. Uncorrected and best-corrected visual acuities were measured using a Snellen chart (Autochart Projector, CP-670; Nidek Co., Ltd., Gamagori, Japan). The uncorrected and best-corrected visual acuities were evaluated at far (4 m), intermediate (60 cm), and near (40 cm) distances using the Snellen chart, and measurements were repeated at the first and sixth postoperative months after the second eye surgery. The visual acuity values were converted to the logarithm of the minimum angle of resolution (logMAR) using a logarithmic reading chart [16]. Intraocular pressure was measured using a non-contact intraocular pressure tonometer (Topcon CT-80; Topcon Corp., Tokyo, Japan). A detailed undilated / dilated slit-lamp biomicroscopy examination (Photo-Slit Lamp BX 900; Haag-Streit, Koeniz, Switzerland)

of the anterior and posterior segments was performed. All eyes underwent non-cycloplegic autorefraction and keratometry assessment (KR-800 autorefractor; Topcon Corp.), along with swept-source macular optic coherence tomography imaging (DRI OCT-1 Triton; Topcon Corp.).

Biometric IOL power calculations were performed during the preoperative evaluations using the Zeiss IOL Master 500 (Carl Zeiss Meditec AG, Oberkochen, Germany). In selected cases, at the discretion of the attending ophthalmologist, the measurements were recalculated using manual keratometry (Haag-Streit Javal-Schiotz-type keratometer; Haag-Streit AG), ultrasonographic biometry using a soft-touch A-scan hand-held probe (Ocuscan; Alcon Laboratories), and Scheimpflug topography (Pentacam HR, Oculus Optikgerate GmbH, Wetzlar, Germany).

A single experienced surgeon (M.U.) performed all surgeries. Specifications of the surgical technique are detailed in the literature [17, 18]. The second eye surgery was performed within 1 - 3 weeks of the first eye surgery.

Postoperatively, we prescribed moxifloxacin 0.5% ophthalmic solution (Vigamox, Alcon Laboratories) every hour on the first day, with tapering from the second day until the end of the second week. Dexamethasone ophthalmic drops (Maxidex, 0.1%; Alcon Laboratories) were administered every hour on the first day, decreased on the second day to one drop four times per day, and gradually tapered to one drop every week for up to four weeks.

The presence of photic phenomena or dysphotopsia [14] was determined based on the patients' reports, and the postoperative need for near or distance spectacles and the development of PCO were evaluated at the six-month follow-up.

IBM SPSS Statistics for Windows (version 21.0; IBM Corp., Armonk, NY, USA) was used for statistical analysis. The normality of the numerical variable distributions was assessed using the Shapiro – Wilk test, a normal quantile-quantile plot, and histograms. Descriptive statistics are expressed as mean and standard deviation (SD) for continuous variables. Categorical variables are expressed as frequencies and percentages. The independent-samples t-test was used to compare two independent groups that included numerical variables with normal distributions. The paired-samples t-test was used to analyze differences between the measurements within groups for variables with a normal distribution. In all statistical analyses, the significance level was set at P < 0.05.

RESULTS

Overall, 164 eyes of 82 patients with a male-to-female ratio of 38 (46.3%) to 44 (53.7%) and a mean (SD) age of 52.37 (7.62) years were included. The preoperative and postoperative visual data are presented in Table 1. Compared to the preoperative values, there were statistically significant improvements in corrected and uncorrected visual acuity measurements across all distances at the one- and six-month follow-up examinations for both eyes (all P < 0.001), except for corrected near visual acuity (CNVA) in the right eye (P > 0.05) at sixmonth (Table 1).

The mean (SD) preoperative corrected distance visual acuity (CDVA) was 0.50 (0.28) logMAR and 0.48 (0.28) logMAR in the right and left eyes, respectively. Postoperative mean (SD) CDVA was 0.09 (0.09) logMAR

Table 1. Comparison of preoperative corrected and uncorrected near, intermediate, and distance visual acuities with one-month and six-month postoperative outcomes for both eyes

Preoperative 1-month postoperative 6-month postoperative

Variable

w - 11	Preoperative		1-month postoperative			6-month postoperative				
Variable	OD	os	OD	$P_{_1}$	os	$P_{_1}$	OD	P_{2}	os	P_{2}
UDVA (logMAR), Mean ± SD	0.58 ± 0.21	0.57 ± 0.21	0.18 ± 0.14	< 0.001	0.20 ± 0.15	< 0.001	0.12 ± 0.12	< 0.001	0.12 ± 0.12	< 0.001
UIVA (logMAR), Mean ± SD	0.36±0.10	0.34±0.13	0.31 ± 0.12	< 0.001	0.29 ± 0.11	< 0.001	0.26±0.09	< 0.001	0.22 ± 0.08	< 0.001
UNVA (logMAR), Mean ± SD	0.37 ± 0.09	0.35 ± 0.08	0.30 ± 0.11	< 0.001	0.29±0.11	< 0.001	0.26±0.09	< 0.001	0.26 ± 0.09	< 0.001
CDVA (logMAR), Mean ± SD	0.50 ± 0.28	0.48 ± 0.28	0.09 ± 0.09	< 0.001	0.10 ± 0.09	< 0.001	0.05 ± 0.06	< 0.001	0.05 ± 0.07	< 0.001
CIVA (logMAR), Mean ± SD	0.29 ± 0.07	0.29 ± 0.09	0.25 ± 0.06	< 0.001	0.23 ± 0.07	< 0.001	0.23 ± 0.04	< 0.001	0.21 ± 0.05	< 0.001
CNVA (logMAR), Mean ± SD	0.32 ± 0.04	0.31 ± 0.04	0.23 ± 0.06	< 0.001	0.23 ± 0.06	< 0.001	0.22 ± 0.05	0.068	0.21 ± 0.05	< 0.001

Abbreviations: OD, right eye; OS, left eye; UDVA, uncorrected distance visual acuity; logMAR, logarithm of minimum angle of resolution; SD, standard deviation; UIVA, uncorrected intermediate visual acuity; UNVA, uncorrected near visual acuity; CDVA, corrected distance visual acuity; CNVA, corrected near visual acuity; CIVA, corrected intermediate visual acuity. Note: P-values < 0.05 are shown in bold; P₁, P-value from test comparing one-month postoperative visual outcomes with baseline or preoperative values; P₂, P-value from test comparing six-month postoperative visual outcomes with baseline or preoperative values.

Table 2. Comparison of visual outcomes between one- and six-month postoperative follow-up

Variable	1-month postoperative	6-month postoperative	P-value
OD UDVA (logMAR), Mean ± SD	0.18 ± 0.14	0.12 ± 0.12	< 0.001
OS UDVA (logMAR), Mean ± SD	0.20 ± 0.15	0.12 ± 0.12	< 0.001
OD UIVA (logMAR), Mean ± SD	0.31 ± 0.12	0.26±0.09	< 0.001
OS UIVA (logMAR), Mean ± SD	0.29 ± 0.11	0.22 ± 0.08	< 0.001
OD UNVA (logMAR), Mean ± SD	0.30 ± 0.11	0.26 ± 0.09	< 0.001
OS UNVA (logMAR), Mean ± SD	0.29 ± 0.11	0.26 ± 0.09	< 0.001
OD CDVA (logMAR), Mean ± SD	0.09 ± 0.09	0.05 ± 0.06	< 0.001
OS CDVA (logMAR), Mean ± SD	0.10 ± 0.09	0.05 ± 0.07	< 0.001
OD CIVA (logMAR), Mean ± SD	0.25 ± 0.06	0.23 ± 0.04	< 0.001
OS CIVA (logMAR), Mean ± SD	0.23 ± 0.07	0.21 ± 0.05	< 0.001
OD CNVA (logMAR), Mean ± SD	0.23 ± 0.06	0.22 ± 0.05	0.068
OS CNVA (logMAR), Mean ± SD	0.23 ± 0.06	0.21 ± 0.05	0.013

Abbreviations: OD, right eye; OS, left eye; UDVA, uncorrected distance visual acuity; logMAR, logarithm of minimum angle of resolution; SD, standard deviation; UIVA, uncorrected intermediate visual acuity; UNVA, uncorrected near visual acuity; CDVA, corrected distance visual acuity; CIVA, corrected intermediate visual acuity; CNVA, corrected near visual acuity. Note: *P*-values < 0.05 are shown in bold.

for the right eye and 0.10 (0.09) logMAR for the left eye at the one-month follow-up, and 0.05 (0.06) logMAR for the right eye and 0.05 (0.07) logMAR for the left eye at the six-month follow-up. Compared to preoperative values, there were significant improvements in CDVA at the postoperative one- and six-month follow-ups for both eyes (all P < 0.001).

We also detected significant postoperative improvements in uncorrected distance visual acuity (UCDVA), uncorrected and corrected intermediate visual acuities (UCIVA and CIVA, respectively), and uncorrected near visual acuity (UNVA) at the first and sixth months in both eyes (all P < 0.001). Despite a significant improvement in CNVA at one month in both eyes and at six months in the left eye (P < 0.001), there was a borderline but insignificant improvement in CNVA in the right eye at six months compared with the preoperative CNVA (P > 0.05) (Table 1).

UCDVA, UCNVA, UCIVA, CDVA, CIVA, and CNVA were significantly improved at the six-month follow-up compared to the one-month values in both eyes (all P < 0.05), except for a borderline but insignificant improvement in the CNVA of the right eye at the six-month follow-up (P > 0.05) (Table 2).

The photic phenomenon was reported by 12 (14.6%) of the 82 patients at the six-month postoperative follow-up. Five (6.1%) and eight (9.8%) of the 82 patients reported using spectacles for distance and near, respectively. Additionally, PCO developed in 19 (11.6%) of the 164 included eyes, although it was not clinically significant at the six-month follow-up. Laser posterior capsulotomy was not required

DISCUSSION

The results of this six-month prospective study revealed that the AcrySof® IQ PanOptix® IOL model TFNT00 led to considerable improvements in visual acuities from near to far distances and was safe and effective.

PanOptix multifocal IOL function is based on nonsequential diffractive optics, enhancing distance visual acuity [2]. Considering the importance of intermediate visual acuity during daily activities, the focal points of trifocal IOLs are essential for maintaining natural and comfortable distances during these activities. A focal point of 80 cm may be greater than the approximate arm length of a person with height < 205 cm. Therefore, the average height of the population should be considered when selecting the intermediate focal point of a trifocal IOL [2]. According to population-based studies, a height of 153 – 161 cm correlates to an arm length of 65 –7 3 cm [2]. The average arm length in Korean individuals is reportedly 54 cm [1]. Considering studies conducted in Indian and Korean populations, relaxed arm length was deemed as 60 cm in this study, which applies to the Turkish population. Accordingly, the PanOptix IOL was selected given its 60-cm intermediate focal length [1, 2]. Although we did not consider the average arm length of our participants, they experienced significant improvement in intermediate vision, along with distance and near vision, in both eyes.

Continuous range of vision after IOL implantation is regarded as an interesting outcome. Previous studies revealed high levels of distance, intermediate, and near visual acuity in patients after PanOptix IOL implantation [12, 19-21]. Ramamurthy et al. [2] demonstrated improvements in binocular and monocular best-corrected and uncorrected visual acuities at all distances. They also found that most patients achieved binocular 0.1 logMAR or better vision across all distances [2]. Kim et al. reported similar outcomes [1]. Garcia-Perez et al. [20] studied short-term (one month) visual outcomes after PanOptix multifocal IOL implantation, reporting good intermediate performance and almost 95% spectacle independence [20]. We observed significant improvement in vision across all distances, with more than 90% spectacle independence. The degree of improvement was not categorized for all the distances. The results of this study were broadly equivalent to those reported in the literature (Table 3). Nevertheless, significant improvements in CDVA were observed at the one- and six-month

Table 3. Summary of outcomes of studies on AcrySof IQ PanOptix trifocal intraocular lens implantation published since 2016

Author (Year)	Type of study	Participants	Outcomes
Jeon et al. (2023) [33]	Retrospective observational study.	Outcomes of AcrySof IQ PanOptix IOL in 296 eyes of 296 patients.	Eyes had a stable visual acuity and refractive error up to three years postoperatively.
Abe et al. (2023) [34]	Prospective comparative study.	Comparing reliability and global indices parameters of perimetry after AcrySof IQ PanOptix IOL (23 eyes of 13 patients) versus extended depth Tecnis Symfony IOL (22 eyes of 14 patients).	Significant changes between preoperative and postoperative pattern standard deviation values with AcrySof IQ PanOptix IOL implantation.
Chang et al. (2023) [28]	Prospective, observational case series.	Bilateral implantation of AcrySof IQ PanOptix IOL in 54 eyes of 27 patients.	Up to three-month postoperative assessment, patients had satisfactory visual outcomes with a high quality of vision and life scores and 100% spectacle independence.
Rementeria- Capelo et al. (2022) [35]	Comparative study.	Comparing vision outcomes after bilateral AcrySof IQ PanOptix IOL implantation (28 eyes of 14 patients) versus RayOne IOL (26 eyes of 13 patients) at 3-month postoperative examination.	Overall good visual outcomes and a high rate of patient satisfaction with both IOLs.
Moshirfar et al. (2022) [36]	Retrospective comparative study.	TECNIS Synergy IOL implantation in 105 eyes of 69 patients and AcrySof IQ PanOptix IOL implantation in 119 eyes of 71 patients.	More eyes with PanOptix IOL had an uncorrected distance visual acuity better than 20 / 40 at three months, and eyes with TECNIS Synergy IOL had a significantly better near visual acuity at three- and sixmonth postoperative examinations.
Rementeria- Capelo et al. (2022) [37]	Prospective case series.	Included 61 eyes of 61 patients with AcrySof IQ PanOptix IOL implantation.	Good toleration of residual astigmatism of up to 0.50 D at all distances.
Imburgia et al. (2022) [38]	Prospective, non- randomized case- series.	Outcomes after bilateral implantation of Rayner RayOne Trifocal IOL, AcrySof IQ PanOptix IOL, and Alcon AcrySof IQ SN60WF monofocal IOL; implantation of each IOL in 32 eyes of 16 patients.	Superior visual acuity at all distances by multifocal IOLs (RayOne and AcrySof IQ PanOptix).
Bamdad et al. (2022) [39]	Cross-sectional prospective study.	Implantation of traditional Acrysof SN60WF IOL and AcrySof IQ PanOptix IOL in 58 and 33 patients, respectively.	Improved vision-related quality of life score with both IOLs. AcrySof IQ PanOptix IOL implantation led to an increased patient satisfaction in near and intermediate vision.
Farvardin et al. (2021) [40]	Prospective, non-randomized, comparative study.	Bilateral implantation of Acrysof IQL PanOptix and Tecnis Symfony IOL in 80 eyes of 40 patients.	Good vision for far, intermediate, and near distances for both IOLs. However, the 25-item National Eye Institute Visual Function Questionnaire score for near vision and sum score was significantly higher after Acrysof Pan
Teshigawara et al. (2021) [41]	Single-center, open- label study.	Bilateral implantation of AcrySof IQ PanOptix IOL ($n = 80$ patients) and TECNIS Symfony IOL ($n = 80$ patients).	A significantly larger halo size with AcrySof IQ PanOptix IOL and a higher halo intensity in Symphony IOL throughout the six-month observation period.
Ison et al. (2021) [29]	Prospective, consecutive, observational study.	Bilateral implantation of AcrySof IQ PanOptix IOL in 134 eyes of 67 patients.	Increased patient satisfaction, excellent visual outcomes, and 96% spectacle independence rate at three-month postoperative assessment.

 $Continued \ Table \ 3. \ Summary \ of outcomes \ of \ studies \ on \ AcrySof \ IQ \ PanOptix \ trifocal \ intraocular \ lens \ implantation \ published \ since \ 2016$

ince 2016 Author (Year)	Type of study	Participants	Outcomes
		•	
Alio et al. (2021)	Prospective,	IOL implantation in 194 eyes: AcrySof	Highest value of far distance retinal image
[42]	comparative,	SA60AT (n = 19 eyes), Miniwell (n = 19 eyes),	quality reported for AT LISA Tri, SA60AT,
	consecutive, case	LENTIS Mplus LS-313 MF30 (n = 24 eyes),	and PanOptix IOLs.
	series.	LENTIS Mplus LS-313 MF15 (n = 33 eyes),	
		AkkoLens Lumina (n = 17 eyes), AT LISA Tri	
		839MP (n = 31 eyes), Precizon Presbyopic	
		(n = 20 eyes), AcrySof IQ PanOptix (n = 20	
		eyes), and Tecnis Eyhance $(n = 11 \text{ eyes})$.	
Moshirfar et al.	Retrospective, single	Bilateral implantation of AcrySof IQ PanOptix	Better near visual acuity with AcrySof IQ
(2021) [43]	center, comparative	non-toric (n = 83), AcrySof IQ PanOptix toric	PanOptix IOL at one-month postoperative
	study.	(n=30), Symfony non-toric $(n=70)$, and	exam, but similar uncorrected or corrected
		Symfony toric (n = 38) IOLs in 221 eyes of	distance visual acuity at day one, one month
		146 patients.	and three months for both AcrySof IQ
			PanOptix and Symfony IOLs.
Hovanesian et al.	Prospective, open-	Outcomes after implantation of AcrySof IQ	Significantly greater spectacle independence
(2021) [30]	label, multicenter,	PanOptix or PanOptix Toric IOL (n = 59	with AcrySof PanOptix IOL.
	comparative study.	eyes) versus AcrySof ReSTOR 2.5 / 3.0 or	•
	,	ReSTOR ActiveFocus 2.5 mini-monovision	
		IOL (n = 191 eyes).	
Nicula et al.	Retrospective, single	Bilateral implantation of Acrysof IQ Panoptix	Good vision at all distances, with a good
(2020) [31]	center study.	IOL in 128 eyes of 64 patients.	quality of vision and refraction, a high
·/ L1			satisfaction rate, and 97.65% spectacle
			independence at one-year postoperative
			assessment.
Lapid-Gortzak et	Prospective, parallel-	Bilateral implantation of AcrySof	Better visual performance at near and
al. (2020) [3]	group, multicenter,	IQ PanOptix (n = 93 patients) or AT LISA tri	intermediate distances with AcrySof IQ
ai. (2020) [3]	randomized, double-	839MP (n = 89 patients) IOL in 182 patients.	PanOptix IOL than with AT LISA tri 839Ml
	masked,	639WII (II = 69 patients) IOL III 162 patients.	IOL.
	postmarketing clinical		IOL.
	trial.		
Serdiuk et al.	Retrospective,	Bilateral implantation of hydrophilic trifocal	All three IOLs were safe and effective for the
(2020) [44]	-	Liberty 677MY capsular bag IOL, hydrophilic	correction of presbyopia.
(2020) [44]	comparative study.		correction of presbyopia.
		AT LISA tri 839M lens, or hydrophobic	
		AcrySof IQ PanOptix IOL in 90 eyes of 45	
I/: t -1 (2020)	Documention	patients.	III. I
Kim et al. (2020)	Prospective,	Bilateral implantation of AcrySof IQ PanOptix	High patient satisfaction and spectacle
[1]	multicenter, single-	IOL in 88 eyes of 44 patients.	independence rates with < 0.1 logMAR
	arm study.		binocular visual acuity at all distances at thre
			month postoperative examination.
Ribeiro et al.	Prospective	Bilateral implantation of FineVision POD F,	All had comparable near, intermediate, and
(2020) [45]	randomized	RayOne Trifocal, or AcrySof IQ PanOptix	distance visual acuities at a three-month
	comparative study.	IOL in 90 eyes of 45 patients.	postoperative examination, and eyes
			experienced a complete vision restoration
			with good Quality of Vision questionnaire
			scores.
C 1 (222)	Dragnactive	Bilateral implantation of AcrySof IQ PanOptix	Both had similar near, intermediate,
Song et al. (2020)	Prospective		
	comparative study.	and mix-and-match implantation of TECNIS	and distance visual acuities at six-month
Song et al. (2020) [46]		and mix-and-match implantation of TECNIS Symfony ZXR00 / TECNIS ZLB00 + 3.25 D	and distance visual acuities at six-month postoperative examination. The AcrySof
		Symfony ZXR00 / TECNIS ZLB00 + 3.25 D	postoperative examination. The AcrySof IQ PanOptix IOL was more appropriate for
		Symfony ZXR00 / TECNIS ZLB00 + 3.25 D	postoperative examination. The AcrySof IQ PanOptix IOL was more appropriate for
[46] Kohnen et al.	comparative study.	Symfony ZXR00 / TECNIS ZLB00 + 3.25 D in a total of 50 patients.	postoperative examination. The AcrySof IQ PanOptix IOL was more appropriate for patients with enhanced near vision demands Good vision outcomes at the one-year
[46] Kohnen et al.	comparative study. Prospective, single-	Symfony ZXR00 / TECNIS ZLB00 + 3.25 D in a total of 50 patients. Bilateral implantation of AcrySof IQ PanOptix	postoperative examination. The AcrySof IQ PanOptix IOL was more appropriate for patients with enhanced near vision demands Good vision outcomes at the one-year
[46] Kohnen et al.	comparative study. Prospective, single- arm, unmasked, and	Symfony ZXR00 / TECNIS ZLB00 + 3.25 D in a total of 50 patients. Bilateral implantation of AcrySof IQ PanOptix	postoperative examination. The AcrySof IQ PanOptix IOL was more appropriate for patients with enhanced near vision demands Good vision outcomes at the one-year postoperative examination with a visual acui
[46] Kohnen et al. (2020) [47]	Prospective, single- arm, unmasked, and nonrandomized interventional study.	Symfony ZXR00 / TECNIS ZLB00 + 3.25 D in a total of 50 patients. Bilateral implantation of AcrySof IQ PanOptix IOL ($n = 149$ patients).	postoperative examination. The AcrySof IQ PanOptix IOL was more appropriate for patients with enhanced near vision demands Good vision outcomes at the one-year postoperative examination with a visual acui of 20 / 25 or better for near to intermediate distance.
[46] Kohnen et al. (2020) [47] Ribeiro et al.	Prospective, single- arm, unmasked, and nonrandomized interventional study. Double-arm,	$Symfony\ ZXR00\ /\ TECNIS\ ZLB00+3.25\ D$ in a total of 50 patients. Bilateral implantation of AcrySof IQ PanOptix IOL (n = 149 patients). Bilateral implantation of FineVision Pod FT	postoperative examination. The AcrySof IQ PanOptix IOL was more appropriate for patients with enhanced near vision demands Good vision outcomes at the one-year postoperative examination with a visual acuit of 20 / 25 or better for near to intermediate distance. Complete patient vision restoration, good
[46]	Prospective, single- arm, unmasked, and nonrandomized interventional study. Double-arm, randomized,	Symfony ZXR00 / TECNIS ZLB00 + 3.25 D in a total of 50 patients. Bilateral implantation of AcrySof IQ PanOptix IOL (n = 149 patients). Bilateral implantation of FineVision Pod FT toric IOL or AcrySof IQ PanOptix toric IOL	postoperative examination. The AcrySof IQ PanOptix IOL was more appropriate for patients with enhanced near vision demands Good vision outcomes at the one-year postoperative examination with a visual acuit of 20 / 25 or better for near to intermediate distance. Complete patient vision restoration, good spectacle independence, and good visual
[46] Kohnen et al. (2020) [47] Ribeiro et al.	Prospective, single- arm, unmasked, and nonrandomized interventional study. Double-arm, randomized, prospective	$Symfony\ ZXR00\ /\ TECNIS\ ZLB00+3.25\ D$ in a total of 50 patients. Bilateral implantation of AcrySof IQ PanOptix IOL (n = 149 patients). Bilateral implantation of FineVision Pod FT	postoperative examination. The AcrySof IQ PanOptix IOL was more appropriate for patients with enhanced near vision demands Good vision outcomes at the one-year postoperative examination with a visual acui of 20 / 25 or better for near to intermediate distance. Complete patient vision restoration, good spectacle independence, and good visual quality outcomes for both IOLs, but superior
[46] Kohnen et al. (2020) [47] Ribeiro et al.	Prospective, single- arm, unmasked, and nonrandomized interventional study. Double-arm, randomized, prospective comparative case	Symfony ZXR00 / TECNIS ZLB00 + 3.25 D in a total of 50 patients. Bilateral implantation of AcrySof IQ PanOptix IOL (n = 149 patients). Bilateral implantation of FineVision Pod FT toric IOL or AcrySof IQ PanOptix toric IOL	postoperative examination. The AcrySof IQ PanOptix IOL was more appropriate for patients with enhanced near vision demands Good vision outcomes at the one-year postoperative examination with a visual acui of 20 / 25 or better for near to intermediate distance. Complete patient vision restoration, good spectacle independence, and good visual quality outcomes for both IOLs, but superior intermediate visual acuity for 60 cm distance.
Kohnen et al. (2020) [47] Ribeiro et al. (2020) [32]	Prospective, single- arm, unmasked, and nonrandomized interventional study. Double-arm, randomized, prospective comparative case series.	Symfony ZXR00 / TECNIS ZLB00 + 3.25 D in a total of 50 patients. Bilateral implantation of AcrySof IQ PanOptix IOL (n = 149 patients). Bilateral implantation of FineVision Pod FT toric IOL or AcrySof IQ PanOptix toric IOL in 60 patients.	postoperative examination. The AcrySof IQ PanOptix IOL was more appropriate for patients with enhanced near vision demands Good vision outcomes at the one-year postoperative examination with a visual acui of 20 / 25 or better for near to intermediate distance. Complete patient vision restoration, good spectacle independence, and good visual quality outcomes for both IOLs, but superio intermediate visual acuity for 60 cm distance with AcrySof IQ PanOptix toric IOL.
Kohnen et al. (2020) [47] Ribeiro et al. (2020) [32] Stredova et al.	Prospective, single- arm, unmasked, and nonrandomized interventional study. Double-arm, randomized, prospective comparative case series.	Symfony ZXR00 / TECNIS ZLB00 + 3.25 D in a total of 50 patients. Bilateral implantation of AcrySof IQ PanOptix IOL (n = 149 patients). Bilateral implantation of FineVision Pod FT toric IOL or AcrySof IQ PanOptix toric IOL in 60 patients. Implantation of AcrySof IQ PanOptix IOL in	postoperative examination. The AcrySof IQ PanOptix IOL was more appropriate for patients with enhanced near vision demands Good vision outcomes at the one-year postoperative examination with a visual acuit of 20 / 25 or better for near to intermediate distance. Complete patient vision restoration, good spectacle independence, and good visual quality outcomes for both IOLs, but superior intermediate visual acuity for 60 cm distance with AcrySof IQ PanOptix toric IOL. Improved visual acuity with a mean follow-up at the superior of the s
[46] Kohnen et al. (2020) [47] Ribeiro et al.	Prospective, single- arm, unmasked, and nonrandomized interventional study. Double-arm, randomized, prospective comparative case series.	Symfony ZXR00 / TECNIS ZLB00 + 3.25 D in a total of 50 patients. Bilateral implantation of AcrySof IQ PanOptix IOL (n = 149 patients). Bilateral implantation of FineVision Pod FT toric IOL or AcrySof IQ PanOptix toric IOL in 60 patients.	postoperative examination. The AcrySof IQ PanOptix IOL was more appropriate for patients with enhanced near vision demands Good vision outcomes at the one-year postoperative examination with a visual acuit of 20 / 25 or better for near to intermediate distance. Complete patient vision restoration, good spectacle independence, and good visual quality outcomes for both IOLs, but superior intermediate visual acuity for 60 cm distance with AcrySof IQ PanOptix toric IOL. Improved visual acuity with a mean follow-up of 27 months and retinal light scattering
Kohnen et al. (2020) [47] Ribeiro et al. (2020) [32] Stredova et al.	Prospective, single- arm, unmasked, and nonrandomized interventional study. Double-arm, randomized, prospective comparative case series.	Symfony ZXR00 / TECNIS ZLB00 + 3.25 D in a total of 50 patients. Bilateral implantation of AcrySof IQ PanOptix IOL (n = 149 patients). Bilateral implantation of FineVision Pod FT toric IOL or AcrySof IQ PanOptix toric IOL in 60 patients. Implantation of AcrySof IQ PanOptix IOL in	postoperative examination. The AcrySof IQ PanOptix IOL was more appropriate for patients with enhanced near vision demands Good vision outcomes at the one-year postoperative examination with a visual acuit of 20 / 25 or better for near to intermediate distance. Complete patient vision restoration, good spectacle independence, and good visual quality outcomes for both IOLs, but superior intermediate visual acuity for 60 cm distance with AcrySof IQ PanOptix toric IOL. Improved visual acuity with a mean follow-u of 27 months and retinal light scattering was observed in 6 eyes of 4 patients but did
[46] Kohnen et al.	comparative study. Prospective, single-	Symfony ZXR00 / TECNIS ZLB00 + 3.25 D in a total of 50 patients. Bilateral implantation of AcrySof IQ PanOptix	postoperative examination. The AcrySof IQ PanOptix IOL was more appropriate for patients with enhanced near vision deman Good vision outcomes at the one-year
[46] Kohnen et al. (2020) [47] Ribeiro et al.	Prospective, single- arm, unmasked, and nonrandomized interventional study. Double-arm, randomized,	Symfony ZXR00 / TECNIS ZLB00 + 3.25 D in a total of 50 patients. Bilateral implantation of AcrySof IQ PanOptix IOL (n = 149 patients). Bilateral implantation of FineVision Pod FT toric IOL or AcrySof IQ PanOptix toric IOL	postoperative examination. The AcrySof IQ PanOptix IOL was more appropriate for patients with enhanced near vision demand. Good vision outcomes at the one-year postoperative examination with a visual acu of 20 / 25 or better for near to intermediate distance. Complete patient vision restoration, good spectacle independence, and good visual quality outcomes for both IOLs, but superior
[46] Kohnen et al. (2020) [47] Ribeiro et al.	Prospective, single- arm, unmasked, and nonrandomized interventional study. Double-arm, randomized, prospective	Symfony ZXR00 / TECNIS ZLB00 + 3.25 D in a total of 50 patients. Bilateral implantation of AcrySof IQ PanOptix IOL (n = 149 patients). Bilateral implantation of FineVision Pod FT toric IOL or AcrySof IQ PanOptix toric IOL	postoperative examination. The AcrySof IQ PanOptix IOL was more appropriate for patients with enhanced near vision demands. Good vision outcomes at the one-year postoperative examination with a visual acre of 20 / 25 or better for near to intermediate distance. Complete patient vision restoration, good spectacle independence, and good visual quality outcomes for both IOLs, but superior
Kohnen et al. (2020) [47] Ribeiro et al. (2020) [32]	Prospective, single- arm, unmasked, and nonrandomized interventional study. Double-arm, randomized, prospective comparative case	Symfony ZXR00 / TECNIS ZLB00 + 3.25 D in a total of 50 patients. Bilateral implantation of AcrySof IQ PanOptix IOL (n = 149 patients). Bilateral implantation of FineVision Pod FT toric IOL or AcrySof IQ PanOptix toric IOL	postoperative examination. The AcrySof IQ PanOptix IOL was more appropriate for patients with enhanced near vision demands Good vision outcomes at the one-year postoperative examination with a visual acui of 20 / 25 or better for near to intermediate distance. Complete patient vision restoration, good spectacle independence, and good visual quality outcomes for both IOLs, but superior intermediate visual acuity for 60 cm distance with AcrySof IQ PanOptix toric IOL.
Kohnen et al. (2020) [47] Ribeiro et al. (2020) [32]	Prospective, single- arm, unmasked, and nonrandomized interventional study. Double-arm, randomized, prospective comparative case series.	Symfony ZXR00 / TECNIS ZLB00 + 3.25 D in a total of 50 patients. Bilateral implantation of AcrySof IQ PanOptix IOL (n = 149 patients). Bilateral implantation of FineVision Pod FT toric IOL or AcrySof IQ PanOptix toric IOL in 60 patients.	postoperative examination. The AcrySof IQ PanOptix IOL was more appropriate for patients with enhanced near vision demands. Good vision outcomes at the one-year postoperative examination with a visual acre of 20 / 25 or better for near to intermediate distance. Complete patient vision restoration, good spectacle independence, and good visual quality outcomes for both IOLs, but superic intermediate visual acuity for 60 cm distance with AcrySof IQ PanOptix toric IOL.
Kohnen et al. (2020) [47] Ribeiro et al. (2020) [32] Stredova et al.	Prospective, single- arm, unmasked, and nonrandomized interventional study. Double-arm, randomized, prospective comparative case series.	Symfony ZXR00 / TECNIS ZLB00 + 3.25 D in a total of 50 patients. Bilateral implantation of AcrySof IQ PanOptix IOL (n = 149 patients). Bilateral implantation of FineVision Pod FT toric IOL or AcrySof IQ PanOptix toric IOL in 60 patients. Implantation of AcrySof IQ PanOptix IOL in	postoperative examination. The AcrySof IQ PanOptix IOL was more appropriate for patients with enhanced near vision demands Good vision outcomes at the one-year postoperative examination with a visual acut of 20 / 25 or better for near to intermediate distance. Complete patient vision restoration, good spectacle independence, and good visual quality outcomes for both IOLs, but superior intermediate visual acuity for 60 cm distance with AcrySof IQ PanOptix toric IOL. Improved visual acuity with a mean follow-to of 27 months and retinal light scattering
Kohnen et al. (2020) [47] Ribeiro et al. (2020) [32] Stredova et al.	Prospective, single- arm, unmasked, and nonrandomized interventional study. Double-arm, randomized, prospective comparative case series.	Symfony ZXR00 / TECNIS ZLB00 + 3.25 D in a total of 50 patients. Bilateral implantation of AcrySof IQ PanOptix IOL (n = 149 patients). Bilateral implantation of FineVision Pod FT toric IOL or AcrySof IQ PanOptix toric IOL in 60 patients. Implantation of AcrySof IQ PanOptix IOL in	postoperative examination. The AcrySof IQ PanOptix IOL was more appropriate for patients with enhanced near vision demands Good vision outcomes at the one-year postoperative examination with a visual acui of 20 / 25 or better for near to intermediate distance. Complete patient vision restoration, good spectacle independence, and good visual quality outcomes for both IOLs, but superior intermediate visual acuity for 60 cm distance with AcrySof IQ PanOptix toric IOL. Improved visual acuity with a mean follow-u of 27 months and retinal light scattering was observed in 6 eyes of 4 patients but did
Kohnen et al. (2020) [47] Ribeiro et al. (2020) [32] Stredova et al.	Prospective, single- arm, unmasked, and nonrandomized interventional study. Double-arm, randomized, prospective comparative case series.	Symfony ZXR00 / TECNIS ZLB00 + 3.25 D in a total of 50 patients. Bilateral implantation of AcrySof IQ PanOptix IOL (n = 149 patients). Bilateral implantation of FineVision Pod FT toric IOL or AcrySof IQ PanOptix toric IOL in 60 patients. Implantation of AcrySof IQ PanOptix IOL in	postoperative examination. The AcrySof IQ PanOptix IOL was more appropriate for patients with enhanced near vision demands Good vision outcomes at the one-year postoperative examination with a visual acui of 20 / 25 or better for near to intermediate distance. Complete patient vision restoration, good spectacle independence, and good visual quality outcomes for both IOLs, but superior intermediate visual acuity for 60 cm distance with AcrySof IQ PanOptix toric IOL. Improved visual acuity with a mean follow-u of 27 months and retinal light scattering

 $Continued \ Table \ 3. \ Summary \ of outcomes \ of \ studies \ on \ AcrySof \ IQ \ PanOptix \ trifocal \ intraocular \ lens \ implantation \ published \ since \ 2016$

Author (Year)	Type of study	Participants	Outcomes
Malyugin et al. (2020) [49]	Retrospective comparative study	Comparing visual outcomes of 25 eyes of 25 patients with AcrySof IQ PanOptix IOL implantation and 25 eyes of 25 patients with AT LISA tri 839 MP IOL implantation at a 1-year postoperative examination.	High visual outcomes at all distances, high level of patient satisfaction, and spectacle independence with both IOLs, yet a rate of spectacle independence was 5.5% less with AcrySof IQ PanOptix IOL.
Velasco-Barona et al. (2019) [50]	Prospective, randomized, comparative, and controlled clinical trial.	IOL implantation in 43 eyes of 43 patients: 23 eyes with Acrysof IQ PanOptix IOL and 20 eyes with AT LISA tri 839MP IOL.	Eyes implanted with either of the IOLs experienced an excellent postoperative visual performance at all distances at the six-month follow-up examination.
Rementeria- Capelo et al. (2019) [51]	Prospective case series.	Bilateral multifocal IOL implantation of AcrySof IQ PanOptix spherical ($n = 166$ eyes) or toric ($n = 84$ eyes) IOL in 125 patients:	Similar visual outcomes and high patient satisfaction with both IOLs.
de Medeiros et al. (2019) [52]	Prospective, nonrandomized, comparative study.	Bilateral implantation of Tecnis Symfony ZXR00 or Acrysof IQ PanOptix multifocal IOL in 52 eyes of 26 patients.	Good subjective quality of vision for distance, intermediate, and near vision for both IOLs.
Cochener et al. (2018) [27]	Single-center, prospective, randomized, comparative, clinical trial	Bilateral implantation of AcrySof IQ PanOptix ($n = 20$ patients), FineVision Micro F ($n = 20$ patients), or TECNIS Symfony ($n = 20$ patients) multifocal IOL.	All participants experienced good visual acuity at all distances, a high rate of spectacle independence, and little or no impact of vision symptoms on daily functioning. Two trifocal IOLs had a better near vision versus TECNIS Symfony multifocal IOL.
Alio et al. (2018) [21]	Prospective consecutive case-series	Bilateral implantation of AcrySof IQ PanOptix in 52 eyes of 26 patients.	Visual function restored with an acceptable postoperative intermediate and near vision, good contrast sensitivity, and a significant improvement in near activity visual questionnaire scores.
de Medeiros et al. (2017) [22]	Prospective, nonrandomized, consecutive, comparative study	Bilateral implantation of AcrySof IQ PanOptix IOL in 20 eyes, and Tecnis Symfony ZXR00 / Tecnis ZMB00 IOL in 20 eyes .	Good quality of vision for distance, intermediate, and near for all IOLs. Better performance for very short distances and for intermediate and long distances with Tecnis IOLs. Better performance for intermediate visual acuity at 60 cm and near visual acuity at 40 cm with Acrysof IQ PanOptix IOL.
Kohnen et al. (2017) [12]	Prospective study	Bilateral implantation of AcrySof IQ PanOptix IOL in 54 eyes of 27 patients.	Good visual performance at all distances, especially intermediate visual acuity at 60 cm, and a high patient satisfaction and spectacle independence rate at three-month postoperative examination.
Lawless et al. (2017) [17]	Retrospective consecutive case series	Bilateral implantation of AcrySof IQ PanOptix IOL in 66 eyes of 33 patients .	Functional improvement in distance, intermediate, and near visual acuities.
Carson et al. (2016) [11]	Experimental study	Comparing the optical performance of 3 trifocal IOLs: the Acrysof IQ Panoptix, AT LISA Tri 839MP, and Finevision Micro F.	The Acrysof IQ Panoptix revealed a similar or better performance in image quality, resolution, and photic phenomena compared with the other two IOLs.
Lee et al. (2016) [6]	Experimental study	Comparing the optical performance of 2 trifocal IOLs: the Acrysof IQ Panoptix and multifocal ReSTOR.	The resolution and image quality with the Acrysof IQ Panoptix compared with ReSTOR IOL was better at the intermediate focus but similar at the near and distance foci.

Abbreviations: IOL, intraocular lens; D, diopters; n, numbers; logMAR, logarithm of minimum angle of resolution.

follow-up compared with preoperative measurements. Additionally, continuous improvements were observed across all distances between the first and sixth months.

The visual acuity outcomes of the PanOptix IOL were compared with those of other extended-range vision or trifocal IOLs in several studies [3, 18, 19, 22-27]. Consequently, improved outcomes were observed after PanOptix IOL implantation, especially in intermediate and near visual acuities. Despite the superiority of trifocal IOLs, preoperative counseling regarding the perception of visual side effects is recommended [24]. Our study did not include implantation of a different IOL device in a comparison group. Therefore, further studies are warranted to verify the performance superiority of PanOptix IOL over that of other available multifocal IOLs.

The photic phenomenon is common after implantation of diffractive multifocal IOLs [2]. Ramamurthy et al. [2] reported halos as a symptom of photic phenomena in 86.6% of patients. The severity was reported as mild in all but one patient. Kohnen et al. [12] reported that 93% of patients experienced photic phenomena, including halos, glare, double vision, ghosting, and distorted vision. Halo development was the most common symptom (89%) reported in their study. In contrast, halo development without any clinical sequelae was reported in 5 – 32.8% of patients in other studies [1, 19, 20]. In comparison, the symptoms included in our definition of photic phenomena were not categorized; however, only 12 patients (14.6%) reported photic symptoms up to six months postoperatively. Thus, explaining the significant variability in these rates is difficult to some extent, although halos are the most frequently reported visual symptoms of photic phenomena. Differences in study designs, follow-up durations, and study populations might explain these discrepancies [12]. Neuroadaptation is a possible mechanism that leads to significant improvements over time [17].

Another important issue is the safety and efficacy profiles of multifocal IOLs. As in previously published studies [2], we detected no significant glaucoma or PCO necessitating medical or surgical intervention among the patients included in our study. Clinically significant PCO was observed in a limited number of patients postoperatively. Kim et al. [1] reported the development of PCO in 3 (3.4%) of 88 eyes in their study, and laser posterior capsulotomy was required in one eye [1]. We detected a PCO rate of 11.6%, which is higher than that previously reported [1, 2], although it was not clinically significant at the six-month follow-up and laser posterior capsulotomy was not required.

A higher rate of spectacle independence has been reported after cataract surgery with trifocal IOLs [1, 12, 27-32]. Ramamurthy et al. [2] reported≥94.0% spectacle independence at all distances at the postoperative three-month follow-up. Similarly, in this study, 6.1% and 9.8% of patients required spectacles for far and near distances, respectively, rates much higher than those reported by Kim et al. [1]. This difference can be attributed to the different follow-up periods, as a longer follow-up period may have led to a relatively higher use of spectacles. Further studies with more prolonged follow-up periods are required to verify our findings.

Studies published since 2016 [1, 3, 6, 11, 12, 17, 21, 22, 27-52] have focused on the safety and efficacy of AcrySof® IQ PanOptix® IOL model TFNT00; we summarize the significant features of these studies and their main outcomes in Table 3.

The relatively extended follow-up period of six months was main strength of this prospective study. However, this study had certain limitations. First, it did not include other multifocal IOLs for comparison to the PanOptix® IOL model in visual performance or PCO rate. Second, postoperative satisfaction was not measured using a standard questionnaire. Patient satisfaction measured using patient self-reports may be essential for evaluating the impact of surgery on patient perception. Third, the decision to implant a trifocal IOL with an intermediate focal length of 60 cm in this study was not evidence-based, as we did not consider the data for average arm length of those in our study population. Further studies are required to address these limitations and verify our observed outcomes.

CONCLUSIONS

We found that the AcrySof® IQ PanOptix® IOL model TFNT00 could be recommended for implantation during phacoemulsification cataract extraction, given its excellent visual performance across all distances and the high rate of postoperative spectacle independence. Further cohort studies of longer duration and including patients implanted with different types of IOLs are needed to evaluate and compare long-term outcomes and complication rates.

ETHICAL DECLARATIONS

Ethical approval: This study was approved by the Akdeniz University Clinical Research Ethics Committee (approval code: 09.09.2020/690), Antalya, Turkey. This study was conducted in accordance with the principles outlined in the Declaration of Helsinki. All patients provided written informed consent after their briefing on the study protocol.

Conflict of interest: None.

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