Original Article

Assessment of Safety, Efficacy and Predictability of a Trifocal Intraocular Lens

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ABSTRACT

Purpose: To evaluate the performance and the visual outcomes of Acrysof PanOptix trifocal IOL in terms of safety, efficacy, predictability and assessment of the quality of vision after implantation as regards; contrast sensitivity and ocular aberrations.

Study Design: Quasi experimental study.

Place and Duration of Study: Dar el Ouyon hospital and Rowad Correction Center, Egypt, from September 2019 and January 2020.

Methods: Forty eyes of twenty-one patients with senile cataract were included by convenient sampling. All eyes underwent phacoemulsification with IOL implantation. They were divided into two groups; group A included twenty eyes of eleven patients who were implanted AcrySof IQ PanOptix trifocal IOL Model TFNT00. Group B included twenty eyes of ten patients who were implanted monofocal AcrySof IOLs as a control group. A questionnaire was given to every patient after explaining to him\her the questions in Arabic, and clarifying the aim of evaluation.

Results: Mean age was 56.6 ± 6.9 years in group A and 62.8 ± 7.1 years in group B, range 50 – 70 (P = 0.861). We found statistical significant difference between both groups with group A showing better post operative uncorrected distance, intermediate, near, and best corrected near visual acuity (P values were 0.001, 0.556, 0.001, 0.177, 0.001, 0.001 respectively). Group B showed statistically significant better post operative contrast sensitivity compared to group A.

Conclusion: In this study, Acrysof PanOptix trifocal IOL showed excellent safety, efficacy, predictability and spectacle independence at all distances, However, contrast sensitivity was compromised in comparison to the monofocal group.

Key Words: PanOptix, Abberations, Trifocal lenses, phacoemulsification, contrast sensitivity.

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INTRODUCTION

The PanOptix Model TFNT00 (henceforth referred as PanOptix) is an ultraviolet (UV) and blue light filtering, non-apodized, foldable presbyopia-correcting IOL. This single-piece IOL has a central biconvex optic, with an inner diffractive and an outer refractive zone, and is made of a hydrophobic material acrylate/ methacrylate copolymer and has 2 open-loop haptics. The lens is 13.0mm in diameter with a central optic of 6.0mm and is available in a diopter (D) range of +6.0 to +30.0 D (0.5 D increments) and +31 D to +34 D (1.0 D increments). The posterior lens surface is spherical, and the anterior surface is aspheric with a

diffractive surface on the central 4.5 mm portion of the optic zone, and divides the incoming light to create an intermediate addition power of +2.17 D (60 cm) and a +3.25 D (40 cm) near add power. The anterior surface is designed with negative spherical aberration to compensate for the positive spherical aberration of the average human cornea.

PanOptix is a trifocal IOL, non apodized 4.5 mm diffractive optical zone that features an optical technology designed to help patients adjust more naturally to their new vision by providing a range of near to intermediate vision (40 – 80 cm) with a crisp focal point at 60 cm and by optimizing light transmission to the retina.[1,2]

Our aim is to evaluate the performance and the visual outcome of Acrysof PanOptix trifocal IOL in terms of safety, efficacy, predictability and assessment of the quality of vision after implantation as regards; contrast sensitivity and ocular aberrations.

METHODS

It was a quasi experimental study carried out in Dar el Ouyon hospital and Rowad Correction Center, between September 2019 and January 2020, in Cairo, Egypt. Study was approved by the Research ethics committee of Cairo university (D-10-2019), using non-probability Quota sampling.

The study included patients older than 50 years of age and younger than 70 years with cataract and decreased best corrected visual acuity seeking spectacle independence with easy going personality and no abnormality detected by fundus examination or history of retinal surgery. The study excluded any patient with corneal opacity, astigmatism more than1.5 dioptre, glaucoma, previous attack of iridocyclitis, narrow or decentred pupil, history of previous refractive surgery, single seeing eye,zonular weakness especially pseudoexfoliation, any abnormality of the optic nerve that restricts potential visual acuity, contrast sensitivity, colour perception, or field of vision, alternating monofixations, such as patients with a large angle alternating strabismus, large angle Kappa, moderate and severe dry eye, intraoperative anterior capsule tear, intraoperative capsular opening smaller than 5.5 mm or decentred capsulorhexis.

Evaluation of subjects included: measurements of visual acuity; monocular unaided, binocular unaided and optimal corrected distancevisual acuity CDVA (with the best manifest correction), uncorrected intermediate visual acuity, best corrected intermediate visual acuity at 60 cm, uncorrected near visual acuity and optimal corrected near visual acuity at 30 – 40 cm. Corneal topography was done using the Oculus Pentacam Scheimpflug cross-sectional imaging for group A. Biometry was done to calculate the IOL power usingthe Barrett Universal II formula in both groups. All patients were adjusted to achieve postoperative emmetropia.

Uncorrected distance visual acuity (UCDVA), best-corrected distance visual acuity (BCDVA) were measured binocularly and monocularly using Snellen chart. Decimal values of visual acuity were converted into log MAR. Uncorrected intermediate visual acuity (UCIVA), best-corrected intermediate visual acuity (BCIVA) was measured at a distance of 60cm using Snellen chart. Uncorrected near visual acuity (UCNVA), best-correctednear visual acuity (BCNVA) were evaluated using Jaeger'schart at a distance between 30 – 40 cm. then converted to log MAR.

Assessment of contrast sensitivity (CS) was done by using Pelli Robsonchart. Values < 1 log CS indicates visual impairment, values between log 1.00 to log 1.5 indicates decreased CS, while values between log 1.5 to log 2.00 indicates normal visual contrast sensitivity.

Slit lamp examination was done for the assessment of corneal edema, anterior chamber reaction, IOL centration, posterior capsular opacification and fundus examination. Applanation tonometer was used to measure the IOP. Aberrometry using the Visxi Design Waves can (USA) was done 2 monthslaterto measure the refractive error and wave front aberrations of the eye and representation of peripheral data using a multi term polynomial.[3]

Quality of vision questionnaire (5 items) was used 2 months later after explaining to him\her the questions in Arabic and clarifyingthe aim of evaluation. The patient had enough time to read and answer all the items mentioned below autonomously, asking him\her kindly to put a tick or X in the suitable square.Our study is concerned with assessing safety, efficacy and predictability ofthe novel PanOptix trifocal IOL, so we evaluated the following indices asfollows:-

Safety was defined as the proportion number of eyes that lost or gained one ormore lines of postoperative BCVA relative to the preoperative BCVA.

Safety index was defined as mean BCVA ÷ mean pre operative BCVA.

Efficacy was defined as the proportion number of eyes achieving an UCVA of 20/20 or better postoperatively.

Efficacy Index was defined as mean postoperative UCVA ÷ mean preoperative BCVA.

Predictability was defined as the proportion number of eyes achieving apostoperative Spherical error (SE) within ± 0.50 D of the intended target refraction.

The collected data were revised, coded, tabulated and introduced into a PC using statistical package for social science. (Statistical Package for the Social Science; SPSS Inc., Chicago, IL, USA) version 22 for Microsoft Windows.

Data was presented as mean and standard Deviation (±SD) for quantitative parametric data, or frequencies (number of cases) and percentages when appropriate. For comparing categorical data, Chi square (c2) test was performed. Exact test was used instead when the expected frequency was less than 5. Comparison over time between pre-operative and post-operative in group A was done by paired t test. All visual acuity results were converted to logMAR units. Contrast sensitivity was presented as log CS units. Wilcoxon signed ranks test was used to compare two related samples or matched samples. Pearson`s correlation coefficient was used to show the relation between two quantitative continuous variables. All p values were two sided. P values ≤ 0.05 were considered significant.

RESULTS

Male to female ratio was 1:1 in group A. Males represented 30% of patients and females represented 70% of patients in group B. We found statistical significant difference between both groups considering post-operative UCDVA, UCIVA, UCNVA, BCNVA and contrast sensitivity (Table 1). We found statistical difference between pre operative and post operative UCDVA, BCDVA, UCIVA, BCIVA, UCNVA, BCNVA with p value of 0.001.

In group A, one patient (10%) was not satisfied with far and night vision, 50% of patients experienced glare and halos. While 100% of patient's were satisfied with intermediate and near vision. In group B 100% of patients were satisfied with far, intermediate, near vision and night vision with glasses and no one experienced glare or halos.

Table 1: *Visual Acuity of both groups in Log MAR and Contrast sensitivity values of both groups in log CS.*

	Group(A) Mean Values	Group(B) Mean Values	P value
Post UCDVA	0.06	0.4	0.001
Post BCDVA	0.08	0.1	0.556
Post UCIVA	0.0	0.3	0.001
Post BCIVA	0.0	0.0	0.177
Post UCNVA	0.0	0.7	0.001
Post BCNVA	0.0	0.1	0.001
Post op. mesopic CS	1.19	1.55	< 0.001
Post op. photopic CS	1.27	1.63	< 0.001

Total HOA% was noted to be higher in group A than group B, coma and trefoil had the highest mean values in group A while trefoil had the highest mean in group B (Table 2, 3).

Multiple linear regression analysis revealed significant direct correlations between postoperative primary coma and postoperative total HOA %. (r = 0.67, p = 0.002) and significant direct correlation between postoperative trefoil and total HOA % (r = -0.52, p = 0.02). In group B, multiple linear regression analysis revealed significant direct correlations between postoperative trefoil, and total HOA % (r = 0.574, p = 0.008) [Table 4].

Regarding safety of group A, two eyes gained 8 lines, 3 eyes gained 5 lines, 4 eyes gained 4 lines, 4 eyes gained 3 lines, 1 eye gained 2 lines of post-operative BCVA, and none lost any lines, so the safety index is 2. In terms of efficacy, 8 eyes gained 8 lines, 2 eyes gained 6 lines, 2 eyes gained 5 lines, 2 eyes gained 4 lines, 2 eyes gained 1 line, 1 eye gained 3 lines, 1 eye gained 2 lines of post operative UCVA and no patients lost any line, so the efficacy index is 2.1 in group (A). In terms of predictability, 16 eyes (88%) achieved post operative spherical error within ± 0.5 D in group (A).

Two patients were excluded from the study from group (A), a male patient who had his IOL explanted two weeks post operative and did not continue follow up due to his complaint of bad quality of vision in spite of good visual acuity including far, intermediate and near vision but, intolerable presence of glare and halos. The other patient underwent bilateral

Table 2: Post operative aberrations in both groups.

Coefficient value for each Zernike term	Group(A)	Mean	Maximum	Minimum	SD
Z_4^0	Secondary spherical aberration	0.023	0.06	0.002	± 0.01
Z_3^1	Coma	0.068	0.2	0.001	± 0.05
Z_4^2	Secondary Astigmatism	0.021	0.06	0.002	± 0.01
Z_3^{-3}	Trefoil	0.079	0.2	0.002	± 0.04
Z_4^4	Tetra foil	0.044	0.097	0.001	± 0.03
	Group(B)				
Z_4^0	Secondary spherical aberration	0.07	0.36	0.11	± 0.07
Z_3^1	Coma	0.14	0.46	0.14	± 0.11
Z_4^2	Secondary astigmatism	0.03	0.07	0.005	± 0.02
Z_3^{-3}	Trefoil	0.12	0.29	0.02	± 0.07
Z_4^4	Tetra foil	0.06	0.15	0.016	± 0.04

Table 3: *Mean values of HOA, RMS error, Effective blur in both groups.*

	Group A		Group B		*p value*
	Mean	(Range)	Mean	(Range)	
HOA %	44.27	(15.3 – 91)	25.83	(13.5 – 69.9)	0.02
RMS error	0.42	(0.17 – 0.78)	1.01	(0.54 – 1.96)	< 0.001
Effective blur	0.64	(0.18 – 1.34)	1.2	(0.17 – 3.37)	0.01

implantation of the IOL, but her left eye did not improve after cataract surgery owing to her deep amblyopia discovered post operatively, she was excluded from the contrast sensitivity assessment and therefore from our study.

Table 4: *Pearson correlation between different aberrations and HOA%.*

	HOA % Group A	
	Pearson Correlation	p value
Coma	0.674	0.002
Trefoil	0.525	0.02
Tetra foil	0.414	0.08
Secondary Spherical aberration	-0.358	0.1
Astigmatism 2nd order	0.037	0.88
	HOA % Group B	
	Pearson Correlation	**p value**
Trefoil	0.574	0.008
Spherical aberration	0.38	0.09
Astigmatism 2nd order	-0.046	0.84
Tetra foil	0.032	0.89
Coma	0.081	0.7

DISCUSSION

In our study we compared the quality of vision after implanting PanOptixIOL, non apodized diffractive aspheric trifocal IOL and Acrysof monofocal IOL following cataract extraction. Visual acuity (distance, intermediate and near vision), contrast sensitivity, (mesopic and photopic), and the aberrations induced after surgery were compared between the two groups. PanOptix trifocal IOL showed excellent safety, efficacy and predictability.

Considering safety in group (A), pre operative mean log MAR of BCVA was 0.42 while postoperatively, it was 0.08, which was statistically significant, there was no increase in the intraocular pressure or visual threatening complications, and in addition, no patients have lost lines of BCVA postoperatively.

We observed similar results in previous studies done by Alió et al, Kohnen et al, García-Pérez et al and Lawless et al.[4,5,6,7] Similar to our study, Alió[4] in 2018 concluded that there was improvement in UCVA results one month after the surgery which remained stable through the 6 months. In addition, Kohnen[5] in 2017 reported better UCIVA results measured at 60 cm than VA measured at 80 cm. He measured both distances, which is similar to our results. García-Peréz[6] in 2017 noticed good visual outcomes in patients implanted with the same IOL during one month. In our study 100% of patients achieved visual acuity better than 20/40 for distance and near vision. Regarding the satisfaction with near vision, 100% of patients in our studywere satisfied with their near vision with no added correction needed.

During the period of follow up, contrast sensitivity was evaluated in both groups using Pelli-Robson chart, this test is easy to be interpreted and reliable. The monofocal group; group B achieved higher levels of

contrast sensitivity than group A. Pre-operative contrast sensitivity values were higher than post-operative values in group A. The difference was statistically significant which indicates that contrast sensitivity was affected by implanting the PanOptix trifocal IOL. Our results are consistent with the work of Alió[4] in 2018 who studied the contrast sensitivity by Pelli-Robson chart and obtained low CS values after Panoptix IOL implantation. Consistent with the work of Gundersen and Potvin[8] in 2017**,** binocular distance low contrast sensitivity values were obtained when comparing the performance between two different designs (Fine Vision and PanOptix).

Considering the questionnaire, in group A, 1 patient (10%) was not satisfied with far vision and night vision, while 100% patients were satisfied with intermediate vision and near vision. Fifty percent patients experienced halos and glare which indicated that PanOptix trifocal IOL achieved excellent results with visual acuity and spectacle independence, though visual quality was reduced. In group B, 100% patients were without halos or glare or any problems with night vision. They were satisfiedwith far ,intermediate and near vision with their glasses.Our results showed 100% spectacle independence, in contrast to the results of García-Peréz.[6] Although all patients in his study were able to perform daily tasks without spectacle correction, one patient reported using spectacles occasionally for all distances. He used the Catquest9-SF questionnaire. Another study showed excellent postoperative visual performance at all distances at the six-month follow-up visit.[9]

Complete spectacle independence was achieved by 96% of patients by Kohnen et al, with only 1 patient who used spectacles for distance.

In our study, one patient chose to have lens exchange after implanting PanOptix 2 weeks postoperatively due intolerable glare and halos that he experienced and was excluded from the study. In our study 50% of the patients suffered glare and halos without impairing their daily activities.Similarly, results obtained by Mennuci who reported that his patients were comfortable with their daily activities.[10]

Cochener used QoV questionnaire and only < 1% of patients reported night time visual disturbances, dry eye, halos, and glare.[11] Outcomes obtained in our study are similar to studies with more than one month follow up period as in Sheppard`s cohort study.**[12]**

Considering the assessment of aberrations in group A, we found that coma ($Z3^{1}$) and trefoil ($Z3^{-3}$) had the highest values withsignificant direct correlation to the total high order aberrations percentage. These results of high order aberrations are consistent with our questionnaire results, as coma and trefoil have high mean values in group A. Both affect the quality of vision more than the acuity ofvision.**[13]** This explains the high percent of patients whocomplained of glare and halos in the questionnaire in group A without affecting their daily activities, and deterioration of contrast sensitivity in comparison to group B, in which, only trefoil had a high mean value and asignificant correlation to total high order aberrations which is less than group A. The difference between HOA % postoperatively between both groups was statistically significant.

In our study, Effective blur was higher in group B than groupA. We explained this higher value in group B due to the higher values of low order aberrations as defocus and astigmatism than group A.Similar to our results, a study done by Chung Yeom Kim[14] in 2007 concluded that high order aberrations, especially spherical aberrations, were increased significantly in the multifocal IOLs in general compared with the monofocal IOL group. However, optical aberrations analysis did not show a significant difference in coma aberrations between the monofocal and the multifocal IOL groups, suggesting that spherical aberrations induced by multifocal IOLs contribute more to the reduction in CS than coma aberration does.

The incidence of PCO and Nd: YAG rates were nil in our study, in contradiction to other studies which showed PCO very earlier in post operative period.[15] Kacerovsky observed the PCO rate to be 0.5% with PanOptix implantation.[16]

Studies have shown that common problems with multifocal lenses were blurred vision, residual ametropia, large pupil size, posterior capsule opacification, dry eye, and lens decentration.[17,18] It is important that before surgery, surgeons should consider individual reading and working requirements when counselling patients to increase postoperative patient satisfaction.[19]

Another very interesting phenomenon related with these problems is the neuroadaptation failure. It is characterized by decreased quality of vision, often without any correlation with optical quality or solid underlying reason such as posterior capsule opacification, dry eye, or retinal disease. The reduction

in this far distance quality of vision is generally due to sensations of blurred vision, dysphotopsia or photic phenomena.[20]

Limitations of the study are short time of follow up due to Covid-19 era and small sample size due to the high cost of the PanOptix IOL in a self funded study.

CONCLUSION

In this study, Acrysof PanOptix trifocal IOL showed excellent safety, efficacy, predictability and spectacle independence at all distances. However, contrast sensitivity was compromised in comparison to the monofocal group and high order aberrations (coma, trefoil) were noted to be higher affecting the quality of vision but not the daily activities of the patient.

Conflict of Interest

Authors declared no conflict of interest.

Ethical Approval

The study was approved by the Institutional review board/Ethical review board **(D-10-2019).**

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Authors' Designation and Contribution

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