TITLE PAGE

Title:

Clinical Outcomes of a Trifocal Compared to an EDOF IOL Following Bilateral Cataract Surgery.

Authors:

Marius A Scheepers. MBBCh, FCOphth, MMed, FRCSC;[a] Catey B Bunce. BSc(Hons), MSc, DSc;[b] Michel Michaelides. MD (Res), FRCOphth;[c] Brad Hall. PhD[d]

[a]University of British Columbia, 3333 University Way, Kelowna, BC Canada V1V 1V7

[b]London School of Hygiene & Tropical Medicine, Keppel Street, London, United Kingdom WC1E 7HT

[c]Moorfields Eye Hospital and UCL Institute of Ophthalmology, Gower Street, London, United Kingdom, WC1E 6BT

[d]Sengi, Penniac, NB Canada E3A 8X8

Corresponding Author:

Dr. Marius A Scheepers, PO Box 2170, Rossland, BC, V0G 1Y0, Canada.

Phone: 250 368 8585

Email: 220eyes@gmail.com

Disclosure of support:

This study was supported with an Investigator Initiated Study Grant (#37232085) from Alcon, Fort Worth, Texas, USA.

Financial Disclosure:

M Michaelides - MeiraGTx (FC), Stargazer Pharma (C), Acucela (FC), Astellas (C), ProQR (C), 2CTech (C)

ABSTRACT:

Purpose: To compare the visual and patient reported outcomes of two presbyopia correcting IOLs.

Methods: 134 eyes (67 patients) that underwent cataract surgery with either a trifocal (PanOptix) or an EDOF (Symfony) IOL bilaterally and were assessed 3 months post-surgery. Outcome measures were binocular distance corrected visual acuity at near (40cm), intermediate (60cm) and distance (6m), Akman modified Quality of Life (QOL) Questionnaire-14, and 10% contrast visual acuity at distance and near, with and without glare.

Results: Mean binocular LogMAR VAs for the PanOptix compared to Symfony lenses: DCNVA 0.054 vs 0.228; DCIVA 0.019 vs 0.063; and BCDVA -0.016 vs -0.021. The QOL questionnaire showed 62% of the Panoptix and 48% of the Symfony group had little or no difficulty with all quality of life related tasks. In a multivariable model controlling for pupil size and angle kappa (Chord mu distance) (right eyes), the differences were -0.005 (-0.03 to 0.02) and 0.165 (0.12 to 0.21) respectively. 10% contrast acuity was comparable in the two different lenses, and was unaffected by glare.

Conclusions: Binocular distance corrected near visual acuity was significantly better in the PanOptix group ($P<0.0001$) This remained statistically significant after controlling for pupil size and chord mu distance ($P < 0.001$). Intermediate and distance visual acuities were similar between the two groups. Quality of life scores were higher in the PanOptix group.

Keywords: trifocal IOL, EDOF IOL, cataract surgery

INTRODUCTION

There is a growing request from patients to have a greater degree of spectacle independence for distance, intermediate, and near ranges of vision following cataract surgery. Patient lifestyles will often benefit from better unaided vision across a broader range of viewing distances to meet recreational and occupational demands.

A frequently utilized option for treating presbyopia at the time of cataract surgery is to implant a (i) multifocal lens (diffractive or refractive), (ii) an accommodating IOL, or (iii) an extended depth of focus (EDOF) technology IOL. Diffractive lens optics is one of the most commonly employed technologies. In a diffractive lens, the optical pattern is based on the principle of light diffraction by microscopic steps across the optical surface of the IOL creating additional focal planes. Near vision is provided primarily by letting the patient perceive the retinal image of one focused plane with the other plane/planes blurred.[1] Multifocal IOLs use the principle of simultaneous vision, in which light is split into 2 or more focal points to extend the range of clear and comfortable vision without glasses.

Both the trifocal diffractive IOLs and the extended range of vision diffractive IOLs have been shown to provide better unaided intermediate, and unaided near visual acuity, while maintaining the same level of distance visual acuity as a monofocal IOL.[2-7] Trifocal diffractive IOLs tend to provide better intermediate vision over traditional bifocal IOLs, with equivalent postoperative levels of visual and ocular optical quality.[4]

The AcrySof IQ PanOptix® Trifocal model TFNT00 (Alcon Vision, LLC., Fort Worth TX, USA), and the TECNIS® Symfony EDOF model ZXR00 (Johnson & Johnson, Santa Ana, CA, USA) are novel technologies available for presbyopia correction. Both lenses are approved for use in

Canada, but there are limited comparative published data to show differences in the performance of the lenses. The purpose of this study was to compare distance corrected visual acuities at near (40cm), intermediate (60cm), and distance (6m). Contrast sensitivity (10%) and the effect of glare induced by a point source of light were assessed. Pupil size and chord mu values were recorded for each eye to determine their possible effect on visual acuity outcomes. Spectacle independence was assessed using the Akman modified 'National Eye Institute Visual Function Questionnaire-14'.

PATIENTS & METHODS

Ethics approval was obtained from the University of British Columbia and the Interior Health Authority Ethics Boards (H18-02962). Written informed consent was obtained for all study participants. This study adhered to the tenets of the Declaration of Helsinki.

This study was a prospective, randomized, patient and observer masked comparative study enrolling 70 consecutive patients (35 per arm) for bilateral cataract surgery with implantation of either bilateral PanOptix or bilateral Symfony intraocular lenses. Sample size calculation derived from power analysis suggested that 35 patients in each group would have a high likelihood in detecting a difference in IOL performance at the 95% confidence interval; specifically to demonstrate superiority at near, with a superiority margin of 1 line of VA. Three of the seventy patients did not complete the study and were excluded from the post-operative analysis; one patient from the PanOptix arm and two patients from the Symfony arm. One patient was excluded from each arm of the study due to surgical challenges requiring a monofocal 3-piece lens to be implanted in their second eye. The other excluded patient refused to attend their 3 month follow up appointment and voluntarily withdrew from the study.

Preoperative biometry measurements were obtained using the IOL Master 700 (Carl Zeiss Meditec, Jena, Germany), and the Barrett Universal II formula was used for IOL calculation. Emmetropia was targeted for all eyes in the study. All surgeries were performed by the same experienced surgeon at one surgical facility (M.S.; Kootenay Lake Hospital, Department of Ophthalmology, Nelson, BC, Canada). Sutureless microincision phacoemulsification was the standard technique for all cataract procedures. The primary keratotomy incisions (2.4mm) were made in the temporal area, followed by manual capsulorhexis. Secondary arcuate keratotomy incisions to treat astigmatism were performed manually on the steep axis. The arcuate keratotomy incisions varied in length from 2.4mm to 2.75mm depending on the degree of astigmatism and the axis of astigmatism. Arcuate keratotomies were performed in 40 of 134 eyes (30%). The postoperative regimen was the surgeon's usual standard of care following IOL implantation. Patients were bilaterally implanted with either the Acrysof IQ PanOptix TFNT00 (Alcon Vision, LLC) or the TECNIS Symfony ZXR00 (Johnson & Johnson Vision). Toric IOLs were not used in this study, as the PanOptix Toric was not available at the time of the study onset.

Patients who were referred for cataract surgery and had chosen to have a monofocal lens implant due to the higher cost of a presbyopia correcting implant, were offered participation in the study. These patients were offered an upgrade to a presbyopia correcting lens implant at no additional cost to them.

Patients were masked as to which lens was implanted at the time of surgery, and the lens choice was only revealed to the patients after completion of the study.

Eligibility Criteria

Inclusion criteria were: Lens opacity causing a reduction in visual quality and motivation for spectacle independence.

Exclusion criteria were: Previous corneal refractive surgery, ocular comorbidity that might limit post-operative visual acuity, irregular corneal astigmatism / keratoconus, chord mu > 0.7mm , higher order corneal aberrations > 0.3 RMS units (to exclude irregular corneas), axial length < 22.0 or > 26.5, mean central corneal power < 41 or > 47 diopters, difficulties comprehending written or spoken language, patients with physical or intellectual disability (e.g. Parkinson Disease; unable to fixate) and patients where Barrett toric calculation recommended TFNT30 / ZXT150 or higher toric IOL.

Assessments

The Akman modified 'National Eye Institute Visual Function Questionnaire-14 was used to assess spectacle independence and patient satisfaction at 3 months post-surgery. The original questionnaire has 14 questions to which Akman et al added 4 more questions to expand the QOL evaluation. Each question was explained to the patient, and it was ensured that the questions were understood. Patients were encouraged not to give falsely positive answers in order to please the study investigators. The questionnaire has a grading scale: 0, no difficulty; 1, a little difficulty; 2, moderate difficulty; 3, quite difficult; 4, impossible to perform.

Post-operative evaluations were performed at 3 months by a masked optometrist who was trained to be an independent masked investigator. An objective and subjective refraction was performed. Binocular distance corrected visual acuities were measured for near, intermediate and distance.

Contrast sensitivity was tested at distance and at near using the 10% low contrast ETDRS format Sloan Letters, with and without glare induced by a point light source directed at the reading eye. For distance induced glare, a 1000 Lumen LED torch light was shone into the observer's eye at 15 degrees from the visual axis, 6 meters from the eye. For near induced glare, an iPhone torch light was used, at 15 degrees from the visual axis, 40cm from the eye. The iPhone was placed next to the near acuity reading card and was directed to shine back towards the observer. The brightness of the iPhone torch light is approximately 10 lumens according to the manufacturer's website. The same model of iPhone 7 plus was used for each test.

RESULTS

Baseline characteristics are reported for patients by study group to assess the performance of the randomization process. Means and standard deviations were used for normally distributed variables, and medians and interquartile ranges were used for non-normally distributed continuous variables. Normality was assessed by inspection of histograms. Categorical variables are reported as counts and frequencies. Figures 1 & 2 show the standard graphs for the PanOptix and Symfony groups respectively.

Baseline characteristics by lens:

The mean age of the patients was 72 years, and the gender distribution was similar between the two arms. The demographic data are summarized in Table 1.

Pre-Operative Ocular Characteristics by eye and lens

Ocular characteristics were measured on both eyes and baseline values are reported for right and left eyes (Table 1). Mean axial length, mean keratometry, and mean chord mu values were

similar between the two study arms. The Symfony arm had slightly better median best corrected distance visual acuity, and a slightly greater average pupil size.

***Primary outcome variable - Best distance corrected near visual acuity**:*

The primary outcome variable showed marked skewness and thus it was compared between lens types using a rank sum test (Table 2). It can be seen that there is strong evidence of a difference in best distance corrected near visual acuity at 3 months post-surgery, with lower values in the PanOptix group.

Secondary outcome variables – Binocular best distance corrected intermediate visual acuity and best corrected distance visual acuity:

Best distance corrected intermediate visual acuity was also evaluated using the Rank Sum Test, with best corrected distance visual acuity having a normal distribution and thus comparison between lens types was conducted using an unpaired t-test.

There was no evidence of a significant difference in distance corrected intermediate or best corrected distance visual acuity between IOLs (Table 2).

Exploratory outcomes (Binocular):

Binocular exploratory outcomes are detailed in Table 2; with no significant differences observed between groups. In both study arms the 10% contrast visual acuity test showed an approximately 2 line reduction in distance and near visual acuity. Inducing glare with a torchlight / iPhone did not decrease the 10% contrast visual acuity for either distance or near visual acuity.

Exploratory outcomes – by lens and eye:

Exploratory outcomes by lens and eye are shown in Table 2. Data show excellent mean uncorrected distance visual acuity in both groups

Quality of Life Scores

The QOL scores are shown in detail in Table 3. There are observed differences in QOL scores by lens types. More patients receiving PanOptix lenses experienced no difficulty in reading small print, newspapers and large print than those receiving Symfony lenses; and more patients receiving PanOptix lenses experienced no difficulty in doing fine handwork, writing checks and playing games such as bingo. More patients receiving Symfony lenses had no issue in recognizing people at a distance and going out to movies. A greater proportion of patients with PanOptix experienced great difficulties in shaving and styling hair. It should be noted that in all cases, numbers are small and differences may have arisen by chance.

Sensitivity analysis

Although baseline Table 1 suggests no differences between lens groups with regards to both chord mu and pupil size, it was considered important to assess whether associations between lens type and outcome were impacted by small differences. Regression models were fitted including lens type, chord mu and pupil size. The adjusted figures are reported in Table 4 and provide evidence that results were not influenced by slight variations in chord mu and pupil size.

DISCUSSION:

Herein we have presented detailed clinical and visual outcome measures following bilateral cataract surgery with 2 different available IOLs, to help inform optimal lens selection and discussions with patients to better address surgeon and patient expectations.

When comparing the two groups, there was no statistically significant difference in BCDVA (6m) or DCIVA (60cm). However, DCNVA (40cm) was significantly better in the PanOptix group ($P<0.0001$); this remained significant after controlling for pupil size and chord mu ($P < 0.001$). This improvement in near visual acuity is in keeping with the PanOptix trifocal lens design, as it is a diffractive lens with 2 step heights (2 step powers), an intermediate add of +2.17D (60cm) and a near add of +3.25D (60cm); with lens light energy distributed 50% to distance vision, and 25% each to intermediate and near vision.

In contrast, the Symfony lens is an extended depth of focus lens using an achromatic diffractive surface that provides low add foci which elongate the range of vision from distance to intermediate. The Symfony lens has an intermediate add of +1.75D, with no near add. It is thus anticipated that the distance corrected near visual acuity would be better in the PanOptix group.

Within our testing parameters, there does not appear to be any difference in the 10% low contrast ETDRS format Sloan Letter sensitivity between the 2 groups. Both lenses appear to show a 2 line reduction in visual acuity on a 10% contrast chart. By comparison, our experience is that monofocal lenses show less than one line reduction in 10% contrast sensitivity.

It is also interesting to note that an LED point source of light did not reduce the contrast sensitivity in either group, neither for distance (6m) or near (40cm) testing. However, since glare induced by a torch light for distance, and an iPhone for near, are not standardized methods for testing the effect of glare on 10% contrast visual acuity, we are unable to directly compare our findings to previous studies.

Ruiz Mesa et al & Cochener et al. similarly found CS to be comparable between PanOptix and Symfony implanted eyes under both photopic and mesopic conditions; with Ruiz Mesa et al.

using the Functional Acuity Contrast Test and Cochener using MTF.[6,8] However, Mencucci et al. found CS to be better with the Symfony lens.[9] Escandon-Garcia et al found CS to be similar between these two lenses, except for spatial frequency of 1.5 cycles under photopic conditions using the Functional Visual Analyzer.[10] They did however postulate that this finding may have been due to a small sample size. Further studies are required to investigate contrast sensitivity.

The QOL questionnaire showed 62% of the PanOptix and 48% of the Symfony group had little or no difficulty with all quality of life related tasks. It is important to note that the quality of life questionnaire is a subjective evaluation tool which is subject to human interpretation of personal experience. Patients were encouraged to give truthful answers to help evaluate the effectiveness of their implants. Surprisingly, there was one patient in each group who reported that they experienced great difficulty with every single task (for each question they answered that they had great difficulty). This occurred despite the intention of the questionnaire being explained, and despite both of these patients having very good unaided distance visual acuity post operatively, and very good post-operative refraction; with both patients having unaided binocular distance visual acuity of 0.0 LogMAR and refractive sphere $\leq$ 0.25 D with 0 cylinder in each eye. Yet subjectively, each of these patients seemed to expect more from their implants and felt that they had great difficulty with their vision. This dissatisfaction with their vision may illustrate the increasing expectation of our patients. It also illustrates how subjective these questionnaires can be, and how psychosocial and environmental factors may influence patients perceived ability to perform tasks with their presbyopia correcting implants.

Our study identifies differences between these 2 implants early after surgery, some of which are likely related to their inherent optical properties/design. The information presented will help to better counsel patients before cataract surgery. There is however a significant need for further

studies of larger numbers of patients with longer follow-up to fully evaluate patient satisfaction, contrast sensitivity, visual disturbances, and unwanted side effects.

REFERENCES:

1. Keates RH, Pearce JL, Schneider RT. Clinical results of the multifocal lens. *J Cataract Refract Surg* 1987; **13**:557–560.

2. Pedrotti E, Bruni E, Bonacci E, Badalamenti R, Mastropasqua R, Marchini G. Comparative Analysis of the Clinical Outcomes With a Monofocal and an Extended Range of Vision Intraocular Lens. *J Refract Surg* 2016;**32**:436-442.

3. Ruiz-Mesa R, Abengózar-Vela A, Aramburu A, Ruiz-Santos M. Comparison of visual outcomes after bilateral implantation of extended range of vision and trifocal intraocular lenses. *Eur J Ophthalmol* 2017;**27**:460-465.

4. Mojzis P, Kukuckova L, Majerova K, Liehneova K, Pin~ero DP. Comparative analysis of the visual performance after cataract surgery with implantation of a bifocal or trifocal diffractive IOL. *J Refract Surg* 2014;**30**:666–672

5. Carson D, Xu Z, Alexander E, Choi M, Zhao Z, Hong X. Optical bench performance of 3 trifocal intraocular lenses. *J Cataract Refract Surg* 2016;**42**:1361-1367.

6. Ruiz-Mesa R, Abengózar-Vela A, Ruiz-Santos M. A comparative study of the visual outcomes between a new trifocal and an extended depth of focus intraocular lens. *Eur J Ophthalmol* 2018;**28**:182-187.

7. Monaco G, Gari M, Di Censo F, Poscia A, Ruggi G, Scialdone. Visual performance after bilateral implantation of 2 new presbyopia-correcting intraocular lenses: Trifocal versus extended range of vision. A. *J Cataract Refract Surg* 2017;**43**:737-747.

8. Beatrice Cochener, Guillaume Boutillier, Mathieu Lamard, Claire Auberger-Zagnoli. A Comparative Evaluation of a New Generation of Diffractive Trifocal and Extended Depth of Focus Intraocular Lenses. *J Refract Surg* 2018;**34**:507-514.

9. Mencucci R, Favuzza E, Caporossi O, Savastano A, Rizzo S Comparative analysis of visual outcomes, reading skills, contrast sensitivity, and patient satisfaction with two models of trifocal diffractive intraocular lenses and an extended range of vision intraocular lens *Graefes Arch Clin Exp Ophthalmol*. 2018;**256**:1913-1922.

10. Escandón-García S, Ribeiro FJ, McAlinden C, Queirós A, González-Méijome JM Through-Focus Vision Performance and Light Disturbances of 3 New Intraocular Lenses for Presbyopia Correction. *J Ophthalmol* 2018;2018:6165493.

APPENDIX

Table 1 Preoperative Demographics, Biometry, and Visual Acuity

Baseline factor	**PANOPTIX** N = 34		**SYMFONY** N = 33	
Sex:				
Male [N (%)]	15 (44)		13 (39)	
Female [N (%)]	19 (56)		20 (61)	
Age (years) [mean ± SD]	72 ± 7		72 ± 7	
Arcuate keratotomy [N (%)]	21 (62)		19 (58)	
	PANOPTIX N = 34 Right Eye	**PANOPTIX** N = 34 Left Eye	**SYMFONY** N = 33 Right Eye	**SYMFONY** N = 33 Left Eye
Axial length (mm) [mean ± SD]	23.65 ± 0.81	23.62 ± 0.68	23.75 ± 0.84	23.63 ± 0.88
Average keratometry (Diopters) [mean ± SD]	43.88 ± 1.00	43.87 ± 0.91	44.04 ± 1.28	44.09 ± 1.34
IOL Master pupil size (mm) [mean ± SD]	3.6 ± 0.61	3.66 ± 0.70	3.81 ± 0.82	3.97 ± 0.80
Chord Mu (mm) [mean ± SD]	0.35 ± 0.14	0.31 ± 0.15	0.34 ± 0.14	0.33 ± 0.14
Best corrected distance visual acuity (logMAR) [median (IQR)]	0.2 (0.14 to 0.34)	0.29 (0.12 to 0.4)	0.16 (0.04 to 0.36)	0.14 (0.06 to 0.24)

IQR = interquartile range; SD = standard deviation

Table 2 Postoperative Visual Acuity

Visual Acuity (logMAR)	**PANOPTIX** N = 34	**SYMFONY** N = 33	**P**
Best distance corrected near visual acuity at 3 months post randomization [median (IQR)]	0.02 (0 to 0.12)	0.2 (0.14 to 0.3)	< 0.001
Distance corrected intermediate visual acuity [median (IQR)]	0 (-0.04 to 0.06)	0.04 (0.02 to 0.1)	0.056
Uncorrected distance visual acuity [median (IQR)]	0 (-0.04 to 0.04)	0 (-0.02 to 0.02)	> 0.05
Distance corrected near visual acuity 10 % contrast [median (IQR)]	0.3 (0.16 to 0.34)	0.44 (0.36 to 0.52)	> 0.05
Best corrected distance visual acuity [median (IQR)]	-0.016 ± 0.060	-0.021 ± 0.052	0.699
Best corrected distance visual acuity 10 % contrast chart [mean ± SD]	0.20 ± 0.12	0.17 ± 0.09	> 0.05
Best corrected distance visual acuity 10 % contrast with glare [mean ± SD]	0.21 ± 0.12	0.17 ± 0.09	> 0.05

Distance corrected near visual acuity 10 % contrast with glare [mean ± SD]	0.27 ± 0.12		0.45 ± 0.14		> 0.05
	PANOPTIX N = 34 Right Eye	**PANOPTIX** N = 34 Left Eye	**SYMFONY** N = 33 Right Eye	**SYMFONY** N = 33 Left Eye	
Uncorrected distance visual acuity [median (IQR)]	0.08 (0 to 0.16)	0.04 (0.02 to 0.14)	0.04 (0 to 0.14)	0.06 (0 to 0.14)	> 0.05

IQR = interquartile range; SD = standard deviation

Table 3 Quality of Life Scores

Activity		**PANOPTIX**		**SYMFONY**	
		N	**%**	**N**	**%**
Reading small print	None	10	29	4	12
	A little	13	38	17	51
	Moderate	6	18	4	12
	Great Deal	4	12	7	21
	Unable to do	1	3	1	3
Reading newspaper	None	18	54	13	39
	A little	5	15	12	36
	Moderate	5	15	4	12
	Great Deal	5	15	4	12
	Unable to do	0	0	0	0
Reading large print	None	28	82	25	76
	A little	0	0	3	9
	Moderate	2	6	0	0
	Great Deal	4	12	5	15
	Unable to do	0	0	0	0
Recognising people when close	None	29	85	28	85
	A little	0	0	0	0
	Moderate	0	0	0	0
	Great Deal	5	15	5	15
	Unable to do	0	0	0	0

Seeing steps, stairs or curbs	None	28	82	26	79
	A little	1	3	1	3
	Moderate	0	0	2	6
	Great Deal	5	15	4	12
	Unable to do	0	0	0	0
Reading traffic signs	None	26	76	25	76
	A little	3	9	2	6
	Moderate	0	0	1	3
	Great Deal	5	15	5	15
	Unable to do	0	0	0	0
Doing fine handwork	None	17	59	11	37
	A little	8	28	11	37
	Moderate	1	3	3	10
	Great Deal	3	10	5	17
	Unable to do	0	0	0	0
Writing checks	None	24	75	21	66
	A little	4	12.5	6	19
	Moderate	0	0	3	9
	Great Deal	4	12.5	2	6
	Unable to do	0	0	0	0
Playing games such as bingo	None	23	85	23	74
	A little	0	0	4	13
	Moderate	0	0	1	3

	Great Deal	4	15	3	10
	Unable to do	0	0	0	0
Taking parts in sports such as bowling	None	18	86	19	79
	A little	0	0	1	4
	Moderate	3	14	3	12.5
	Great Deal	0	0	1	4
	Unable to do	0	0	0	0
Cooking	None	27	84	25	76
	A little	0	0	3	9
	Moderate	1	3	2	6
	Great Deal	4	12.5	3	9
	Unable to do	0	0	0	0
Watching television	None	24	71	25	78
	A little	4	12	2	6
	Moderate	1	3	1	3
	Great Deal	5	15	4	12.5
	Unable to do	0	0	0	0
Driving during the day	None	24	77	25	78
	A little	1	3	1	3
	Moderate	1	3	1	3
	Great Deal	5	16	5	16
	Unable to do	0	0	0	0

Driving at night	None	16	57	16	52
	A little	6	21	5	16
	Moderate	4	14	4	13
	Great Deal	1	4	5	16
	Unable to do	1	4	1	3
Recognising people at a distance	None	22	65	25	76
	A little	5	15	4	12
	Moderate	3	9	1	3
	Great Deal	4	12	3	9
	Unable to do	0	0	0	0
Using a personal computer	None	20	67	22	81
	A little	5	17	3	11
	Moderate	1	3	0	0
	Great Deal	4	13	2	7
	Unable to do	0	0	0	0
Shaving, styling hair	None	27	79	27	87
	A little	2	6	2	2
	Moderate	0	0	0	0
	Great Deal	5	15	2	2
	Unable to do	0	0	0	0
Difficulty in going out to	None	22	82	29	97
	A little	2	7	0	0
	Moderate	1	4	0	0

see movies, theatre	Great Deal Unable to do	2 0	7 0	1 0	3 0

Table 4 Sensitivity Analysis

	Right Eye			**Left Eye**		
	Coefficient	**95 % CI**	**P**	**Coefficient**	**95 % CI**	**P**
Distance corrected near visual acuity at 3 months post randomisation	0.165	(0.123 - 0.209)	< 0.001	0.171	(0.125 - 0.216)	< 0.001
Distance best corrected distance visual acuity	-0.005	(-0.033 - 0.022	0.68	-0.004	(-0.033 0.023)	0.733
Distance corrected intermediate visual acuity	0.04	(-0.004 - 0.085)	0.075	0.04	(-0.005 0.085)	0.08

CI = confidence interval

FIGURE LEGENDS

Figure 1. Standard graphs for reporting refractive outcomes for the PanOptix Group: (A) uncorrected distance visual acuity (UDVA); (B) UDVA vs corrected distance visual acuity (CDVA); (C) spherical equivalent refraction accuracy; and (D) postoperative refractive cylinder. D = diopters

Figure 2. Standard graphs for reporting refractive outcomes for the Symfony Group: (A) uncorrected distance visual acuity (UDVA); (B) UDVA vs corrected distance visual acuity (CDVA); (C) spherical equivalent refraction accuracy; and (D) postoperative refractive cylinder. D = diopters