DOI 10.1007/s004170100348

Tony Walkow Ulrich M. Klemen

Patient satisfaction after implantation of diffractive designed multifocal intraocular lenses in dependence on objective parameters

Received: 1 March 2001 Revised: 3 July 2001 Accepted: 3 July 2001 Published online: 18 August 2001 © Springer-Verlag 2001

This work was presented in part at the Annual Meeting of the DOG, Berlin, September 2000

The authors have no proprietary interest in any of the materials used in this study

T. Walkow (⊠) · U.M. Klemen Department of Ophthalmology, A.Ö.K. St. Pölten, St.Pölten, Austria

Correspondence address: T. Walkow, Steinergasse 2a-4, St. Pölten, A-3100, Austria e-mail: tonywalkow@hotmail.com, Fax: +43-2742-3003337 Abstract Background: For optimal patient satisfaction and greatest independence from spectacles after implantation of a diffractive designed multifocal intraocular lens (IOL), emmetropia with a low postoperative astigmatism must be achieved. The aim of this study was to prospectively determine patient satisfaction after implantation of diffractive designed multifocal IOLs in relation to objective parameters. Patients and methods: A total of 69 eyes of 50 patients without additional ocular pathology (mean age 64.8 years) received a diffractive designed multifocal IOL and were examined 12 months postoperatively. Overall patient satisfaction, visual phenomena (halos, glare), and frequency of use of reading spectacles and distance correction were assessed as subjective parameters. As objective parameters, uncorrected and best-corrected distance visual acuity (UCVA, BCVA, respectively), uncorrected, distance corrected and best-corrected near visual acuity, contrast sensitivity (Pelli-Robson charts), pre- and postoperative astigmatism, postoperative spherical equivalent and depth of focus (defocusing curve from +5.0 to -5.0 D)

were measured. Results: The mean overall satisfaction on a scale from 5 (excellent) to 1 (poor) was 4.49. Mean postoperative UCVA was 0.85 and BCVA was 1.03. Mean uncorrected near visual acuity was J1.04, distance corrected near visual acuity J1.0 and best corrected near visual acuity J1.0. Postoperative mean spherical equivalent was -0.17±0.43 D and absolute mean astigmatism was 0.64 D. The use of spectacles was highly correlated with postoperative spherical equivalent and absolute postoperative astigmatism. On a subjective scale from 0 (none) to 4 (very disturbing), a mean halo score of 0.45 and a mean glare score of 0.44 was recorded. Overall satisfaction was significantly correlated with UCVA, age, use of spectacles for distance purposes, contrast sensitivity, postoperative astigmatism, and postoperative spherical equivalent (P<0.05). Linear stepwise regression analysis identified UCVA as the most influential factor for overall patient satisfaction. Conclusions: For diffractive designed multifocal IOLs, emmetropia and a low astigmatism postoperatively are the most important factors for high patient satisfaction.

Introduction

In several previous studies good functional results have been found after implantation of diffractive designed multifocal intraocular lenses (IOLs) [1, 2, 5, 10, 12, 14]. In general, multifocal designed IOLs should provide the patient with a greater depth of focus and less dependence on spectacles, thereby improving overall satisfaction compared to monofocal IOLs.

The primary objective of the present study was to determine whether there are correlations between objective parameters (e.g. uncorrected visual acuity, UCVA), subjective sensations (e.g. glare) on the one hand and overall patient satisfaction on the other, and how to use this knowledge to improve postoperative results.

Material and methods

This prospective study evaluated 69 eyes of 50 patients scheduled for elective cataract surgery with no other ocular pathology. After obtaining informed consent, all eyes received a diffractive designed IOL. The mean age of the patients was 64.8 years (range 32 to 83 years).

The Pharmacia 811E lens was chosen as representative of the diffractive design. The 811E is a one-piece PMMA lens with 20 to 30 concentric rings superimposed on its posterior surface providing a theoretical power add of approximately 4 D. This lens has a 12.5 mm overall diameter with a 6-mm optic, 10° angulated capsular C-haptics, a heparin-modified surface, and no positioning holes. The distance power of this diffractive designed lens is the combined optical power of the anterior and posterior lens surfaces and the zero order of diffraction, which focuses approximately 41% of the light at the distance focus point. The near power is the combined power of the two lens surfaces and the first order of diffraction, focusing 41% of the light is lost for higher orders of diffraction.

Patient exclusion criteria for the study were a monofocal IOL in the fellow eye, more than 2 D of astigmatism before surgery, significant corneal opacities, chronic drug miosis, iris neovascularization or fundus abnormalities which could cause significant vision impairment. Patients who were professional car drivers at night (e.g. taxi drivers, police officers) were also excluded.

Two experienced surgeons performed a standard no-stitch cataract extraction on all patients. The location of the incision was chosen depending on the preoperative astigmatism. Based on our experience concerning the mean absolute postoperative astigmatism, in patients with preoperative astigmatism with the rule, a 12-o'clock access was used. For patients with astigmatism against the rule, a lateral incision was performed. Five biometric measurements were taken preoperatively using the SRK II formula. Keratometric data were obtained with three consecutive measurements using a Zeiss keratometer.

Routine phacoemulsification was done using a standard technique through a scleral tunnel incision. After continuous curvilinear capsulorhexis (CCC) and hydrodissection, phacoemulsification was performed with the phaco chop or the divide and conquer technique. After irrigation and aspiration of the residual cortex, the capsular bag was filled with a viscoelastic substance (sodium hyaluronate) and the scleral incision widened with the phacolance. All IOLs were implanted in the bag. There were no intraoperative complications such as rupture of posterior capsule, rupture of zonule, vitreous loss, iris lesions, or significant hyphema. The patients were examined on the first postoperative day. The next follow-up was scheduled 4 weeks after surgery, the next one after 6 months, and the last after 12 months. The data presented here are based on the 12-month data (64 eyes).

Visual acuity measurements were always performed under the same conditions with standard visual acuity charts. Near visual acuity was assessed with and without distance correction and a second time with the distance correction and any necessary addition from a distance of 25 to 40 cm, as chosen by the patient, using Jaeger charts. Conversion of the Jaeger charts to the Snellen equivalents is listed in Table 1. Contrast sensitivity was assessed using the Pelli Robson chart, which is scored from 0.05 to 2.25 (log units) and gives progressively decreasing contrast. The chart consists of fixed-sized letters of varying contrast. The size of the letters subtends 0.5° at a distance of 3 m.

Table 1 Acuity conversion	
-----------------------------------	--

Jaeger	Snellen	
J1+ J1 J2 J3 J5	20/20 20/25 20/30 20/40 20/50	

In addition, we assessed overall visual function with defocusing curves. They predict how the patient can see from distance through intermediate to near ranges in distance. The test first determines the patient's best-corrected distance vision, and then the patient is defocused in 0.50-D increments (from +5.0 to -5.0 D). Distance visual acuity is noted at each defocusing point.

A standardized questionnaire was used to rate the patients' overall satisfaction 12 months after surgery and to register their subjective visual phenomena. The survey included a careful questionnaire about halos and glare for different light conditions including daylight, artificial light, dimmed light, and night. The patients were asked to rate their overall satisfaction as excellent (5), very good (4), good (3), fair (2), or poor (1). The patients were also asked to rate the intensity of visual phenomena between none (0) and very disturbing (4). In addition, subjects were asked to specify the frequency with witch they wore spectacles for near and distance tasks as never (0), seldom (1), sometimes (2), very often (3), or always (4).

For the statistical calculations the SPSS for Windows statistical package with a general significance set at P<0.05 was used. Associations with categoric variables and continuous variables were assessed using Spearman's correlation coefficient and Pearson's correlation coefficient, respectively.

Results

The mean overall satisfaction on a scale from 5 (excellent) to 1 (poor) was 4.49 ± 0.72 . Details of this questionnaire are shown in Fig. 1. All patients had a monocular UCVA of at least 20/50, 75.4% achieved a UCVA of 20/25. Mean postoperative UCVA was 0.85 ± 0.22 and mean best-corrected visual acuity (BCVA) was 1.04 ± 0.15 (detailed data are listed in Table 2). Mean spherical equivalent postoperatively was -0.17 ± 0.43 D (range -1.25D to +0.63 D). Emmetropia occurred in 44.7% of the eyes, and 84.2% were within ±0.5 D. Mean absolute postoperative astigmatism of all operated eyes was 0.64 ± 0.59 D (range 0-3.0 D). In 54.1% of eyes, astigmatism after 12 months was 0.50 D or less.

Mean UCVA was J1.03 \pm 0.18, distance corrected near visual acuity J1.0 \pm 0 and best corrected near visual acuity J1.0 \pm 0. Both 20/40 and J3 could seen unaided by 96.9% of the patients. Mean monocular contrast sensitivity (Pelli-Robson charts) was 1.50 \pm 0.08 (range 1.35–1.65). The average defocusing curve of all eyes is shown in Fig. 2.

During the first 12 months in four eyes a capsulotomy had to be performed. After the capsulotomies were performed there was no statistically significant difference concerning UCVA, BCVA, uncorrected near visual acuity, contrast sensitivity, subjective phenomena (e.g. halos

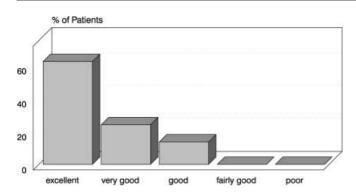


Fig. 1 Patients were asked to rate their satisfaction 1 year after surgery from excellent to poor. Generally, patients with an uncorrected distance visual acuity of 20/25 or better (73.4% of patients) felt significantly more satisfied with the implanted lens (*P*=0.023)

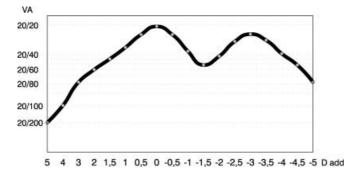


Fig. 2 The mean monocular defocusing curves (64 eyes) after implantation of a diffractive designed multifocal IOL with best distance correction

 Table 2
 Distance visual acuity

Snellen	Uncorrected,	Best-corrected,
visual acuity	monocular (<i>n</i> =64)	monocular (<i>n</i> =64)
20/20 or better	31 (48.4%)	49 (76.4%)
20/25	16 (25.0%)	15 (23.4%)
20/30	8 (12.5%)	0
20/40	7 (10.9%)	0
20/50	2 (3.1%)	0

or glare), use of spectacles or overall patient satisfaction between capsulotomized and non-capsulotomized eyes.

The average score for the use for spectacles for distance was 0.26 ± 0.94 . The score for use of spectacles for near was 0.39 ± 0.87 (0 never, 1 seldom, 2 sometimes, 3 often, 4 always). The use of spectacles for distance was significantly correlated with overall patient satisfaction (*r*=-0.459, *P*=0.006). It was also correlated with postoperative astigmatism (*r*=0.455, *P*=0.006), with preoperative astigmatism (*r*=0.482, *P*=0.027) and with absolute postoperative spherical equivalent (*r*=0.351, *P*=0.036). The latter was also highly correlated with the

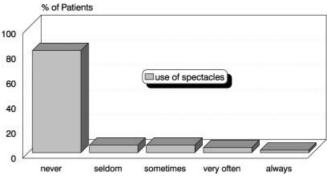


Fig. 3 Frequencies of spectacle wear

uncorrected distance visual acuity (r=-0.649, P<0.0001). Figure 3 shows the frequency of spectacle wear.

The mean halo and glare scores were 0.45 ± 0.63 and 0.44 ± 0.66 , respectively (0 none to 4 very disturbing). Subjective glare was correlated with age (*r*=-0.418, *P*=0.015).

Overall patient satisfaction was moderately correlated with postoperative spherical equivalent (r=-0.398, P=0.016), contrast sensitivity (r=0.427, P=0.030), and absolute postoperative astigmatism (r=-0.355, P=0.036), and was highly correlated with UCVA (r=0.378, P=0.002), use of spectacles for distance purposes (r=-0.459, P=0.006) and age (r=0.289, P=0.009). None of the other investigated subjective and objective parameters had a significant influence on the patients' overall rating.

Stepwise regression analysis revealed uncorrected distance visual acuity as the most important predictor for overall patient satisfaction (R=0.457, P=0.025) (model 1). As model 2 includes all significant predictors the combination of uncorrected distance visual acuity, age, and postoperative spherical equivalent was determined. In this model, the correlation increased to R=0.738 (P=0.001).

For determining the importance of UCVA, we compared patients with a visual acuity of lower than 20/25 (group I, n=17, 26.6%) and patients with a UCVA of 20/25 or higher (group II, n=47, 73.4%). In the latter group overall satisfaction was 4.62±0.57, which was significantly better than in the former with an overall rating of 4.06 ± 0.97 (P=0.038). Further analysis of both groups revealed the following significant differences (group I vs group II): mean spherical equivalent -0.58 ± 0.59 D vs -0.02 ± 0.24 D (P=0.002), mean absolute spherical equivalent 0.7±0.41 D vs 0.16±0.17 D (P<0.0001), postoperative astigmatism 0.94 ± 0.94 D vs 0.54 ± 0.42 D (P<0.05), preoperative astigmatism 1.25±0.75 D vs 0.64±0.45 D (P < 0.05), use of spectacles for distance 0.9 ± 1.66 vs 0.04 ± 0.20 (P=0.023). The use of spectacles for near, BCVA, near visual acuity, halos, glare, contrast sensitivity, and age were not significantly different between the two subgroups (P > 0.05).

Discussion

Overall, all patients had good functional results, and the mean patient satisfaction score of 4.49 fell between "very good" and "excellent" on the response scale. A monocular UCVA of 20/25 or better was found in 75.4% of the patients. Our results concerning UCVA and BCVA were in the same range as the monocular results of other studies with diffractive designed IOLs [1, 6, 10, 11, 12, 14] (see also Table 2).

In contrast to refractive designed multifocal IOLs, where uncorrected near visual acuity has been found to be the most important factor for patient satisfaction [3, 13], with diffractive designed multifocal IOLs this factor did not play a role in patient satisfaction due to the overall excellent reading results, but uncorrected distance visual acuity was identified as the most important factor. Other factors correlated with overall patient satisfaction were age, absolute postoperative astigmatism, postoperative spherical equivalent, need for spectacles for distance purposes and contrast sensitivity.

The mean UCVA was 0.85. However, patients with a UCVA of less than 20/25 (24.6% of all patients) reported a lower grade of satisfaction. In this group the mean overall satisfaction was 4.06 (equal to an overall rating of "very good") whereas in the group with a UCVA of 20/25 or better (75.4% of all patients), the mean overall satisfaction was 4.62, which is equal to an overall rating of nearly "excellent". This difference was statistically significant. In the former group the use of spectacles was also significantly lower. Factors contributing to these differences were preoperative astigmatism (patient preselection) and postoperative astigmatism (operation technique), as well as postoperative spherical equivalent (preoperative biometry and keratometry).

Another very important factor for a good near visual acuity was postoperative astigmatism. Postoperative astigmatism was moderately correlated with overall patient satisfaction. In addition to the operation technique, with a low induced astigmatism, patient preselection is crucial for these good postoperative results, especially concerning UCVA and therefore overall patient satisfaction. This is also supported by the correlation between preoperative astigmatism and use of spectacles postoperatively (r=0.482, P=0.027) as well as the correlation of the latter with postoperative astigmatism (r=0.455, P=0.006). We also found a correlation between uncorrected contrast sensitivity and postoperative astigmatism (r=-0.450, P=0.024). This is supported by the experimental study of Ravalico et al. [8], in which it was found that a low postoperative astigmatism after implantation of a multifocal IOL minimizes the decrease in contrast sensitivity.

The functional results were such that 80.6% of patients never needed to wear spectacles. Including patients who only seldom needed spectacles, this percentage increased to 86.2%. Comparing the results after nonselective implantation of multifocal IOLs again the benefit of patient preselection is striking. In a nonselective study by Kamath et al. [4], 28.4% of the eyes achieved a UCVA of 20/40 or better and 71.6% had a BCVA of 20/40 or better, whereas in the present study 96.9% of the eyes had a UCVA of 20/40 or better and all patients achieved a BCVA of at least 20/25 monocularly. The role of patient preselection was also confirmed in a study by Slagsfold [10], in which 98.7% of patients without ocular pathology had a BCVA of 1.0 or better. In general, due to the contrast loss with multifocal designed IOLs, we would not recommend implanting a multifocal IOL when ocular pathologies other than cataract are present.

In addition, Kamath et al. [4] analyzed patients who had a UCVA <20/40 and a BCVA >20/40. Of 133 eyes, 24 (18%) fulfilled this criterion and had a spherical equivalent of greater than 1 D, confirming the need for an exact IOL calculation. In the present study only one eye had a spherical equivalent of >1 D (maximum spherical equivalent was 1.25 D), confirming our strategy of multiple measurements of the K reading as well as axial length by experienced investigators with a permanent quality control of the postoperative outcome. These results are further supported by the results of Avitabile et al. [1]. They found good overall satisfaction in 94.3% of patients with best distance correction, but in only 68.6% without distance correction.

It was not possible to detect any association between patient-reported bother by glare, halos, or other subjective phenomena and overall patient satisfaction. This is consistent with previous studies with multifocal IOL [3, 13]. None of the implanted IOLs in the present study had to be explanted due to such phenomena or due to other causes.

Compared with the age-matched preoperative data of Rubin et al. [9] (Pelli-Robson score 1.34 ± 0.23), our patients achieved a higher contrast sensitivity postoperatively. Still, the contrast sensitivity of the multifocal eyes (Pelli-Robson score 1.50 ± 0.08) was about one log unit lower than those of patients equipped with monofocal lenses (Pelli-Robson score 1.65 ± 0.14) [9]. In the present study, some patients did notice a loss of contrast sensitivity. In combination with even small visual deterioration due, for example, to capsule fibrosis, the overall satisfaction was altered because of the lower contrast sensitivity. This was also confirmed by the high correlation of UCVA with patient satisfaction, and confirms the necessity for preselection of patients excluding those with, for example, with corneal opacities or a maculopathy.

In general, trade-offs, such as decreased contrast, are acceptable especially for patients who wish to decrease their dependence on spectacles. These patients are prepared to exchange some clarity of image quality for an increased depth of focus and reduced dependence on spectacles associated with multifocal IOL use. This is supported by the results of the present study, especially when concerning UCVA and the use of spectacles for distance purposes.

The defocusing curve confirmed the laboratory results of Ravalico et al. [7]. For the Pharmacia 811E IOL the authors found a distribution of light energy for the distance focus of 44.9% versus 36.9% for the near focus. The mean defocusing curves in the present study confirm these results with a visual acuity of 1.04 at 0 D and 0.81 at -3.0 D. Similar results have also been found in previous studies [13, 14]. The difference in the theoretical distribution of 41% for both foci is explained by the central zone of the diffractive designed multifocal IOLs that contributes only to the distance focus. However, near reading results showed that this is in general good enough for reading J2 or better without any additional correction.

Before deciding whether a patient will benefit from a multifocal lens, a review of the patient's lifestyle is very helpful. Some patients may not have thought about

are very important because expectations arising from confirm cataract surgery have increased dramatically. Patients D and must understand that spectacles may eventually be required for certain tasks (such as reading small print) after surgery. d by the Overall patients with diffractive designed multifocal IOLs were very satisfied with the postoperative results, which were mostly influenced by the UCVA. The latter

IOLs were very satisfied with the postoperative results, which were mostly influenced by the UCVA. The latter can be optimized by preoperative patient selection (no ocular pathologies, low preoperative astigmatism), an excellent IOL calculation management (keratometry, axial length measurement), and surgical technique (low induced astigmatism, good IOL positioning).

which tasks (reading, driving, computer work) they

would most like to accomplish without spectacles, and such needs of the patient influence our decision as to

whether a monofocal or a multifocal IOL should be rec-

ommended. These data should be combined with de-

tailed information on the patient. These considerations

References

- Avitabile T, Marano F, Canino EG, et al (1999) Long-term visual results of bifocal intraocular lens implantation. J Cataract Refract Surg 25:1263–1269
- Gimbel HV, Sanders DR, Raanan MG (1991) Visual and refractive results of multifocal intraocular lenses. Ophthalmology 98:881–887
- 3. Javitt JC, Wang F, Trentacost DJ, et al (1997) Outcomes of cataract extraction with multifocal intraocular lens implantation: functional status and quality of life. Ophthalmology 104:589–599
- Kamath GG, Prasad S, Danson A, et al (2000) Visual outcome with the Array multifocal intraocular lens in patients with concurrent eye disease. J Cataract Refract Surg 26:576–581
- 5. Percival SPB, Setty SS (1991) Comparative analysis of three prospective trials of multifocal implants. Eye 5:712–716

- 6. Pieh S, Weghaupt H, Skorpik C (1998) Contrast sensitivity and glare disability with diffractive and refractive multifocal intraocular lenses. J Cataract Refract Surg 24:659–662
- Ravalico G, Parentin F, Sirotti P, et al (1998) Analysis of light distribution by multifocal intraocular lenses through an experimental optical model. J Cataract Refract Surg 24:647–652
- Ravalico G, Parentin F, Baccara F (1999) Effect of astigmatism on multifocal intraocular lenses. J Cataract Refract Surg 25:804–807
- Rubin GS, Adamsons IA, Stark WJ (1993) Comparison of acuity, contrast sensitivity, and disability glare before and after cataract surgery. Arch Ophthalmol 111:56–61
- Slagsvold JE (2000) 3 M diffractive multifocal intraocular lens: eight year follow-up. J Cataract Refract Surg 26:402–407
- Voigt U, Strobel J (1999) YAG-Laserkapsulotomie bei multifokalen Intraokularlinsen. Ophthalmologe 96:578–582

- Walkow T, Liekfeld A, Anders N, et al (1997) A prospective evaluation of a diffractive versus a refractive designed multifocal intraocular lens. Ophthalmology 104:1380–1386
- Walkow T, Liekfeld A, Anders N, Hartmann C (1999) Funktionelle Ergebnisse nach binokularer Implantation von Multifokallinsen – diffraktives versus refraktives Design. In: Ohrloff (ed) 13. Jahrestagung der DGII 1999, Frankfurt/M. Springer, Berlin Heidelberg, pp 141–150
- Weghaupt H, Pieh S, Skorpik C (1998) Comparison of pseudoaccommodation and visual quality between a diffractive and refractive multifocal intraocular lens. J Cataract Refract Surg 24:663–665