REFRACTIVE OUTCOME AFTER BILATERAL IMPLANTATION OF AN APODIZED DIFFRACTIVE INTRAOCULAR LENS

*SALLET G.**

ABSTRACT

Purpose : Evaluation of the results of the first 30 patients, bilaterally implanted with the bifocal Acrysof Restor Apodized Diffractive intraocular lens (IOL) (SA60D3). The optics of this lens are designed to restore near and distance vision.
Setting: Department of Ophthalmology, Aalsters Stedelijk Ziekenhuis, Aalst, Belgium
Methodes: Sixty eyes of 30 patients had implantation of the Alcon Acrysof Restor SA60D3 IOL in this prospective nonrandomized clinical study. Fourty-eight eyes were evaluated at 6 months and 60 eyes at 3 months. Patient selection included no other eye disease besides cataract and corneal astigmatism of one diopter or less. Uncorrected distance visual acuity (UCVA-D), uncorrected near visual acuity (UCVA-N), best corrected distance visual acuity (BCVA-D) and distance corrected near visual acuity (DCVA-N) were recorded. Glare phenomena, halos and night vision difficulties were evaluated as well as patient satisfaction.
Results: Postoperative UCVA-D was better than 20/40 at 3 months and better than 20/30 at 6 months in all eyes. UCVA-N was equal or better than Jaeger (J) 3 at 3 months in 91% and all eyes achieved J3 or better at 6 months. BCVA-D was 20/30 or better in all eyes at 3 months and 20/25 or better at 6 months. DCVA-N was J2 or better in all eyes at 3 and 6 months. Patient satisfaction was excellent (76%), good (10%) or acceptable (14%). No patient was dissatisfied with the result. Twenty percent of patients mentioned glare or halos when specifically asked.
Conclusion: 3- and 6-month data indicate that the Acrysof Restor Apodized diffractive IOL (SA60D3) provides excellent near visual acuity without compromising distance visual acuity. The incidence of visual disturbances is low and patient satisfaction high.

RÉSUMÉ

Objectif: Evaluation des premiers 30 patients ayant reçu une implantation bilatérale d'une lentille intra-oculaire bifocale (Acrysof Restor Diffractive IOL SA60D3). Les optiques de ce type de lentille sont faites de façon à améliorer l'acuité visuelle de loin et de près.
Méthodes: Une lentille intra-oculaire Alcon Acrysof Restor SA60D3 a été implantée dans 60 yeux de 30 patients et les yeux ont ensuite été analysés à l'aide d'une étude clinique prospective et non randomisée. Quarante-huit yeux ont été évalués après six mois et 60 yeux après 3 mois. Les patients sélectionnés n'avaient pas d'autre maladie que la cataracte. Les patients avec un astigmatisme cornéen de plus de 1 Dioptrie ont été exclus. L'acuité visuelle non corrigée de loin et de près, l'acuité visuelle corrigée de loin et de près et l'acuité visuelle de près avec la correction de loin ont été étudiées. La satisfaction des patients ainsi que les problèmes éventuels de la vue ont été évalués.
Résultats: En postopératif, l'acuité visuelle non corrigée de loin était de 20/40 ou plus à 3 mois et de 20/30 à 6 mois dans tous les yeux. L'acuité visuelle non corrigée de près était égale à ou meilleure que le Jaeger (J) 3 à 3 mois dans 91% des yeux et tous les yeux ont atteint le J3 ou plus à 6 mois. La meilleure acuité visuelle de loin était de 20/30 ou plus dans tous les yeux à 3 mois et de 20/25 ou plus à 6 mois. L'acuité visuelle de près avec la correction de loin

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était de J2 ou plus dans tous les yeux à 3 et 6 mois. Le degré de satisfaction des patients était excellent (76%), bon (10%) ou acceptable (14%). Aucun patient n'était mécontent.
Conclusion: Les résultats à 3 et 6 mois indiquent que la lentille intra-oculaire SA60D3 (Acrysof Restor) donne une bonne acuité visuelle de près et de loin. La plupart des patients sont très satisfaits et l'incidence des effets secondaires est très petite.

SAMENVATTING

Doel: Evaluatie van de resultaten van de eerste 30 patiënten, geïmplanteerd met de bifocale Acrysof Restor Apodized Diffractieve intra-oculaire lens (IOL) (SA60D3). De optiek van deze lens zou het ver zicht en nabij zicht moeten herstellen.
Methode: Zestig ogen van 30 patiënten werden geïmplanteerd met de Alcon Acrysof Restor SA60D3 IOL in een prospectieve niet-gerandomiseerde klinische studie. Achtenveertig ogen werden geëvalueerd op 6 maand en 60 ogen op 3 maand. Behalve cataract en corneaal astigmatisme van minder dan 1 dioptrie, werden geen oogziekten toegestaan in de selectiecriteria. Vertezicht zonder en met beste correctie en nabij zicht zonder correctie en met beste vertecorrectie werden onderzocht. Strooilicht en zien van lichtkringen of nachtproblemen werden onderzocht evenals de tevredenheid van de patiënten.
Resultaten: Postoperatief ongecorrigeerd vertezicht was beter dan 20/40 op 3 maand en beter dan 20/30 op 6 maand in alle ogen. 91% van de ogen las Jaeger (J3) op 3 maand en 100% op 6 maand. Beste vertezicht bedroeg 20/30 of beter in alle ogen op 3 maand en 20/25 of beter op 6 maand. Nabij zicht met de vertecorrectie was J2 of beter in alle ogen op 3 en 6 maand. Tevredenheid was excellent (76%), goed (10%) of aanvaardbaar (14%). Geen enkele patiënt was ontevreden met het resultaat. Twintig percent van de patiënten vernoemden strooilicht of zien van halo's rond lichtbronnen.
Conclusie: De resultaten op 3 en 6 maand tonen aan dat de Acrysof Restor IOL (SA60D3) excellent zicht geeft voor nabij zonder dat het vertezicht vermindert. De incidentie van visuele stoornissen is laag en tevredenheid van patiënten hoog.

KEY WORDS

multifocal intraocular lens, Acrysof Restor, diffractive intraocular lens, apodisation

MOTS-CLES

Lentille intra-oculaire multifocale, Acrysof Restor, lentille intra-oculaire diffractive, apodisation

INTRODUCTION

Cataract surgery has evolved from a visual rehabilitating procedure to a true refractive surgical procedure (4,5,12). Monofocal intraocular lenses (IOL) provide excellent distance vision, but patients are still dependent on spectacles for near and intermediate vision. A number of multifocal and accomodating IOLs (1,2,3,6,7,10,11) address this problem and try to improve distance and near visual acuity without glasses. One of the latest designs of a multifocal IOL is the Acrysof Restor Apodized Diffractive IOL SA60D3 (Alcon Laboratories, Fort Worth, TX, USA).
It is a single piece hydrophobic acrylate IOL with a 6 mm optic consisting of a diffractive central 3.6 mm optical zone and an exclusively refractive zone of 2.4 mm peripherally. The central diffractive zone has a controlled reduction in step heights, designed to minimize unwanted nigh time effects such as glare and halos. The physical term for improvement of the image quality of a lens system is called apodization. The lens also incorporates +4.0 Diopter (D) add power which approximates a 3.2 D at the corneal plane.
The aim of this study is to evaluate the efficacy of this IOL in restoring distance and near visual acuity after bilateral cataract removal.

PATIENTS AND METHODS

From October 2003 to June 2004, 60 eyes of 30 patients were bilaterally implanted with an apodized diffractive IOL (Acrysof Restor SA60D3). All patients had a comprehensive ophthalmic examination. Exclusion criteria included ocular pathology other than cataract and more than 1 D of astigmatism. As the IOLs were only available from 16 D to 25 D , no patients with extreme ametropia were included in this study.

Inclusion criteria for implantation were as follows: desire to be spectacle independent for far and near vision, realistic expectations and signed informed consent.

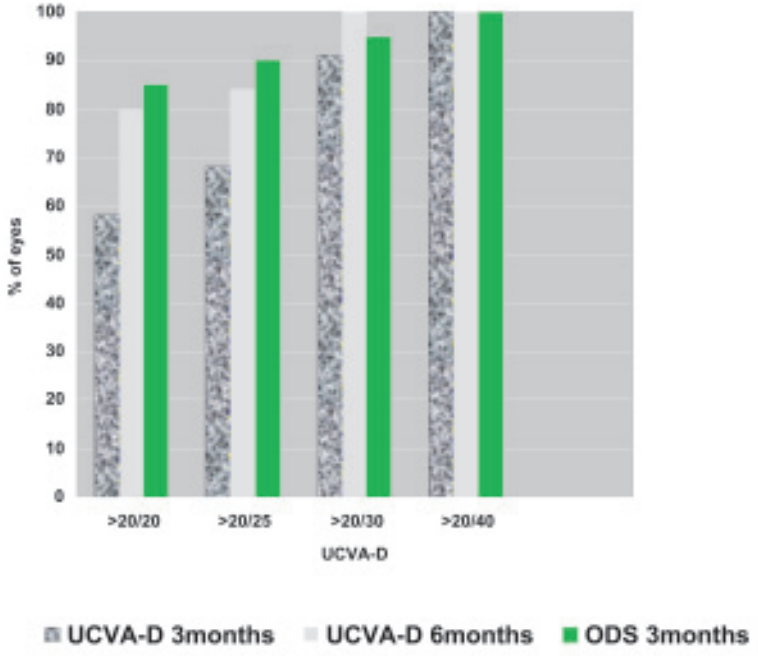

Fig. 1 Uncorrected distance visual acuity (UCVA-D) at 3 (60 eyes) and 6 months (20 eyes) and binocular at 3 months (30 patients).

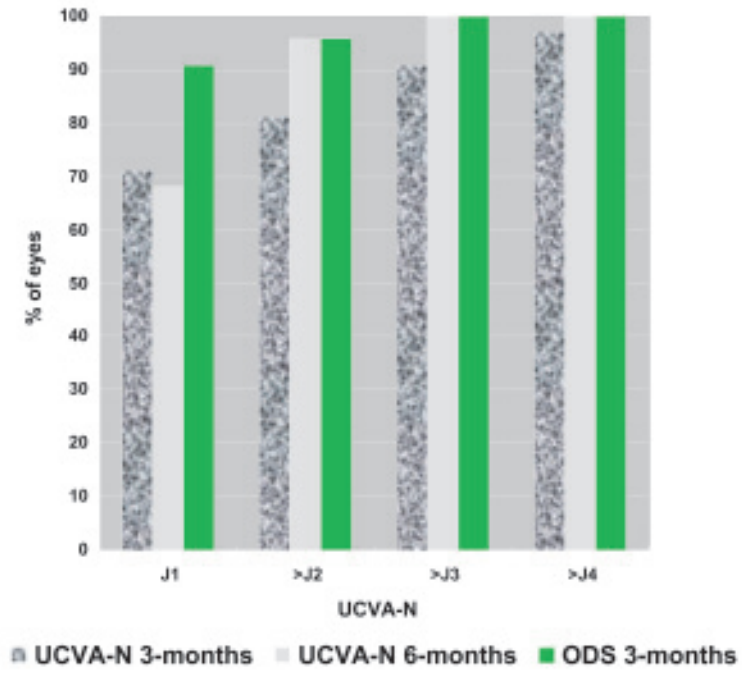

Fig.2 Uncorrected visual acuity for near (UCVA-N) at 3 (60 eyes) and 6 months (20 eyes) and binocular (ODS) at 3 months (30 patients).

Biometry was done using immersion ultrasonography aiming for slight hyperopia between 0 and +0.25 D. All surgery was performed at a single site by the author. Cataract extraction was performed using a standard phacoemulsification technique. After a 3 mm temporal clear corneal incision, a 5.5 mm continuous circular capsulorhexis was created with the intention of covering the optic edge after lens implantation. The IOL was inserted into the capsular bag using the Monarch II insertion device.

Refractive outcomes were evaluated at 3 and 6 months. Uncorrected visual acuity for distance (UCVA-D) and near (UCVA-N), best corrected visual acuity for distance (BCVA-D) and near (BCVA-N), and distance corrected visual acuity for near (DCVA-N) was assessed. Near visual acuity was recorded using a Jaeger chart (J) at 30 cm. Each patient was asked if they had any visual disturbance such as glare and halos or diminished night vision. To determine patient satisfaction, all patients were asked if they used spectacles and if they found the results excellent, good, acceptable or not acceptable.

RESULTS

Results of forty-eight eyes (24 patients) and 60 eyes (30 patients) were recorded at 6 and 3 months after implantation of the second eye. Two weeks was established as the standard time-delay between implanting the second eye.

All eyes achieved UCVA-D of 20/40 or better at 3 months and 20/30 or better at 6 months (fig 1). UCVA-N was J3 or better at 3 months in 91% and all eyes achieved J3 or better uncorrected at 6 months (fig.2). One eye had corneal refractive surgery (LASIK) for postoperative hyperopia of 1.25 D at 3 months. This eye was emmetropic after LASIK with 20/20 UCVA-D and J1 UCVA-N and not included in the 6 months results. BCVA-D was better than 20/30 in all eyes at 3 months and better than 20/25 in all eyes at 6 months. Three months postoperatively, all patients had 20/20 binocular (fig.3) and could read J1 with binocular distance correction (DCVA-N) (fig. 4). All eyes saw J2 or better binocularly.

Sixteen percent of patients mentioned glare and 20% halos at night when specifically asked. Patient satisfaction at 3 months was excellent (76%), good (10%) and acceptable (14%). No patient was dissatisfied with the outcome. All patients reported to be spectacle independent.

DISCUSSION

The results of this study show the efficacy of the Alcon Restor Apodized Diffractive IOL (SA60D3) in correcting cataract patients for distance and near vision. All study patients exhibited spectacle free functional vision. With best distance correction, all patients could read at least J 2 and had 20/25 or better vision at distance. This means that using the diffractive portion of the IOL, near visual acuity as well as far vision is highly functional. Although 20% of patients had some night vision problems, no patients felt disabled by this occurrence.

Comparing our findings with the results of other multifocal or accommodating IOL's, we find that the Alcon Restor has a better ability to correct near and distance visual acuity.

According to Cumming et al. the Crystalens AT-45 achieved in 97% of patients a DCNVA of J3 or better at 6 months (3). However, in a study by Marchini et al. (7), only 45% of eyes could read J3 with a mean accommodative amplitude of 1.08D at 6 months. Alio et al.(1) had a 83% DCNVA of 0.6 or better at 1 year. In comparison, our study with the ReSTOR IOL showed UCVA-N of J3 or better in 91% and DCVA-N of J1 or better in 100% at 3 months. In a study by Claoué et al. (2), only 44% of eyes implanted with 1-CU accommodating IOL (Human Optics) achieved reasonable uncorrected near visual acuity at 6 months. The accommodative 1-CU IOL revealed an accommodation of no more than 1D with dynamic retinoscopy. Kuchle et al.(6) found a median DCVA-N of 0.4 at 6 months with the 1- CU and a mean accommodative range of 0.98 to 1.85 depending on the method used for accommodation measurement. Stachs et al.(11) found only a theoretically accommodative amplitude of 0.5D. So, these results of the several mentioned studies suggest that at present the accommodative effect after implantation of accommodative IOLs is unpredictable and is highly variable.

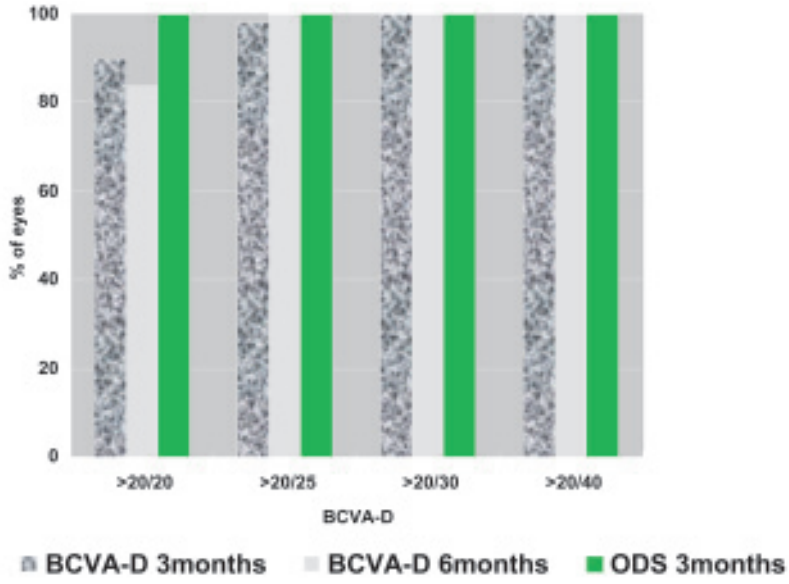

Fig. 3 Bestcorrected visual acuity for distance (BCVA-D) at 3 (60 eyes) and 6 months (20 eyes) and binocular (IDS) at 3 months (30 patients).

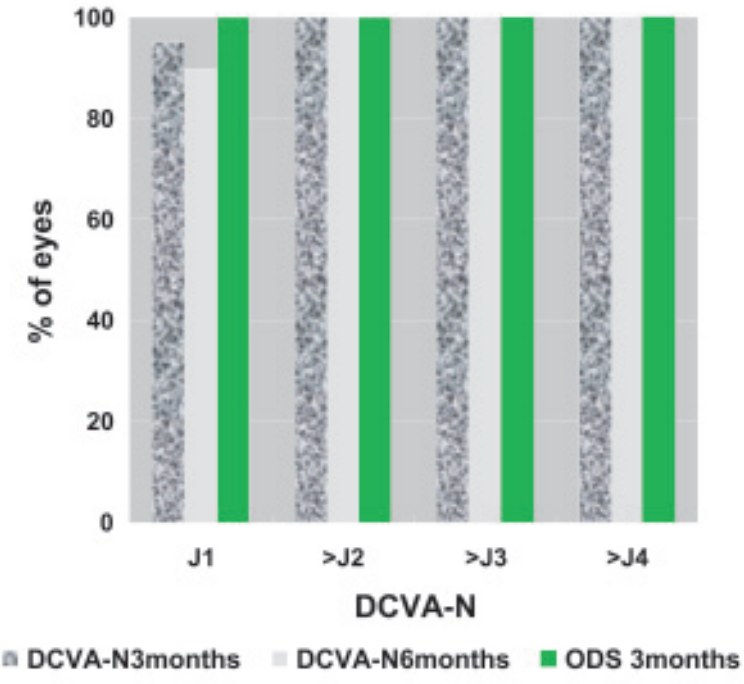

Fig.4 Distance corrected visual acuity for near (DCVA-N) at 3 months (60 eyes) and 6 months (20 eyes) and binocular (ODS) at 3 months (30 patients).

In a study of Pineda-Fernandez et al.(10) with the Array multifocal IOL all eyes achieved UCVA-D of 20/40 at distance and read J5 for near at 3 months after surgery. 71% were very satisfied, 26 satisfied and 3% dissatisfied. In our study, the results are comparable although near vision was J3 or better in all patients and for distance vision all eyes achieved 20/30 or better. One eye in our study had corneal refractive surgery (LASIK) for postoperative hyperopia, improving in this way the final result. Our study with the Restor IOL indicated 76% of very satisfied patients and no dissatisfied patients. Pineda-Fernandez et al. had 31% of patients spectacle free at 3 months. In our study, no patients wore glasses after 3 and 6 months. A possible reason might be the better near visual acuity obtained with the Alcon Restor IOL. Both studies encountered glare and halos as possible side-effects. Nida Sen et al (9) had a 67% DCVA-N of achieving J6 or better with the Array IOL at 6 months. With this same IOL Alio et al. (6) reported a 93% DCVA-N of 0.6 or better at one year. In our study all patients achieved DCVA-N of J2 (0.8) or better monocular and J1 binocular at 6 months, which might be due to the diffractive portion of the IOL. Diffractive lenses such as the Acrysof Restor give simultaneous vision for far and near for all pupil sizes , whereas zonal refractive lenses as the Array-IOL give only limited near vision for smaller pupils.

Comparing the Array IOL to a late generation full-optic diffractive IOL (Acri-Twin), Mester et al. found similar results as ours for binocular uncorrected near and distance visual acuity at 6 months for both IOL's. Although the incidence of dysphotic phenomena was almost 100%, compared to 20 % in our study (8).

Intermediate distance vision was not studied. However no patient asked for glasses for intermediate vision in our study. Further study is needed to investigate the quality of vision and possible adaptation to intermediate vision.

CONCLUSION

We can state that the Acrysof Restor SA60D3 IOL performed well for far and near visual acuity. All our patients were spectacle independent at 3 (30 patients) and 6 months (24 patients) after surgery. Successful refractive outcome with high patient satisfaction can be achieved with good patient selection, accurate biometry and good surgical technique.

REFERENCES

(1) ALIO J.L., TAVOLATO M., DE LA HOZ F., CLARAMONTE P., RODRIGUEZ-PRATS J., GALAL A. – Near vision restoration with refractive lens exchange and pseudoaccomodating and multifocal refractive and diffractive intraocular lenses. Comparative clinical study. J Cataract Refract Surg 2004; 30:2494-2503

(2) CLAOUÉ C. – Functional vision after cataract removal with multifocal and accommodating intraocular lens implantation. Prospective comparative evaluation of Array multifocal and 1-CU accommodating lenses. J Cataract Refract Surg 2004; 30:2088-2091

(3) CUMMING J.S., SLADE S.G., CHAYET A., AT-45 STUDY GROUP. – Clinical evaluation of the model AT-45 silicone accommodating intraocular lens: results of feasibility and the initial phase of the Food and Drug Administration clinical trial. Ophthalmology 2001; 108:2005-2009

(4) FINE I.H., MALONEY W.F., DILLMAN D.M. – Crack and flip phacoemulsification technique. J. Cataract Refract Surg 1993; 19:797-802

(5) GIMBEL H.V., NEUHANN T. – Development, advantages and methods of the continuous capsulorhexis technique. J Cataract Refract Surg 1990; 16:31-37

(6) KUCHLE M., SEITZ B., LANGENBUCHER A., GUSEK-SCHNEIDER G.C., MARTUS P., NGUYEN N.X., The Erlangen Accommodative Intraocular Lens Study Group. – Comparison of 6-month results of implantation of the 1CU accommodative intraocular lens with conventional intraocular lenses. Ophthalmology, 2004; 111:318-324

(7) MARCHINI G., PEDROTTI E., SARTORI P., TOSI R. – Ultrasound biomicroscopic changes during accommodation in eyes with accommodating intraocular lenses. Pilot study and hypothesis for the mechanism of accommodation. J Cataract Refract Surg 2004; 30:2476-2482

(8) MESTER U., DILLINGER P., ANTERIST N., KAYMAK H. – Functional results with two multifocal intraocular lenses (MIOL) Array SA40 versus Acri.Twin. Ophthalmologe, 2005; 102: 1051-1056

(9) NIDA SEN H., SARIKKOLA A, UUSITALO RJ, LAATIKAINEN L. – Quality of vision after AMO Array multifocal intraocular lens implantation. J Cataract Refract Surg 2004; 30:2483-2493
(10) PINEDA-FERNANDEZ A., JARAMILLO J., CELIS V., VARGAS J., DISTACIO M., GALINDEZ A., DEL VALLE M. – Refractive outcomes after bilateral multifocal intraocular lens implantation. J Cataract Refract Surg 2004 ; 30 :685-688
(11) STACHS O., SCHNEIDER H., STAVE J., GUTHOFF R. – Potentially accommodating intraocular lenses- an in vitro and in vivo study using three dimensional high frequency ultrasound. J Refract Surg 2005; 21:37-45
(12) STEINERT R.F., BRINT S.F., WHITE S.M., FINE I.H. – Astigmatism after small incision cataract surgery; a prospective, randomised, multicenter comparison of 4- and 6.5-mm incisions. Ophthalmology 1991; 98:417-423

The author has no proprietary or financial interest in the mentioned products

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