Original Article

Long-term clinical outcomes obtained with bilateral implantation of a multifocal intraocular lens through two different-sized corneal incisions

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Abstract:

PURPOSE: To evaluate the long-term visual function and patient satisfaction in patients implanted bilaterally with the same type of multifocal intraocular lens (MIOL), using either a 2.2 mm small corneal incision with bimanual irrigation/aspiration (I/A) or a conventional 2.75 mm incision with coaxial I/A.

METHODS: Prospective nonrandomized study including 100 eyes of 50 patients who underwent bilateral implantation of ReSTOR SN6AD1 through a 2.2 mm or 2.75 mm corneal incision. Outcomes included visual function measures (near, intermediate, and distance visual acuity [VA]), achievement of targeted refraction and postoperative astigmatism. Patient satisfaction was evaluated using a subjective questionnaire.

RESULTS: Three and 12 months postoperatively, distance uncorrected best VA (UBVA) was 0.98 ± 0.07, UBVA at 30 cm was J1 in 100% of cases and UBVA at 60 cm was J3 in 72% of cases. Targeted refraction was achieved in 84% of cases and postoperative astigmatism was -0.4 ± 0.3 diopters. There was no statistically significant difference in UBVA in all distances, targeted refraction and postoperative astigmatism between the small-incision bimanual and the conventional coaxial group. Sixty percent of the patients were satisfied, 30% were very satisfied and 10% declared that the result did not meet their expectations. Three out of 5 nonsatisfied patients had an angle kappa of 4° and the MIOL was not well-centered.

CONCLUSION: An incision size of 2.2 mm compared to 2.75 mm, did not appear to result in less surgically induced astigmatism after the implantation of a MIOL. SN6AD1 is a reliable MIOL choice for spectacle independence. Good preoperative patient selection is of crucial importance for the outcome in MIOLs.

Keywords:

Bimanual irrigation/aspiration, coaxial irrigation/aspiration, corneal incision, multifocal intraocular lens, SN6AD1

Introduction

Multifocal introcular lenses (MIOLs) have been available for almost 30 years and they still remain the method of choice for many surgeons due to their ability to provide functional uncorrected vision over a range of distances.[1] They are designed with concentric zones or rings in the lens which enable patients to see both distant and near targets, without major adverse effects on distance visual acuity (VA).[2] However, some patients are dissatisfied with their vision, possibly due to glare, halo, starburst, poor contrast sensitivity, refractive errors, and neural adaptation failure.[3,4]

The bimanual irrigation/aspiration (I/A) technique was introduced as an alternative to conventional single-piece I/A in complex cases as it provides constant pressure and enhanced maneuverability.[5] Bimanual systems offer better access to the sub-incisional cortex, bimanual stabilization of the eye globe[6] and the opportunity to operate through smaller corneal incisions, which allows the surgeon to incorporate a refractive element into the cataract surgery procedure.

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The purpose of this study was to assess postoperative distance, intermediate, near visual acuities, and patient satisfaction in patients having cataract extraction and bilateral implantation of ReSTOR® SN6AD1. Targeted refraction was achieved with two different I/A techniques, using either a 2.2 mm-microincisional coaxial phacoemulsification with bimanual I/A or a larger conventional 2.75 mm-incision coaxial phacoemulsification with coaxial I/A.

Methods

This prospective nonrandomized comparative clinical study included 100 eyes of 50 patients with senile cataract, who underwent sequential bilateral cataract extraction with implantation of AcrySof® IQ ReSTOR® SN6AD1 +3.0 Diopters (D) (Alcon Laboratories Inc, Fort Worth, Texas, USA) MIOL from September 2017 to September 2018. SN6AD1 has a single-piece design with an apodized diffractive multifocal optic that occupies the central 3.6 mm region, and a refractive region which surrounds the apodized diffractive region and directs light to a distant focal point for larger pupil diameter and is dedicated to distance vision.[7] Its anterior surface is aspheric to reduce postoperative ocular spherical aberrations and +3.0D addition corresponds to +2.5D at the spectacle plane. In this study of uneventful cataract surgeries, eyes were equally divided into two groups; group 1 with 50 eyes to have small-incision phacoemulsification with bimanual I/A through a 2.2 mm corneal incision and group 2 with 50 eyes to undergo phacoemulsification with coaxial I/A through a 2.75 mm corneal incision.

The study was conducted in accordance with the Declaration of Helsinki and was approved by the Ethics Committees of the Hospitals involved. The MIOLs used were available on the Greek IOL market and approved as a surgical device by the National Organization for Medicines and the Greek Ministry of Health. All patients provided written informed consent before the study.

Inclusion criteria were bilateral cataract with VA <0.6, strong motivation for spectacle independence postoperatively, preoperative corneal astigmatism <±0.75D and refractive error <±3.00D. Exclusion criteria included age ≤40 years, pseudoexfoliation, preexisting ocular pathologies, amblyopia, previous ocular or refractive surgery, history of ocular trauma or inflammation, history of intravitreal injection therapies or laser treatment, and angle kappa (AK) >5°.

Patients were examined preoperatively and postoperatively after 1 day, 1 week, and 1, 3, and 12 months. They underwent a standard comprehensive ophthalmic examination including manifest refraction, slit-lamp biomicroscopy, Goldmann applanation tonometry, and dilated fundoscopy. Optical coherence tomography was performed preoperatively in all patients to exclude macular pathology and AK was measured for far vision using the Orbscan II topography system (Bausch and Lomb, Rochester, NY, USA). Preoperative biometry was performed using IOL Master 500 partial coherence interferometry (Carl Zeiss Meditec AG, Dublin, CA, USA). The IOL power was targeted for +0.25D using the SRK/T formula according to the measured axial length. Uncorrected and best-corrected VA at all three distances were assessed by the same ophthalmologist. Distance VA was measured and recorded using the Snellen Chart. Near (30 cm) and intermediate (50 to 70 cm) VA were measured with the Jaeger card and aim of J1 scale at near and J3 scale at intermediate distance. Precise centration of the MIOL with respect to the center of the pupil was also evaluated postoperatively.

All operations were performed by a single fully qualified and highly experienced surgeon using a peristaltic pump machine (Infiniti, Alcon Laboratories, Inc., Fort Worth, TX, USA). The eye with greater blur was operated first, regardless of dominance, and the second eye was operated at least 3 weeks after the first operation. Topical anesthesia and mydriatic drops were instilled in all cases before the surgical procedure. Two different surgical approaches were used. The first with a superior small main 2.2 mm-incision created with a precalibrated diamond knife and two 1.2 mm corneal side ports, using a 15° blade at the 2 o'clock and 10 o'clock positions for bimanual I/A. This group was designated as bimanual group. The second approach included a superior conventional larger main 2.75 mm-incision using a precalibrated diamond knife, with a second paracentesis of 1.2 mm at 2 o'clock using a 15° blade. This group was designated as coaxial group. Due to the small degree of preoperative astigmatism (<±0.75D) in all subjects, the main clear corneal incisions were not performed on the steepest corneal meridian and in both approaches it was from the top, with the main incisions placed at 11 o'clock. The incision size was measured using a DK incision gauge (Duckworth and Kent Ltd.) at an initial time point, after phacoemulsification, and after MIOL implantation. A central capsulorhexis of 5 mm and no more than 6 mm was performed to have the MIOL optic fully covered with the anterior capsule at the end of the procedure. Phaco fracture was by the stop-and-chop or the quick-chop technique. After cortex peeling and capsule polishing using the bimanual or coaxial I/A technique, SN6AD1 was loaded in the cartridge D (Alcon Laboratories, Inc.) and then inserted in the Monarch III injector (Alcon Laboratories, Inc.). MIOL was then implanted in the capsular bag through the main incision. After ensuring the correct positioning and centration of the lens in the capsular bag, viscoelastic material was removed from the anterior chamber and posterior surface of the MIOL. The procedure ended with intracameral administration of Cefuroxime Axetil 1 mg/0.1 ml for endophthalmitis prophylaxis. The incisions were hydrated with balanced salt solution to aid the tight closure. No stitches were used in any eye. A postoperative therapy based on a combination of topical antibiotics and steroids was prescribed to be applied four times daily for 2 weeks.

Three and 12 months after the surgery, near, intermediate, and distance VA were recorded. A self-completion questionnaire was completed by each patient assessing postoperative patient

satisfaction and spectacle independence based on questions about distance, intermediate, near, and night vision. A scale of 1–3 was used, in which a score of 1 indicated "very satisfied," 2 reflected "satisfied," and 3 indicated that 'the postoperative result did not meet their expectations." Patients were asked to state if they had any additional complaints or photic phenomena such as halo and glare. Each eye was defined as a single case and all patients were asked for the symptoms uniocularly. This, in a way, validates the fact that the symptoms were due to surgery and not due to the patient "psyche."

Statistical analysis of the data was performed using SPSS 20.0.0 software (IBM Corporation, Armonk, NY, USA). The normality was checked using the Shapiro–Wilk test. Descriptive statistics are expressed as mean ± standard deviation. For each parameter, statistical analysis between the small-incision bimanual group and the larger-incision coaxial group was done using the independent samples *t*-test. Within-group comparison of numerical variables was done using the paired-samples *t*-test. Categorical variables are presented as number (%) and between-group differences were compared using the Chi-square test. All statistical tests were two-sided and $P < 0.05$ was considered statistically significant.

Results

One hundred eyes of 50 patients (68% males, 32% females), with a mean age of 62.60 ± 9.32 years at the time of surgery, were included in this study. Fifty eyes underwent surgery with small-incision phacoemulsification with bimanual I/A and 2.2 mm main incision port, and 50 eyes underwent phacoemulsification with coaxial I/A and 2.75 mm incision port. All patients were followed up for at least 12 months. Mean axial length measurement with the IOL Master 500 was 23.68 ± 0.85 mm for the bimanual group and 23.87 ± 0.67 mm for the coaxial group ($P = 0.237$).

Visual and refractive outcomes

Three months postoperatively, the decimal score for the mean uncorrected distance VA (UDVA) was 0.98 ± 0.07 in the sum of 100 eyes. An uncorrected near best VA (UNVA) of J1 at 30 cm was achieved in 100% of the patients and an uncorrected intermediate VA (UIVA) of J3 at 60 cm was achieved in 72% of the patients. A targeted refraction of 0.0D to + 0.25D was accomplished in 84% of patients. Mean postoperative astigmatism was -0.4 ± 0.3D in the sum of patients. The mean near distance for reading preferred by the patients was 36.2 ± 0.3 cm. UDVA and corrected distance VA postoperatively was significantly better than the preoperative counterpart ($P = 0.009$, $P = 0.02$, respectively). Visual and refractive outcomes of both techniques remained stable through the 12-month follow-up period.

Table 1 shows the best uncorrected VA and the refraction for each group of patients 3 months and 1 year after each eye was operated. No statistically significant difference was noted between the groups in terms of VA and refraction.

Table 1: Best uncorrected visual acuities and refraction in the Bimanual and Coaxial Group 3 months and 1 year after phacoemulsification

	Bimanual Group ($n=25$)	Coaxial Group ($n=25$)	*P*
UBVA-Distance (mean±SD)*	0.982±0.06	0.979±0.09	0.255
UBVA-30cm : J1 (photopic lighting)**	100%	100%	1.0
UBVA–60 cm: J3**	76%	68%	0.208
Target refraction: 0 - (+0.25) D**	88%	80%	0.123
Mean postoperative astigmatism (mean±SD)*	−0.3±0.5	−0.5±0.4	0.07

*Independent *t*-test, **Chi-square test. UBVA=Uncorrected best visual acuity; SD=Standard deviation

There were significant reductions in the sphere, cylinder, and spherical equivalent after the surgery. Three months postoperatively, spherical equivalent decreased significantly from −2.25 ± 0.3D to −0.08 ± 0.2D ($P < 0.001$) in the sum of 100 eyes. Three months after surgery, the spherical equivalent ranged from −1.38D to + 0.75D, with 86% of the eyes being ±0.50D. In the comparison between the right and the left eye, there was no statistically significant difference between the refractive outcome ($P = 0.857$). No statistically significant difference was also observed regarding the postoperative spherical equivalent between the bimanual and the coaxial group ($P = 0.079$).

Ninety-one percent of patients reached binocular UDVA of 1.0, 79% of patients reached binocular UIVA of J3, and 87% binocular UNVA of J1. 100% of patients reached at last binocular UDVA of 0.5 or better. The effect of binocular fusion gave an average gain of one line for distance VA. All binocular VA measurements were superior to the monocular measurements.

Well-centered implantation of the MIOL at the end of the procedure was observed in 94% of the eyes. It was observed in 92% of the eyes which underwent small-incision phacoemulsification with bimanual I/A and in 96% of the eyes which underwent phacoemulsification with coaxial I/A. No statistical difference was observed in terms of "well-centration" of the IOL between the two techniques ($P = 0.234$). AK was positive in all cases, ranging from +1° to +4°. The mean AK was 2.10°. All the cases of MIOL decentration were associated with an AK of 4°.

Patient satisfaction

Very high levels of satisfaction postoperatively were achieved in 30% of the operated cases. Sixty percent were satisfied with the postoperative result, regarding the spectacle independence status for everyday life and routine activities such as reading the newspaper and book print without glasses, watching TV, and driving during the daytime. Ten percent answered that the results did not fulfil their expectations [Graph 1]. Six out of ten cases of nonsatisfied patients, i.e. three patients, had

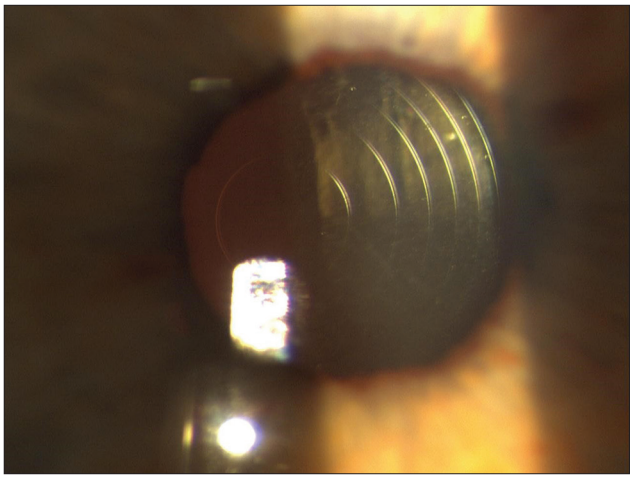


Figure 1: A case of Acrysof IQ ReSTOR SN6AD1 decentration associated with an angle kappa of 4°

an AK of 4° and the MIOL was not well-centered [Figure 1]. No patient reported the presence of any bothersome visual artifact such as glare, halos or dysphotopsia. No statistically significant difference in terms of patient satisfaction was observed between the two groups.

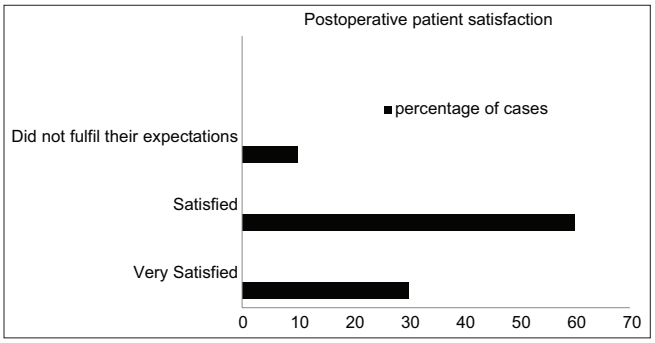
Complications

There was no intraoperative complication noted in any of the operations. After surgery and MIOL implantation, the pupils in all eyes were round and showed good responsiveness to light. No serious complications, such as posterior capsule opacification, endophthalmitis, or corneal decompensation, occurred during the follow-up period of 1 year in none of the patients.

Discussion

The results in this study showed that SN6AD1 implantation after a 2.2 mm-incision with bimanual I/A or a larger 2.75 mm-incision with coaxial I/A, provided excellent visual and refractive outcomes. No technique seemed to have better postoperative results. Acceptance of the MIOL was almost immediate and long-lasting in all 50 patients, residual refractions were minimal, lens decentration was isolated to a few cases and the reported quality of vision was very high.

All the cases with lens decentration in our study were associated with AK of 4°. A large AK could contribute to functional decentration if the MIOL is centered on one axis (pupillary or visual) and is not aligned with the other. Usually, AK is defined as the angular difference between the visual and the pupillary axis.[8] Decentration and tilt of MIOL are very important for visual quality, especially when inserting an asymmetrical MIOL.[9,10] Prakash *et al*.[11] reported that larger preoperative AK values in MIOL placement were correlated with complaints of glare. Tchah *et al*.[12] reported that AK was associated with subjective visual problems, such as glare and halo after implantation of rotationally asymmetric MIOLs. Karhanová *et al*.[13] demonstrated that shallow anterior chamber depth in connection with higher AK



Graph 1: Postoperative levels of satisfaction and spectacle independence, assessed by a self-completion questionnaire

were important risk factors for pronounced photic phenomena after implantation of a diffractive MIOL. Even if we did not record visual phenomena such as glare and halos in any of the patients, we found that 60% of cases with patient dissatisfaction were associated with large AK and lens decentration, implying that some kind of visual disturbances probably decreased our patients' satisfaction.

After evaluating the implantation of SN6AD1 in a respectable number of cataract surgeries, our outcomes confirmed its established favorable results. There are many studies assessing its visual and refractive outcomes, while many of them compare it with other IOLs. Alfonso *et al*.[7] studied the bilateral implantation of SN6AD1 in 40 eyes for a follow-up period of 6 months and concluded that it provided good functional vision at far and near, with lower performance at intermediate distance and a low incidence of visual disturbances Souza *et al*.[14] evaluated the implantation of Acrysof IQ ReSTOR in 50 eyes and concluded that it provided a satisfactory full range of vision and achieved a more satisfactory quality of life when compared with 30 eyes with monofocal IOL implantation, though with lower contrast sensitivity. Chaves *et al*.[15] implanted 34 Acrysof IQ ReSTOR and demonstrated good quality of distance and near vision, whilst the assessment of intermediate vision showed low performance. Ang *et al*.[16] implanted 54 Acrysof IQ ReSTOR and concluded in excellent acuity results at all distances. Alió *et al*.[17] described excellent results in terms of distance, intermediate, and near VA 6 months after the implantation of 34 SN6AD1. Nuzzi and Tridico[18] concluded that SN6AD1 was the best choice for far, intermediate, and near working distances when they compared it with two other multifocal and one accommodative IOL. Maurino *et al*.[19] suggested that SN6AD1 produced high levels of spectacle independence and patient satisfaction, with a minority of patient dissatisfaction 4–8 months postoperatively.

Even if there are found many studies in the literature evaluating the visual and refractive outcomes of SN6AD1, to the best of our knowledge, there are no studies comparing its implantation through two different-sized corneal incisions. Incision size and axis of the entrance, apart from a key role in the cataract surgery process, have been proven that may contribute to postoperative astigmatism and visual function.[20] However,

the available evidence on ideal incision size is inconsistent. The primary outcome is surgically induced astigmatism, which is an important factor to evaluate. The less astigmatism, the better the visual quality. As the field of cataract surgery has trended toward minimally invasive approaches, some scholars now hold the view that smaller incisions contribute to less surgically induced astigmatism.[6,21,22] In our case study, we did not observe any statistically significant difference in terms of postoperative astigmatism, refraction, or patient satisfaction when a smaller corneal incision was adopted. This is in discordance with Kim *et al*.[23] who demonstrated a significantly higher surgically induced astigmatism with an incision size of 2.75 mm compared to 2.2 mm and 1.8 mm, when they implanted monofocal IOLs. On the other hand, our results are in accordance with Klamann *et al*.,[24] who could not find a statistically significant difference between the 2.2 mm- and the 2.75 mm-incision in terms of postoperative astigmatism after the implantation of monofocal IOLs.

The excellent outcomes in the present study may be attributed to the careful patient selection before the implantation, as well as the diligent capsule polish, cortical clean-up, targeting, biometry, and capsulorhexis, and the assurance that the MIOL was vaulted in the posterior position to optimize arching and translational movement. The absence of difference between smaller-incision bimanual and larger-incision coaxial techniques could be ascribed to the small 0.55 mm difference in the length of corneal incisions. Meticulous surgical technique is paramount for optimal results with all IOLs.

Like any other study, this study is not without limitations. First, we did not evaluate contrast sensitivity, which is a common cause of patients' intolerance to their MIOLs.[25] The questionnaire which was administered evaluated patient satisfaction and the presence of photic phenomena; however, it did not quantify visual phenomena such as halos, dysphotopsia, or glare. This might be the reason we did not record this kind of visual disturbances. We believe that these visual artifacts were mirrored in patients' overall level of satisfaction, which was affected in some cases. In addition, being our study a nonrandomized clinical trial could lead to a bias of selection. Finally, the lack of a control group did not permit head-to-head comparison with other implantation modalities.

MIOLs of varying designs have been used to correct presbyopia for many years. Despite good distance and near VA, difficulty in appropriate patient selection, reduced contrast sensitivity, and increased quality-of-vision issues have prevented their widespread use.[26] Patients should be carefully screened before surgery and surgeons should choose the right IOL for the patients' individual needs. In our study, the use of SN6AD1 provided a good range of vision, excellent uncorrected acuity results at all distances, no symptoms negatively affecting patients' quality of life and a good safety profile, which confirm the previously established effectiveness of these MIOLs. We also found that the incision size had no influence on surgically induced astigmatism. Our results suggested the importance of involving AK in the preoperative evaluation of patients and the selection of IOL. Taken together, the data can guide surgeons and patients in making informed choices when choosing the optimal IOL for their lifestyle, needs, personality, and anatomic features. Additional studies with large sample size and further preoperative correlations are warranted to optimize the use of MIOLs.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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