Experience with ARRAY multifocal lenses in a Singapore population

J C Wang, A W T Tan, R Monatosh, P T K Chew

ABSTRACT

Introduction: To evaluate the clinical efficiency, safety and subjective visual outcomes of multifocal intraocular lenses (IOL) in the Singapore population

Methods: This is a retrospective case series of 45 phacoemulsification with multifocal lens implantation performed in 27 patients for cataracts, over a two-year period. The efficacy, stability and safety of the lens were assessed up to six months of follow-up. A telephone interview enquiring about ratings of vision, spectacle independence, glare, driving difficulty and photic phenomena, was conducted and the results were compared with those published in the literature.

Results: The best corrected distance Logmar acuity was 0.1 (0.1 and near visual acuity was N5 (range N5 to N8) at six months. The distance visual acuity stabilised by one month whereas near vision remained unchanged from day one post-surgery. Posterior capsular opacification was seen in 17 patients (38.6 percent) of which two patients (4.55 percent) required YAG capsulotomy. Total spectacle independence was achieved in 12 patients (54.4 percent). Among those who required spectacles, 50 percent required spectacles more than 50 percent of the time. Five patients (22.7 percent) reported glare usually at night (80 percent) as compared with daytime glare (20 percent). The most common photic phenomena report after surgery was halo.

Conclusion: The Advanced Medical Optics ARRAY multifocal IOL showed good efficacy, predictability, stability and safety. The subjective visual outcomes in the Singapore population were comparable to those of their Western counterparts.

Keywords: ARRAY multifocal lens, cataract extraction, intraocular lens, presbyopia

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INTRODUCTION

Presbyopic correction is an exciting new frontier in cataract and refractive surgery. The multifocal intra-ocular lens (IOL) allows both distance and near vision, thereby offering new options for presbyopic patients who demand treatment for presbyopia while requiring cataract surgery. Therefore, it has advantages over the traditional monofocal IOL by removing the need for reading glasses after surgery. Current monofocal lens only allows good distance vision because, at best, the accommodative effort does not allow adequate accommodation for near work. Current strategies to overcome presbyopia post-surgery included the use of reading glasses, contact lens or monovision.

Monovision is the correction of the dominant eye for emmetropic distance vision while the fellow eye has surgically induced myopia usually in the region of -1.5 to -3.0 diopter sphere to allow reading and near work. Although some patients found this form of vision acceptable, approximately 30 percent found it intolerable. Moreover, these patients also lose the benefits of binocular vision i.e. stereopsis and enhancement of distance visual acuity by bilateral visual cortex stimulation.

The Advanced Medical Optics (AMO, Irvine, CA, USA) ARRAY (SA40N) multifocal lens was the first lens to be approved by the US Food and Drug Administration (FDA) for use in cataract surgery for presbyopic correction. Its efficacy has been widely reported in both FDA and independent trials. Patients' functional status and quality of life were reported as superior to those with monofocal lens. However, significant shortcomings such as halos, glare and loss of contrast sensitivity, especially in dim lights, have been reported in the Western population[1-2]. The results and visual symptoms of multifocal IOL were not audited and its performance in the Singapore population remained unknown. Our centre has been implanting this lens in patients from 1999 and had thus accumulated significant experience. Therefore, it is timely that we undertook this retrospective study to examine

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Fig. 1 Comparison of best-corrected visual acuity before and after surgery.

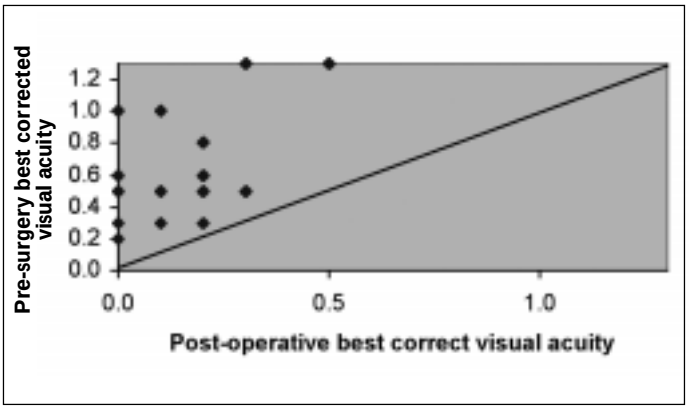

Table I. Efficacy – post-operative spherical equivalent, cylinder and distance visual acuity in all patients.

	Pre-operative	Post-operative
Sphere	-0.62 ± 3.67	-0.41 ± 0.71
Cylinder	-0.67 ± 0.76	-0.70 ± 0.47
Spherical equivalent	-1.00 ± 3.98	-0.76 ± 0.74
Visual acuity Logmar	0.5 ± 0.3	0.1 ± 0.1

the clinical efficacy, stability, safety and visual symptoms of multi-focal IOL in the Singapore population.

METHODS

This retrospective comparative study comprised 45 patients with senile cataract who had phacoemulsification and posterior capsule intraocular lens implant from March 1999 to March 2001 in a tertiary hospital (National University Hospital, Singapore). The approval of the ethics committee of National University Hospital was not required for this study. Inclusion criteria were ages 50 to 75 years, and axial length between 23.0mm to 24.00mm. Patients with at least six months of follow-up were included in the study. Exclusion criteria were anterior segment pathology, such as chronic uveitis, zonular dialysis, pseudoexfoliation syndrome, glaucoma, and posterior pathologies such as diabetic retinopathy and macular pathologies. Previous anterior and posterior segment surgery; and intra-operative or post-operative complications were excluded as well.

The ARRAY SA40N (AMO, Irvine, CA, USA) is a silicone, zonal progressive multifocal lens. It has five continuous zones of near and distance powers on the anterior surface of the silicone optic with PMMA haptics. These zones refract light and present six images of varying distances to the retina. The central 2mm zone is used for distance focus while at a pupil diameter of 4mm, 50% of the light is directed to the distance focus point, 35% to the near focus point and 15% to the intermediate foci. It can provide up to +3.50D of near add and vision for intermediate distances at 50 to 150cm (20-59 inches). As a result, functional vision over a wide range of distances could be achieved together with spectacle independence. However, with reduction of light delivered to each focal point, contrast sensitivity may be reduced especially in dim lights. Also, multiple out-of-focus images with large diameter than sharp images, contributed to the halos experienced by patients.

All patients had phacoemulsification with lens implantation by a single surgeon. A 2.7 mm clear cornea incision was made, followed by curvilinear capsulorrhexis and hydro-dissection. Nucleus was removed by phaco-chop method and remnant cortical material removed by automated irrigation and aspiration. The IOL was implanted in the bag using injectors. Incisions were hydrated but not sutured. Post-operative therapy consisted of Gutt Pred Forte qds for six weeks and G Chloramphenicol qds for four weeks. Patients were examined at days one and five, and one month, six months and one year after surgery.

One author conducted a telephone interview of these patients with the Post Cataract Surgery Satisfaction Survey instrument, which is a visual function, telephone interview questionnaire modified from the Cataract TyPE Specification instrument for local patients[1]. Main outcomes measured were rating of vision, spectacle dependence, glare and photic phenomena. This survey was conducted in February 2004, which was three to five years post-surgery for this group of patients. Demography, pre-operative visual acuity and biometry were collected. Post-operative outcome measures such as subjective refraction, uncorrected and best-corrected distance acuity, uncorrected and best-corrected near acuity, as well as post-operative complications such as posterior capsular opacity, were recorded.

A proprietary statistical software package, Statistical Package for Social Sciences (SPSS) version 9.05 (Chicago, IL, USA) was used for all calculations. Differences in mean values of parametric data between study groups were examined using an independent samples t-test (two-tail). The Wilcoxon rank sum test was used to compare nonparametric data. Pearson chi-square test with 1 degree of freedom was used to compare categorical data on a 2x2 table while Fisher's exact test was used when frequency in one of the cells was less than five. P-value <0.05 was used to indicate statistical significance.

Table II. Stability of best-corrected visual acuity over a six-month post-operative period.

Duration post-surgery	Visual acuity Logmar equivalent	Standard error	Near vision median	Range
One day	0.27	0.22	N5	N5-N6
One month	0.1	0.14	N5	N5-N12
Three months	0.1	0.22	N5	N5-N12
Six months	0.1	0.10	N5	N5-N8

RESULTS

There were 27 patients who had a total of 45 cataract surgeries, of which 18 patients had bilateral implants while nine patients had unilateral implants. The average age was 62.8 years, with equal spread between the genders, and with Chinese being the most frequent race. No surgical complications such as posterior capsular rupture, suprachoroidal haemorrhage, uveitis, and endophthalmitis were encountered in the series. However, one case of branch retinal vein occlusion and one case of retinal detachment were discovered during the follow-up period.

Post-operative spherical equivalent, cylinder and visual acuity in all patients were evaluated (Table I). The spherical error and spherical equivalents were significantly reduced ($p<0.05$), but conversely, no significant reduction in visual acuity was seen (Fig. 1). Astigmatism was not significantly altered due to the small incision (3mm) used in the procedures. Two patients with significant visual loss from branch retinal vein occlusion and retinal detachment were excluded for the analyses because both disorders were surgical complications. The post-operative spherical equivalent was slightly myopic with a small standard error.

The distance visual acuity was slightly poorer in the immediate post-operation but usually stabilises by one month and maintained to at least six months (Table II). Conversely, near visual acuity was stable for all patients except for one patient who had N12 vision for the first three months but achieved N5 by six months. The lenses were generally well-centred and stable, as no optic or haptic dislocation was detected. No lens exchange was required for lens-related problems or subjective patient symptoms in this series. Posterior capsular opacification was seen in 17 patients (38.6%), of which two patients (4.55%) required YAG capsulotomy for treatment.

The telephone survey was conducted on 27 patients, of which 22 responded (81.4%) (Table III). It showed that patients are generally satisfied in terms of unaided vision. Total spectacle independence was achieved in 12 patients (54.4%). Among those who required spectacles, 50% required spectacles more than 50% of the time. Five patients (22.7%) reported glare usually at night (80%) as compared with daytime glare (20%). The most common photic phenomena report after surgery was halo.

DISCUSSION

Our study showed that multifocal lens, and in this case, the ARRAY SA40N multifocal lens, had results comparable to previous reports from the West in terms of efficacy, stability and safety at six months after surgery. There seemed to be less complaints of photic phenomena and visual symptoms in our population. Our study reports independence from spectacle wear in 54.5% of patients, slightly higher than those achieved in reported literature (26% to 47%)[1-4]. Steinart et al reported that a significantly higher proportion of their bilateral multifocal subjects could function comfortably without glasses at near vision (81%, 96 of 118) compared with monofocal subjects (56%; 93 of 165; $p<0.001$) and unilateral multifocal subjects (58%; 56 of 97; $p<0.001$)[5]. However, we did not find significant differences in terms of spectacle independence between the unilateral and bilateral multifocal implants. Firstly, we could not draw a conclusion because the numbers dealt with were small, and secondly, the dominance of the eyes with unilateral implantation could not be ascertained from our data. Evidence reported by Shoji et al showed that implantation of ARRAY in the dominant eye could have a better visual outcome as compared to the nondominant eye[6].

The median score of eight for distance, intermediate, near and overall visions was similar and comparable to that reported in a previous paper[7]. Although our patients were able to achieve a satisfactory level of unaided distance and near visions, the frequent complaint was about experiencing a slight general blur and overall reduction in the clarity. This can be explained by the fact that the lens design utilised only 50% of the available light for distance, 37% for near and 13% for intermediate

Table III. Results of a questionnaire (telephone interview) on patient satisfaction after cataract surgery.

	Median score			p-value
	All patients	Bilateral implants	Unilateral implant	
Rating of vision				
Based on a scale of 0 to 10, where 0 is equated with the worst possible vision and 10 with the best possible vision, please rate your vision without glasses.				
• (1a) Near vision, e.g. reading newspaper small print, labels and price tags.	8	8	8	0.445[α]
• (1b) Intermediate vision, e.g. watching television, cooking.	8	8	8	0.164[α]
• (1c) Distance vision, e.g. reading street signs, recognizing people or objects across a street.	8	8	8	0.04[α]
• (1d) Overall vision.	8	8	8	0.096[α]
	Number of patients (%)			
Dependence on spectacle wear				
Yes	10 (45.4)	7 (46.7)	3 (42.9)	0.62[β]
No	12 (54.5)	8 (53.3)	4 (57.1)	
(2b) If yes, is it				
• All the time?	3 (13.6)	1 (6.7)	0 (0.0)	
• More than half of the time?	2 (9.1)	2 (13.3)	0 (0.0)	
• About half of the time?	4 (18.2)	4 (26.7)	0 (0.0)	
• Less than half of the time?	1 (4.5)	0 (0.0)	1 (14.3)	
(2c) When do you have to use glasses?				
• Near vision.	9 (40.9)	7 (46.7)	2 (28.6)	0.28[β]
• Far vision.	0 (0.0)	0 (0.0)	0 (0.0)	
• Both distance and near.	1 (4.5)	0 (0.0)	1 (14.3)	
Glare/difficulty driving				
Do you experience				
• Daytime glare?	1 (4.5)	0 (0.0)	1 (14.3)	0.19[β]
• Night time glare?	4 (18.2)	2 (13.3)	2 (28.6)	
• Difficulty driving or taking public transport in the day/night?	0 (0.0)	0 (0.0)	0 (0.0)	
Photic phenomena				
Have you noticed any new onset of symptoms after surgery?				
• Light flashes.	1 (4.5)	1 (6.7)	0 (0.0)	0.72[β]
• Halo.	4 (18.2)	3 (20.0)	1 14.3)	
• Flare.	0 (0.0)	0 (0.0)	0 (0.0)	
• Streaks of light.	0 (0.0)	0 (0.0)	0 (0.0)	

*: Fisher's exact test; [α]: Mann-Whitney U test; [β]: Pearson's chi-square.

foci[5]; as such, the luminance and contrast of retinal images are generally reduced.

The patients' acceptance of unilateral multifocal lens implants was generally poor. Physiologically, the cortical visual processing for foveal images could tolerate only a small range of dissimilarities in terms of spatial, temporal and luminance characteristics, because the processing of different-sized foveal and peripheral images utilises different cortical pathways. When differing images of size and contrast of the same object were presented simultaneously to the foveal and peripheral retina, the difficulty in cortical processing and fusion can lead to an overall confused visual perception.

Therefore, bilateral multifocal implants, as opposed to unilateral implants, can present similar images to both retina, resulting in better acceptance and satisfaction[8]. Hence, bilateral consecutive surgeries are normally recommended to our patients. The inclusion of unilateral implants in our study does not reflect a contradiction to our practice because these patients were either in the process of receiving their second implant or had subsequently declined surgery for various reasons during the time of data gathering. We do not routinely encourage unilateral implants because bilateral multifocal IOL implants perform better in terms of contrast sensitivity[12], spectacle dependence[5] and glare[12].

The incidence of halo and night glare in our population was surprising lower: 18.2% as compared to other reports of 40.4%[1]. Since high contrast conditions, i.e. very bright light source in the presence of a very dark background, were required to stimulate halos in both distance and near vision[8], we hypothesised that the local background luminance of our Singapore city at night might be higher than that in the suburb, rural as well as some urban areas in the West. Therefore, even a bright light source such as the head-lights from an oncoming vehicle was less halogenic when the streets are well-lit. This hypothesis is highly intuitive, and we have yet to find published evidence to collaborate with this. The daytime glare was less of an issue in tropical Singapore, where the sun is overhead rather than facing the patient, as in a temperate country.

Driving difficulties were not reported by our patients; this is in keeping with the results of a prospective, test-operator masked, parallel-group comparison study of driving performance conducted by Featherstone et al. They compared patients with bilateral ARRAY multifocal IOL and those with bilateral AMO Clariflex SI40 SN silicone lens in three poor visibility conditions (clear weather at night, clear weather at night in the presence of a glare source, and fog) and found no consistent differences in driving performance and safety[9].

Several large studies including non-randomised comparisons with monofocal IOL implantation, had indicated that there was no difference in mean best-corrected visual acuity[10]. Our mean visual acuity was 0.1 on the Logmar chart, which was equivalent to 6/7.5 vision on the Snellen chart, and this was maintained at six months post-operatively. The posterior capsular opacification and YAG-capsulotomy rates were 38.6% and 4.55%, respectively, in ARRAY multifocal lens and these compared well with rates of 27.5% and 9.68% reported by Beltrame et al for AMO SI 40 SN silicone lens[11]. The ARRAY lens and SI40 SN lens are similar in materials and design except for the presence of multi-zonal anterior optical surface in the ARRAY IOL.

This study was limited because it was a case series rather than a randomised comparative study. However, it provided vital information about the local population for both surgeons and prospective patients, and allowed comparisons with international literature. With the advent of pseudoaccommodative lenses, further studies would be needed to compare these lenses with pseudoaccommodative ones, in the treatment of presbyopia. We conclude that the ARRAY multifocal IOL implantation in the Singapore cataract population could expect similar visual outcomes enjoyed by their Western counterparts. In addition, they seemed to be less bothered by glare and halo.

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