

Multifocal Apodized Diffractive Intraocular Lens Implantation: Three Years' Results

Bilateral Multifokal Apodize Difraktif Göz İçi Mercek İmplantasyonu:
3 Yıllık Sonuçlar

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ABSTRACT

Purpose: To evaluate visual performance in patients who had multifocal apodized diffractive intraocular lens (IOL) implantation, regarding age, preoperative astigmatism, and preoperative visual acuity.

Materials and Methods: This analysis comprised the right eyes of 220 patients who had bilateral implantation of bilateral AcrySof SN60D3 IOL. The best corrected distance visual acuity, distance-corrected (near intermediate, far) visual acuities, distance glare test under mesopic conditions, and patient satisfaction were measured. The results were compared according to age, preoperative astigmatism, and preoperative visual acuity.

Results: For the comparison of age, in the first group, age younger than 65 years, the results were more satisfactory than they were in the second group, except for the halos. In the grouping according to preoperative astigmatism, the first group had 0.5 diopter (D) or less preoperative astigmatism, while the second group had more than 0.5 D; and mean distance logMAR and mean halo values were better in the first group. For preoperative visual acuity, the first group had over 0.5 logMAR preoperative visual acuity, while the second group had 0.5 logMAR. For this comparison, in the first group, near vision logMAR, satisfaction with near sight, satisfaction overall, and glare test results were better.

Conclusions: The AcrySof Natural ReSTOR IOL provided good visual performance at distance and near. The younger age group had better compliance with the lens while halos were still a problem. Astigmatism less than 0.5 D gave favorable results, while preoperative good vision had a negative correlation with postoperative intermediate vision.

Key Words: Multifocal apodized diffractive intraocular lenses, multifocal intraocular lenses, glare test, halos.

ÖZ

Amaç: İki taraflı multifokal apodize difraktif göz içi mercek (GİM) implantasyonu yapılan hastalarda uzak, ara mesafe ve yakın görme fonksiyonlarının yaş, ameliyat öncesi astigmatizma ve ameliyat öncesi görme keskinliğinden etkilenme durumunu saptamak.

Gereç ve Yöntem: Bu geriye dönük çalışmaya iki taraflı katarakt cerrahisi geçirmiş Acrysof SN60D3 GİM implantasyonu uygulanmış 220 hastanın sağ gözleri dahil edildi. Hastaların en iyi görme keskinlikleri, yakın görme keskinlikleri, kamaşma (glare) testi ve hasta memnuniyeti ölçüldü. Hastalar yaşa göre, ameliyat öncesi astigmatizmaya göre ve ameliyat öncesi görme keskinliklerine göre gruplandırıldı.

Bulgular: İki yüz yirmi hastadan 118'i (%54) 65 yaş altında, 102'si (46%) 65 yaş ve üstündeydi. İlk grupta uzak görme logMAR, yakın görme logMAR, yakın görmedeki memnuniyet, ara mesafe görmedeki, memnuniyet, toplam memnuniyet ve kamaşma (glare) testi sonuçları 2. gruba göre daha iyi sonuçlar verdi, ancak halo (ışık halkası) iki grup için de problem olmaktaydı. Ameliyat öncesi astigmatizması 0.5 dioptri (D) ve altında olan ilk grupta 151 (%68.6) hasta, 0.5 D üzerinde astigmatizması olan 2. grupta ise 69 (%31.4) hasta vardı ve uzak görme logMAR ve halo düzeyleri 1. grupta daha iyi bulundu. Ameliyat öncesi 0.5 logMAR'ın üzerinde görme keskinliği olan ilk grupta 110 hastada yakın görme logMAR, yakın görmedeki memnuniyet, toplam memnuniyet ve kamaşma testi sonuçları, 0.5 logMAR ve altında gören 2. gruptaki hastalara göre daha iyi sonuçlar verdi.

Sonuç: Acrysof SND3 GİM takiplerde iyi uzak ve yakın görsel sonuçlar vermiştir. Genç hasta grubu daha iyi uyum sağlamıştır ancak, ışık halkası (halo) bir sorun olarak karşımıza çıkabilmektedir. Ameliyat öncesi astigmatizmanın 0.5 D ve altında olması daha iyi sonuçlar verirken, ameliyat öncesi görme keskinliği yüksek olan olgularda ara mesafelerde görme daha düşük düzeyde kalmıştır.

Anahtar Kelimeler: Multifokal göz içi lensleri, multifokal apodize difraktif göz içi lensi, halo, kamaşma testi.

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INTRODUCTION

With the developments in technology, intraocular lenses (IOL) have changed a lot. Monofocal IOLs may provide excellent visual function but, for many patients today, good near, intermediate, and distance vision is not available together without the use of spectacles. Pseudoaccomodating IOLs have been developed to provide patients with better visual quality.¹⁻³

These include multifocal IOLs, which have both advantages and disadvantages like dysphotopsia and glare or halos.⁴⁻⁹ These results also may be affected by many other factors, like bilateral or unilateral implantation of the multifocal IOL, the age of the patient, pupil size, preoperative refractive status, preoperative visual acuity, and the expectations of the patient.¹⁰⁻¹²

In this paper, we discuss the effect of age, preoperative astigmatism, and preoperative visual acuity on the postoperative distance, intermediate, and near visual performance in patients with multifocal apodized diffractive IOL implantation.

MATERIALS AND METHODS

This prospective study comprised right eyes of 220 patients undergoing uneventful cataract surgery with bilateral implantation of multifocal apodized diffractive IOL, Arcysf SN60D3 (Arcysf Natural ReSTOR), between June 2006 and June 2009 in Mesa Hospital Eye Clinics, Ankara, Turkey. All patients provided informed consent before participation in the study.

Before their inclusion in the study all patients underwent a complete ophthalmic examination: manifest and cycloplegic refraction, slit lamp biomicroscopy, Goldmann applanation tonometry, dilated direct and indirect ophthalmoscopy, and keratometry.

Exclusion criteria included a history of amblyopia, fundus abnormalities that cause significant visual impairment, previous eye surgery, ocular diseases like diabetic retinopathy, corneal opacity, glaucoma, chronic uveitis, or any history of eye trauma.

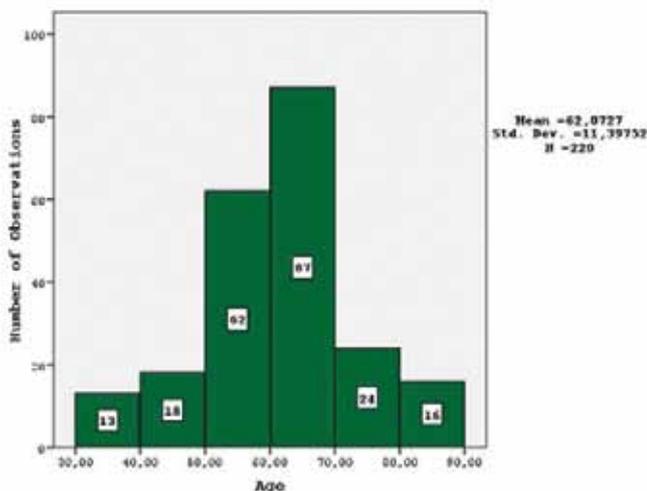
For the surgical technique, under topical anesthesia and through a 2.2-2.8 mm clear corneal incision, phacoemulsification (Infiniti Vision System, Alcon) was performed. Irrigation and aspiration of the cortical material were followed by Arcysf SN60D3 IOL implantation by Monarch injector system.

The patients were divided into two groups according to three variables: according to age (younger or older than 65 years), according to preoperative astigmatism (lower or higher than 0.5 D cylinders), and according to the preoperative visual acuity (higher or lower than 0.5 logMAR). The effects of all these three factors were discussed, compared, and evaluated in terms of best corrected distance visual acuity, best distance-corrected near visual acuity, intermediate visual acuity, distance glare test under mesopic conditions, and patient satisfaction. An Allergan Humphrey Autorefractor was used for evaluation. Visual acuity (logMAR) was assessed with distance correction using the Early Treatment Diabetic Retinopathy Study (ETDRS) chart at 4 m for distance vision, at 40 cm for near vision, and at 60 cm for intermediate distance.

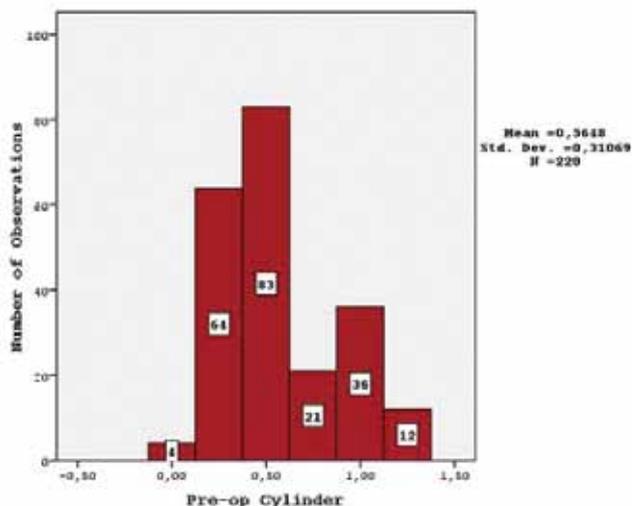
At the postoperative visits patients were asked about their satisfaction at near, intermediate, and overall to rank from 1 to 5 (1=least, 5=most). Contrast sensitivity testing was done under mesopic conditions for glare and halos using the CSV-1000 system (Vector Vision, Inc). Patients were also asked to rank halos from 1 to 5 (1=least, 5=most). Postoperative assessments were done at 12 months and 36 months. Statistical analysis was done by t-test and independent samples test using SPSS for Windows (version 14.0, SPSS, Inc).

Table 1: Statistics of post-operative visual outcomes according to age younger or older than 65 years.

	AGE	N	Mean	Standart Deviation
Distance LogMar	Age<65	118	0.0398	0.07296
	Age>65	102	0.0843	0.09307
Near Vision LogMar	Age<65	118	0.0508	0.06762
	Age>65	102	0.0990	0.7
Satisfaction Near	Age<65	118	4.3390	0.76483
	Age>65	102	3.5980	0.89287
Satisfaction Intermediate	Age<65	118	1.5339	0.64955
	Age>65	102	1.3235	0.47013
Satisfaction Overall	Age<65	118	3.9915	0.89152
	Age>65	102	3.6667	0.92633
Glare Test	Age<65	118	0.6907	0.10859
	Age>65	102	0.5873	0.12717
HALOS	Age<65	118	1.7881	0.78285
	Age>65	102	1.8627	0.85642



Graphic 1: Distrubution of patients by age.

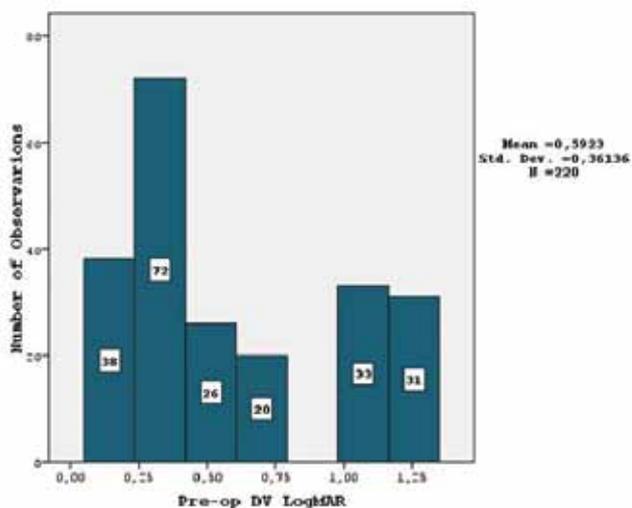


Graphic 2: Preoperative cylinder statistics.

RESULTS

Of the 220 patients, 118 were under 65 years age (54%) and 102 were over 65 years (46%), while mean age was 62 ± 11.3 (30-90 years old). Distribution of the patients by age is shown in graphic 1.

In the first group (age <65 years old), mean distance logMAR, mean near vision logMAR, mean satisfaction at near, mean satisfaction at intermediate distance, mean satisfaction overall, mean glare, and mean halo test results were 0.039 ± 0.072 , 0.050 ± 0.067 , 4.339 ± 0.764 , 1.533 ± 0.649 , 3.991 ± 0.891 , 0.690 ± 0.108 , and 1.788 ± 0.782 , respectively. In the second group (age >65 years), these results were 0.084 ± 0.093 , 0.099 ± 0.7 , 3.598 ± 0.892 , 1.323 ± 0.470 , 3.666 ± 0.926 , 0.587 ± 0.127 , and 1.862 ± 0.856 , respectively (Table 1). In the first group, mean distance logMAR, mean near vision logMAR, mean satisfaction at near, mean satisfaction intermediate, mean satisfaction overall, and mean glare test results were better than those in the second age group, as seen in Tables 1, 2.



Graphic 3: Preoperative distance vision logMAR statistics.

Table 2: Comparison of post-operative visual performances according to age (younger or older than 65 years).

	t-test for Equality of Means		
	T	df	Significance (2-tailed)
Distance LogMar	-3.901	190.416	0.000
Near Vision LogMar	-5.005	218	0.000
Satisfaction Near	6.630	218	0.000
Satisfaction Intermediate	2.778	211.709	0.006
Satisfaction Overall	2.647	218	0.009
Glare Test	6.507	218	0.000
HALOS	-0.675	218	0.500

df: difference

There was statistical significance between the first and second groups ($p < 0.01$), but the halos did not show any significant difference ($p > 0.01$) and remained a problem in both age groups.

Regarding the comparison of preoperative astigmatism, the first group including 151 patients (68.6%) had 0.5 D or less preoperative cylinder, while the second group with 69 patients (31.4%) had cylindrical values more than 0.5 D, and mean cylindrical value was 0.56 ± 0.31 as seen in graphic 2.

In the first group, mean distance logMAR, mean near vision logMAR, mean satisfaction at near, mean satisfaction at intermediate distance, mean satisfaction overall, mean glare, and mean halo test results were 0.047 ± 0.082 , 0.067 ± 0.073 , 4.039 ± 0.863 , 1.423 ± 0.559 , 3.834 ± 0.859 , 0.651 ± 0.120 , and 1.721 ± 0.833 , respectively. In the second group with astigmatism more than 0.5 D these results were 0.088 ± 0.086 , 0.085 ± 0.077 , 3.898 ± 0.987 , 1.463 ± 0.631 , 3.855 ± 1.047 , 0.623 ± 0.142 , and 2.043 ± 0.736 , respectively (Table 3). In this comparison, mean distance logMAR and mean halo values were significantly better ($p < 0.01$ in both) in the first group with less astigmatism, which shows that if the astigmatism was over 0.5 D vision deteriorates, while no significant effect of astigmatism was detected in the mean near vision logMAR, mean satisfaction at near, intermediate distances, and overall and mean glare test results between the two groups ($p > 0.01$), which means that preoperative astigmatism has no effect on these, as seen in tables 3,4.

As for the comparison of preoperative visual acuity, the mean value was 0.59 ± 0.36 logMAR. In the first group, with 110 patients, preoperative visual acuity was over 0.5; in the second group, with 110 patients, preoperative visual acuity was lower than 0.5 logMAR as seen in graphic 3.

Table 3: Statistics of post-operative visual outcomes according to pre-operative cylinders.

		Group Statistics		
		N	Mean	Std Deviation
Distance LogMar	Pre-op cylinder<0.5	151	0.0477	0.08233
	Pre-op cylinder>0.5	69	0.0884	0.08666
Near Vision LogMar	Pre-op cylinder<0.5	151	0.0675	0.07353
	Pre-op cylinder>0.5	69	0.0855	0.07722
Satisfaction Near	Pre-op cylinder<0.5	151	4.0397	0.86318
	Pre-op cylinder>0.5	69	3.8986	0.98735
Satisfaction Intermediate	Pre-op cylinder<0.5	151	1.4238	0.55901
	Pre-op cylinder>0.5	69	1.4638	0.63198
Satisfaction Overall	Pre-op cylinder<0.5	151	3.8344	0.85969
	Pre-op cylinder>0.5	69	3.8551	1.04706
Glare Test	Pre-op cylinder<0.5	151	0.6517	0.12047
	Pre-op cylinder>0.5	69	0.6232	0.14261
HALOS	Pre-op cylinder<0.5	151	1.7219	0.83394
	Pre-op cylinder>0.5	69	2.0435	0.73634

pre-op :preoperative

In the first group, with the better preoperative visual acuity, mean distance logMAR, mean near vision logMAR, mean satisfaction at near, mean satisfaction at intermediate distance, mean satisfaction overall, mean glare, and mean halo test results were 0.072±0.094, 0.094±0.075, 3.709±0.912, 1.409±0.653, 3.554±0.883, 0.606±0.125, and 1.900±0.800, respectively, while in the second group, these results were 0.048±0.0738, 0.051±0.068, 4.281±0.802, 1.463±0.500, 4.127±0.868, 0.679±0.121, and 1.745±0.828, respectively (Table 5).

In this comparison, in the second group, with better preoperative visual acuity, postoperative near vision logmar, satisfaction at near, satisfaction overall, and glare test results were significantly better (p< 0.01 all), while there were no statistical differences for distance logMAR, satisfaction intermediate, and halo values between the two groups (p>0.01) as shown in tables 5, 6.

DISCUSSION

Many studies have shown the efficacy and the safety of Arcysof SN60D3 IOL (Arcysof Natural ReSTOR).^{5, 7, 10, 13} Our study also confirmed these results. We found good visual performance at distance and near at the 36-month postoperative visit. Patient satisfaction was also better at that time.

We grouped our patients according to age and obtained significantly better results in terms of distance vision logMAR, near vision logMAR, satisfaction at near and intermediate distance, and glare tests, overall which shows that younger age group had better compliance with this IOL, whereas halos were a still problem in both age groups.

That result may be interpreted as showing that younger patients would have better compliance with the multifocal lenses: this may also be related to better neuroadaptation mechanisms. That was also supported in recent studies.^{10,13-15} Preoperative astigmatism was another determining factor in our study; we have shown that astigmatism less than 0.5 dpt gave favorable results in terms of distance vision and halos.

The effect of astigmatism was also discussed by Ravalico et al.,¹¹ previous studies usually have accepted 1.0 D as the cut-off point for preoperative cylindrical value, but we grouped the preoperative astigmatism as lower or higher than 0.5 D. We think that the amount of preoperative astigmatism should be evaluated very carefully and the lowest possible value must be accepted for multifocal IOL implantation.

Table 4: Comparison of post-operative visual performance results according to pre-operative cylinders.

	t-test for Equality of Means		
	t	Df	Significance (2-tailed)
Distance LogMar	-3.348	218	0.001
Near Vision LogMar	-1.654	218	0.100
Satisfaction Near	-1.023	117.306	0.309
Satisfaction Intermediate	-0.472	218	0.638
Satisfaction Overall	-0.143	111.548	0.886
Glare Test	1.440	114.084	0.153
HALOS	-2.881	148.020	0.005

df: difference

Table 5: Group statistics of post-operative outcomes according to pre-operative distance vision LogMAR.

Group Statistics		N	Mean	Std. Deviation
Distance LogMar	Pre-op LogMar<0.5	110	0.0727	0.09473
	Pre-op LogMAR>0.5	110	0.0482	0.07386
Near Vision LogMar	Pre-op LogMar<0.5	110	0.0945	0.07522
	Pre-op LogMAR>0.5	110	0.0518	0.06871
Satisfaction Near	Pre-op LogMar<0.5	110	3.7091	0.91215
	Pre-op LogMAR>0.5	110	4.2818	0.80288
Satisfaction Intermediate	Pre-op LogMar<0.5	110	1.4091	0.65379
	Pre-op LogMAR>0.5	110	1.4636	0.50096
Satisfaction Overall	Pre-op LogMar<0.5	110	3.5545	0.88397
	Pre-op LogMAR>0.5	110	4.1273	0.86850
Glare Test	Pre-op LogMar<0.5	110	0.6064	0.12509
	Pre-op LogMAR>0.5	110	0.6791	0.12123
HALOS	Pre-op LogMar<0.5	110	1.9000	0.80080
	Pre-op LogMAR>0.5	110	1.7455	0.82880

pre-op: preoperative, std deviation: standart deviation

The value of the cut-off point needs further investigation and more related studies. In our study, the effect of astigmatism value was not significant in terms of near vision logMAR, satisfaction near, intermediate, or overall, or on glare tests.

These results would imply that preoperative astigmatism plays an important role in assessing patients for multifocality and some unexpected and undesirable results would occur if ignored.

We also grouped the patients according to pre-operative distance visual acuity. The group with better preoperative visual acuity showed worse postoperative intermediate visual performance but this result was not statistically significant.

Near vision logMAR, satisfaction at near, satisfaction overall, and glare test results were significantly better in the group with better preoperative visual acuity.

Table 6: Comparison of post-operative results according to pre-operative distance vision LogMAR.

	t-test for Equality of Means		
	t	df	Significance (2-tailed)
Distance LogMar	2.143	205.784	0.033
Near vision LogMAR	4.399	218	0.000
Satisfaction Near	-4.943	218	0.000
Satisfaction Intermediate	-0.695	218	0.488
Satisfaction Overall	-4.847	218	0.000
Glare Test	-4.379	218	0.000
HALOS	1.406	218	0.161

df: difference

Moreover, the distance vision logMAR was better in the group with better preoperative vision, but the difference was not statistically significant. There has not been much research based upon multifocal IOL implantation in terms of preoperative visual acuity and its effects on postoperative visual performances.

Our study may indicate that preoperative visual acuity plays a role in postoperative visual performance in the case of multifocal intraocular lenses, and better near vision and better glare results may be achieved but intermediate visual acuity was inversely affected in our study. This outcome may be seen in most of the multifocal intraocular lenses; as we know from the literature, the most annoying aspects of these IOLs are glare and intermediate dissatisfaction results. Overall, the patients with better preoperative visual acuity are also usually younger and have lower spherical and cylindrical values that would also come out with better results for near vision and less glare.

To conclude, the AcrySof Natural ReSTOR IOL provided good visual performance at distance and near at the 36 month postoperative visit. Patient satisfaction was also better at the 36 month postoperative visit.

The younger age group had better compliance with the multifocal lens, while the halos were still a problem at any age. Astigmatism should be an important nominator and in our study we achieved more favorable results in cases of low astigmatism while preoperative good vision had a negative correlation with postoperative intermediate vision.

That means that preoperative visual acuity as well as preoperative astigmatism and age of the patient may influence the postoperative visual performance in cases of multifocal intraocular lens implantation.

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