CLINICAL RESULTS OF FOLDABLE HYDROPHOBIC ACRYLIC INTRAOCULAR LENS ZARACCOM F260: COMPARATIVE STUDY WITH ACRYSOF NATURAL SN60AT

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Tamer Takmaz, İzzet Can, Hakan Bilkay, Şenay Aşık

Atatürk Training and Research Hospital, 2nd Ophthalmology Department, Ankara, Turkey

ABSTRACT

PURPOSE: To evaluate early term clinical results of locally manufactured foldable hydrophobic acrylic intraocular lens (IOL) Zaraccom F260 and compare the results with Acrysof Natural SN60AT which is widely used in the world.

METHODS: In this prospective randomized study, the results of the cases who had phacoemulsification surgery and implantation of hydrophobic acrylic IOLs Zaraccom F260 (Group 1; 50 eyes) and Acrysof Natural SN60AT (Group 2; 50 eyes) were compared. The IOLs were implanted either by injection method through 3.0 mm incision or by folding method through 4.1 mm incision. Complications like capsulorhexis break, posterior capsule rupture, zonular dialysis which occured during cataract surgery and the problems occured while implanting the IOLs were recorded. The follow-up examinations were performed at days 1, 7, 30 and 90 and the last examination date has been recorded as follow-up time. Corneal edema, anterior chamber cellular reaction, fibrin reaction, fibrosis of the anterior capsule, posterior capsule opacification and deviation from the target refraction value were all evaluated other than the routine follow-up examinations.

RESULTS: There was not difference between the groups according to age, sex, effective phaco time, cataract type, follow-up period, preoperative and postoperative visual acuities ($p>0.05$). The IOL implantation techniques were similar ($p=0.539$). There was not difference according to intraoperative complication rates ($p=0.617$). The main problem in Group 1 was exfoliated material seen on the optic surface of the IOLs in 9 eyes during implantation by injection method and in 3 eyes cracks occurred in the Monarch II B cartridge while implanting the IOLs. When corneal edema and cellular reaction in the anterior chamber were evaluated, no difference was seen between the groups ($p>0.05$). Anterior capsule fibrosis and posterior capsule opacification formations were similar in both groups ($p>0.05$). Deviation from the postoperatively targeted refraction value was not different between the groups ($p>0.05$).

CONCLUSIONS: Similar results were seen while comparing Zaraccom F260 and Acrysof Natural SN60AT. Visual results and the capsular biocompatibility of the lenses were good in the early postoperative period. According to many characteristics, there was not important difference between the IOLs, but special implantation systems for must be developed Zaraccom F260.

INTRODUCTION

Rapid advancements have been made in the surgical technique and intraocular lense (IOL) materials since the introduction of IOL implantation in cataract cases. Moreover, introduction of the foldable IOLs reduced the incision size and provided more nontraumatic and safer surgical techniques.

The aim while developing IOLs are to minimize the surgical complications and trauma, to gain most efficient and comfortable vision and to get best uveal and capsular biocompatibility. An IOL's performance in the eye depends on several factors like surgical technique, perioperative treatment, biomaterial and design of IOL, the instruments used during surgery and the host reaction to the IOL.[1-3] Today, the material of foldable IOLs are divided into two groups; acrylate/methacrylate group containing poly(methyl methacrylate), hydrogel or acrylic and silicone group.[4]

The biomaterial and surface properties of an IOL (hydrophilic or hydrophobic) is very important. Posterior capsule opacification (PCO) rate is lower in hydrophobic acrylic IOLs and there is a tendency of anterior capsule edge fibrosis with these IOLs, but PCO rate is higher and more severe in hydrophilic IOLs and appears earlier on this material.[3,5] The clinical trials show that the hydrophilic IOLs cause less lens epithelial cell metaplasia and because of this anterior capsule fibrosis rate is lower. However these cells migrate to the anterior surface of hydrophilic IOLs.[3,6,7] The biocompatibility of hydrophobic materials, whether acrylic or silicone, are told to be better than hydrophilic acrylic materials, but also in some studies it is pointed out that there is much inflammation and rapid development of anterior capsule opacification in hydrophobic IOLs compared to hydrophilics.[3,8,9]

In this study we evaluated the early term clinical results of the first locally manufactured foldable hydrophobic acrylic IOL Zaraccom F260 (Anatolia Medicine Tecnologies Co., Sivas, Turkey) and compare the results with Acrysof Natural SN60AT (Alcon Laboratories, Fort Worth, Texas, USA) which is used widely in the world.

PATIENTS AND METHODS

In this prospective randomized study, the results of the cases who had phacoemulsification surgery and implantation of hydrophobic acrylic IOLs Zaraccom F260 (Group 1; 50 eyes) and Acrysof Natural SN60AT (Group 2; 50 eyes) between October 2005 – March 2006 were compared.

All patients enrolled in this study agreed to participate and met the inclusion criteria and signed an informed consent agreement before any procedures were performed. The study was performed in accordance with the ethical principles as described in the Declaration of Helsinki and approval by Ethics Committee was obtained.

All patients had routine eye examination before the operations. Patients who had any eye surgery previously, eye disease like uveitis, exfoliation syndrome and glaucoma, and systemic disease like diabetes mellitus were not included in the study. Three cases had traumatic cataract without any other eye pathologies.

All patients received standart dilation regimen of cyclopentolate hydrochloride 1% (Sikloplejin), phenylephrine HCl (Mydfrin 2.5%) and ketorolac tromethamine 0.5% (Acular), 30

minutes before the operations. The operations were performed under local anestesia with a mixture of lidocaine HCl + adrenaline (Jetokain) and bupivacaine hydrochlorur (Marcaine %0.5).

The surgeries were performed with standard phacoemulsification technique by İC. Following side-port and clear corneal 3.0 mm incisions, capsulorhexis was performed under sodium hyaluronate 2% (Cohaerens®; LCA Pharmaceutical, France). After hydrodissection, phacoemulsification was performed using the stop-and-chop phacoemulsification technique with Infiniti phacoemulsification unit (Alcon Laboratories, Fort Worth, TX, ABD). In all cases, a 0.9 mm flared, 30-degree, ABS Kelman microtip was used. The cortex was removed with bimanual infusion/aspiration cannulas. The IOLs were implanted either by injection method through 3.0 mm incision with Monarch II B cartridge (Alcon Laboratories, Fort Worth, TX, ABD) or by folding method through 4.1 mm incision. For implantation through 4.1 mm incision sodium hyaluronate 2% (Cohaerens®; LCA Pharmaceutical, France) was injected into the anterior chamber and than the incision was enlarged to 4.1 mm. Zaraccom F260 IOLs were implanted in 50 eyes (Group 1) and Acrysof Natural SN60AT were implanted in the other 50 eyes (Group 2). The ophthalmic viscosurgical device was removed from the anterior chamber carefully until no viscoelastic material was visible and the procedure was completed after closure of the incisions by stromal hydration.

Techniqual features of the two IOLs compared are as follows: Zaraccom F260 is a single piece foldable IOL produced from olugoretanmethacrylate copolymer hydrophobic acrylic material and it has a biconvex optic design with square edge, the haptic angle is 0 degrees, the optic diameter is 6.0 mm and the overall lenght is 12.5 mm. The refractive index of the IOL is 1.51 and A-constant is 118.4. The central thickness of the optic is 0.936 mm for 20.5 D IOL. Acrysof Natural SN60AT is also a single piece foldable IOL produced from acrylate/methacrylate copolymer material. It has an anterior asymmetric biconvex optic design with square edge, the haptic angle is 0 degrees, the optic diameter is 6.0 mm and the overall lenght is 13.0 mm. The refractive index of the IOL is 1.55, A-constant is 118.4 and the central thickness of the optic is less than 0.65 mm for 20.5 D.

Complications like capsulorhexis break, posterior capsule rupture, zonular dialysis which occured during the cataract surgery and the problems occured while implanting the IOLs were recorded. The effective phaco time was calculated.

The follow-up examinations were performed at days 1, 7, 30 and 90 and the last examination date has been recorded as follow up time. During the examinations visual acuities were measured and routine anterior and posterior examinations were performed. Corneal edema, cellular reaction in the anterior chamber, fibrin reaction, fibrosis of the anterior capsule, posterior capsule opacification (capsular and uveal biocompatibility) and deviation from the target refraction value were evaluated, other than the routine follow-up examinations. The corneal edema was graded as follows; mild (mild corneal edema limited in the surgical area), moderate (diffuse corneal edema where anterior chamber and iris details may be seen), severe (diffuse corneal edema where evaluation of anterior chamber and details is difficult). The cell counting in the anterior chamber has been performed by slit-lamp biomicroscopy examination adjusting the lamp as 3 mm height and 1 mm width and defined as 0; 0-4, 1+; 5-10, 2+; 11-20, 3+; 21-50 and 4+; more than 50 cells. Postoperative aqueous flare (fibrin

reaction) was also evaluated and graded graded as follows; none, mild (just detectable), moderate (iris details clear) and severe (iris details hazy and considerable fibrin). Anterior capsule fibrosis and posterior capsule opacification were evaluated in maximally dilated eyes by adjusting the angle and light of slit-lamp biomicroscope. Anterior capsule fibrosis was evaluated at the edge of the capsulorhexis and at the capsule over the optic and posterior capsule opacification was evaluated at central 6 mm area. The anterior capsule fibrosis and the posterior opacifications were graded as follows: 0; no opacification, clear capsule, 1; mild-moderate (capsule opacification where the structures behind it may be evaluated easily), 2; severe (white capsule where the structures behind it can not be evaluated).

Statistical analysis was performed using SPSS 13.0 for Windows (SPSS Inc.). Chi-square, Fisher's exact test and t tests were used to compare the parameters. Two-way analysis was used for all tests and P values less than 0.05 were considered to be statistically significant in all analysis.

RESULTS

There was not difference between the groups according to age, sex and follow up time ($p>0.05$) (Table 1).

When we examine the type of cataract in eyes underwent surgery, it was seen that nuclear cataract was seen in 15 and 28, cortical cataract in 13 and 5, posterior subcapsular cataract in 10 and 10, mature cataract in 7 and 4, congenital cataract in 3 and 2 and traumatic cataract in 2 and 1 eyes in Gruop 1 and 2 respectively. There was not difference between the groups according to cataract type ($p=0.098$).

The effective phaco time was similar in both groups ($p>0.05$) (Table 1). The IOLs were implanted by injection method through 3.0 mm incision in 29 eyes (58%) and in 32 eyes (64%), and by folding method in 21 eyes (42%) and in 18 eyes (36%) in Groups 1 and 2 respectively ($p=0.539$).

Preoperative and postoperative logarithm of the minimum angle of resolution (logMAR) visual acuities were not different between the two groups ($p>0.05$) (Table 1).

When we compared the complications occured during surgeries it was seen that there was capsulorhexis break in 1 eye (2%), posterior capsule rupture in 1 eye (2%) and partial zonular dialysis in 1 eye (2%) in Group 1 and posterior capsule rupture in 1 eye (2%) in Group 2 and there was not difference between the groups ($p=0.617$). The main problem during IOL implantation in Group 1 was exfoliated material seen on the optic surface of the IOL in 9 eyes (18%). In all of these eyes IOL implantations were performed with Monarch II B cartridge. These materials were also seen on the IOL during the postoperative examinations, but in 4 eyes (44.4%) it was lost 90 days after the operations (Figure 1). Moreover, cracks occurred in the Monarch II B cartridge while implanting the IOLs in 3 eyes (6%) in Group 1.

There was no difference between the groups according to corneal edema (Table 2) and cell amount in the anterior chamber (Table 3) ($p>0.05$). In both groups, corneal edema was not seen in any eye 1 month after the operations. There was a mild aqueous flare, fibrin reaction in 8 eyes (16%) in Group 1 and in 6 eyes (12%) in Group 2 on the first postoperative day ($p=0.564$).

There was a mild posterior capsule opacification in 3 eyes (6%) in Group 1 and in 1 eye (2%) in Group 2, 90 days postoperatively (p=0.617). Also, mild anterior capsule fibrosis was seen in 3 eyes (6%) in Group 1 and in 2 eyes (4%) in Group 2 (p=1.000). Anterior capsule fibrosis and posterior capsule opacification formations were similar in both groups (p>0.05).

Deviation from the postoperatively targeted refraction value was not different between the groups (p>0.05) (Table 4).

DISCUSSION

The hydrophobic acrylic foldable IOLs Zaraccom F260 and Acrysof Natural SN60AT compared in this study are technically similar in many characteristics. The main difference is the refractive index of the material which is lower in Zaraccom F260 (1.51) than Acrysof Natural SN60AT (1.55) and consequently the central thickness of Zaraccom F260 is thicker than Acrysof Natural SN60AT.

When the results were evaluated according to intraoperative complications, it was seen that there was not difference between the groups. The capsulorhexis break seen in Group 1 occured during phacoemulsification and it was not related to the IOL. The partial zonular dialysis was seen in 1 of the eyes with traumatic cataract. It was seen at the beginning of the operation and neither phacoemulsification nor IOL implantation had direct effect on zonular dialysis development.

The main problem during IOL implantation in the cases that injector system used in Group 1was exfoliated material seen on the optic surface of the IOL. In some of the cases cracks were seen on the cartridge. However, when the IOLs in these cartridges were rubbed with wet sponges these materials went away easily. When it was investigated whether the problem arised from the IOL or not, it was clarified that it was due to the peeling of the inside surface of the cartridges. The spontaneously disappearance of these materials in some cases was also a proof that it was not caused by IOLs. It was thought that, as the Monarch II injector system and B cartridge were developed for Acrysof IOLs and as the central thickness of Zaraccom F260 was thicker than Acrysof SN60AT, the cartridge was narrow for Zaraccom F260 and that's why the exfoliated material was seen on the IOLs and there were cracks on the cartridges. Exfoliated material was not seen over any IOLs implanted by folding method and also there was no difficulty arisen during folding and implantation of these lenses. Because of these findings, it was thought that the company have to develop its own special injector system for Zaraccom F260 to implant the IOLs through small incisions.

In both groups, mild corneal edema was seen frequently, which was located to the incision site and there was not significant difference between the groups according to the corneal edema. The thickness or the material structure of Zaraccom F260 IOL did not have disadvantage on this context.

The biocompatibility of the IOLs are well known and the uveal and capsular biocompatibilities are evaluated separately.[1-3,8,10,11] The biocompatibility is defined as the capability of a prosthesis implanted in the body to exist in harmony with tissue without causing deleterious changes.[2,4] There is early and late foreign body reaction (inflammatory cell ongrowth) on one hand and lens epithelial cell (LEC) complications (anterior capsule opacification, posterior capsule

opacification, LEC ongrowth on the IOL's anterior surface) on the other hand when we evaluate the biocompatibility of IOLs.[2]

The uveal biocompatibility defines the reaction of uvea to the IOL. Immediate postoperative inflammation is mainly attributed to surgical irritation of the anterior uvea, which causes changes in the blood aqueous barrier.[8] Longterm postoperative inflammation is caused by other factors such as immunological reactions.[10] Monocytes and macrophages migrate through the uvea's vessel walls into the aqueous humor and onto the IOL surface. It was shown that materials of the IOLs affect not only the quantity of macrophages adhering to their surface, but also the shape of fibroblast-like cells, and the process of their maturation from mononuclear macrophages to multinuclear giant cells.[1] On hydrophobic acrylic IOLs, a peak of mononuclear macrophages was seen 1 week postoperatively and a peak of epitheloid and multinuclear giant cells were seen 4 weeks postoperatively.[1,3] Miyake et al.[8] found that IOLs with hydrophobic surfaces induced higher postoperative inflammation than lenses with hydrophilic surfaces. Scaramuzza et al.[9] determined that the hydrophobic acrylic lenses induced greater postoperative inflammation and more rapid anterior capsule opacification.

When we evaluated the cell amount in the anterior chamber, it was seen that there was not significant difference between the groups 1 week postoperatively. Postoperative fibrin reaction was similar in both groups on the first postoperative day, but all disappeared after a week. Although it was not significant statistically, there were cells in the anterior chamber of a small number of cases with Zaraccom F260 IOLs on long term. It was thought that the reason of this situation should be the optic thickness of the IOL. As cells were seen in the anterior chamber long after the operations, the uveal biocompatibility should be evaluated in a wide group of cases. Schauersberger et al.[11] stated that even after 3 years they have seen inflammatory cells and this indicated that a persistent late foreign body reaction may occur.

Researchs have delineated that factors shown to reduce the development of PCO include a central capsulorhexis that completely covers the anterior surface of the IOL[12], the IOL material[5,11,13,14] and square, sharpe edged lens design.[5,11,14,15] Kugelberg et al.[5] determined that the incidence and the severity of PCO were seen more with hydrophilic IOLs compared to the hydrophobic IOLs. The studies with Acrysof IOL showed that it had a low rate of PCO but a higher incidence of giant cell reaction, besides it was seen that despite the excellent capsular biocompatibility, the uveal biocompatibility was not good.[3] In our study the early term capsular biocompatibility of both IOLs were found to be good. The development of PCO and fibrosis at the edge of the anterior capsule and on optic surface were similar in both groups and they were both mild and seen in a small number of cases. In the postoperative early periods, no patient required Nd:YAG laser capsulotomy. However more definite comments should be done after long term follow ups. According to early clinical results, as there was not significant difference between Zaraccom F260 and Acrysof Natural IOLs, it seems that Zaraccom F260 has a good early postoperative biocompatibility.

It is expected from IOLs to continue their optical performance for a long time. On this respect, there was not significant refractive change in the postoperative early period in both groups. Also, when deviation from the postoperatively targeted refraction value was evaluated, it was seen that there

was not difference between the groups and the refraction deviation was between ±0.50 D, over 70 % of patients in both groups.

As a result, there was not significant difference between the newly introduced Zaraccom F260 and Acrysof Natural SN60AT IOLs and they were similar according to many characteristics. The visual outcome of patients and the capsular biocompatibility of the lenses was very good in the early postoperative period. It was also concluded that special cartrigdes or implantation systems for Zaraccom F260 should be developed because of the exfoliated material seen on the optic surface of the IOL and also as cells were seen in the anterior chamber long after the operations, the uveal biocompatibility should be evaluated in a wide group of cases .

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Table 1.Demographic data of patients, visual acuity and effective phacoemulsification time.

Characteristics	Group 1 (Zaraccom) (n = 50)	Group 2 (Acrysof) (n = 50)	*P* Value
Mean age (years)	57.5 ± 17.3	60.8 ± 12.2	.274
Sex (male/female)	23/27	21/29	.687
Follow up period (days)	126.5 ± 32.8	119.1 ± 14.2	.145
Effective phaco time (sec)	5.2 ± 5.7	4.8 ± 3.8	.662
Preoperative BCVA* (logMAR)	0.99 ± 0.73	0.83 ± 0.60	.215
Postoperative BCVA (logMAR)	0.16 ± 0.25	0.09 ± 0.09	.078

*BCVA: Best corrected visual acuity

Table 2. Postoperative corneal edema grades.

Corneal edema	Group 1 (Zaraccom) (n = 50)	Group 2 (Acrysof) (n = 50)	*P* Value
Day 1			.732
Mild	7 (14%)	6 (12%)	
Moderate	3 (6%)	2 (4%)	
Severe	-	1 (2%)	
Day 7			.549
Mild	3 (6%)	2 (4%)	
Moderate	-	1 (2%)	

Table 3. Postoperative cell amount in the anterior chamber*.

Postoperative	Group 1 (Zaraccom) (n = 50)	Group 2 (Acrysof) (n = 50)	*P* Value
Day 1			.292
1+	31 (62%)	37 (74%)	
2+	6 (12%)	5 (10%)	
3+	4 (8%)	5 (10%)	
4+	9 (18%)	3 (6%)	
Day 7			.684
1+	16 (32%)	12 (24%)	
2+	5 (10%)	4 (8%)	
3+	1 (2%)	1 (2%)	
4+	1 (2%)	-	
Day 30			.269
1+	6 (12%)	2 (4%)	
Day 90			.153
1+	2 (4%)	-	

*1+; 5-10, 2+; 11-20, 3+; 21-50 and 4+; more than 50 cells

Table 4. Deviation from the postoperatively targeted refraction value.

Deviation (Diopter)	Group 1 (Zaraccom) (n = 50)	Group 2 (Acrysof) (n = 50)	*P* Value
≤ 0.25	22 (%44)	21 (% 42)	.972
0.26 - 0.50	12 (%24)	15 (%30)	
0.51 - 1.00	8 (%16)	7 (%7)	
1.01 – 2.00	6 (%12)	5 (%10)	
2.01 ≤	2 (%4)	2 (%4)	

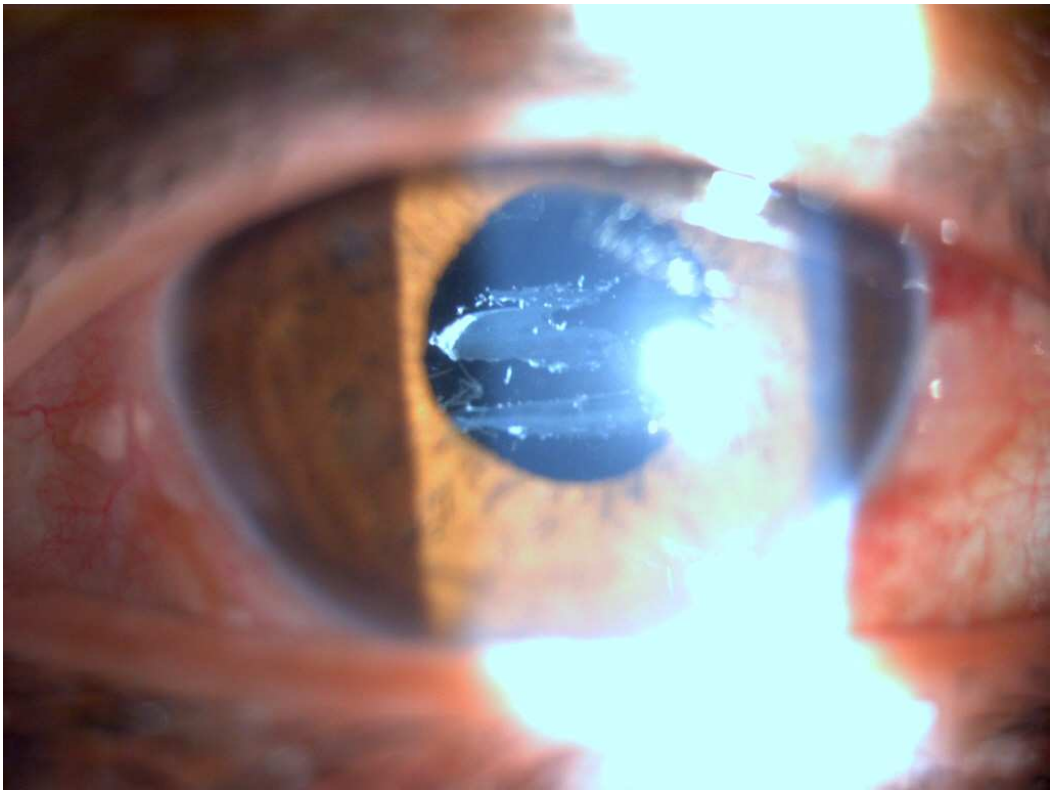

Figure 1. Exfoliated material seen on the optic surface of Zaraccom F260 implanted by injection method.