EFFICACY OF FIRST TURKISH MADE SINGLE-PIECE FOLDABLE HYDROPHOBIC ACRYLIC INTRAOCULAR LENS ZARACCOM F260 ON CATARACT TREATMENT

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Running title: Efficacy of foldable hydrophobic acrylic intraocular lens Zaraccom F260

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Abstract

Purpose: To evaluate efficacy of Zaraccom F260 intraocular lenses (IOL) on cataract treatment.

Setting: Department of Ophthalmology, Cumhuriyet University School of Medicine, Sivas, Turkey

Methods: In this study, 114 eyes of 97 adult cataract patients underwent phacoemulsification and Zaraccom F260 IOL implantation were included. The mean age of all patients was 63.03 ± 17.23 (24 to 95) years. The mean postoperative follow-up time was 12.43 ±6.30 months. The main outcome criteria were visual acuity, anterior and posterior capsular biocompatibility and opasifications, intraoperative application properties, lens position and centralization, lens color and clarity, harmony of the lens with viscoelastic material, complications, and adverse effects.

Results: The mean preoperative best corrected visual acuity (BCVA) was 0.26 ± 0.26. One week after surgery and the final mean BCVA were 0.49 ± 0.25 and 0.9 ± 0.28, respectively. Eighty-five eyes (74.6%) had no ACO, 25 (21.9%) had mild ACO, and 4 (3.5%) had anterior capsule fibrosis. Lens epithelial cells (LEC's) on the capsule-free anterior surface and posterior capsule pacification (PCO) occurred in 6 eyes (5.3%) and 5 eyes (4.4%), respectively. The all lenses were easily implanted and in the bag and centralized along the follow-up period.

Conclusions: Foldable hydrophobic acrylic intraocular lens Zaraccom F 260 can be an alternative choice for the patients with cataract requiring lens replacement.

Keywords: Zaraccom F260, foldable hydrophobic acrylic intraocular lens, biocompatibility

Introduction

Several studies have attempted to assess the extent of intraocular lens (IOL) biocompatibility in healthy eyes with cataract and have classified IOLs according to their surface properties (hydrophilic, hydrophobic) or biomaterial.[1-4] Uveal and capsular biocompatibility is a tissue-specific classification that is defined as the reaction of the uvea to the IOL and the reaction of LECs and the capsule to IOL material and design, respectively. It is appropriate to distinguish between the uveal reaction (cell reaction) and the capsular reactions (LEC outgrowth, posterior capsule opasification (PCO), anterior capsule opacification (ACO), capsule contraction).[4] Optimal uveal and capsular biocompatibility should be the main goal in cataract surgery.[5]

Zaraccom F260 lens (Anatolia Medicine Technologies Co., Sivas, Turkey) is a first Turkish made CE certified single piece foldable hydrophobic acrylic intraocular lens. Its manufacturing technique photopolymerization is different from the other traditional foldable hydrophobic acrylic intraocular lenses manufacturing by lathe cutting such as single-piece AcrySof SA60AT. The photopolymerization technique is a cast-moulding method. It is known that cast-moulded contact lenses are associated with apparently ‘stickier’ surfaces, which may be indicative of surface degradation during the manufacturing process.[6] For this reason, the surface properties of Zaraccom F260 lenses can be different from the other foldable hydrophobic acrylic intraocular lenses. In this study, we evaluated efficacy of Zaraccom F260 lenses on cataract treatment.

Methods

This single-center prospective study was conducted at the ophthalmology clinic of Cumhuriyet University Hospital in Sivas. It comprised of 114 eyes of 97 adult cataract patients who had phacoemulsification and IOL implantation between June 2005 and June

2006. All the eyes underwent implantation of Zaraccom F260 lenses. The mean age of all patients was 63.03 ± 17.23 (24 to 95) years. No patient had systemic or ocular disease (e.g., diabetic retinopathy, age-related macular degeneration, glaucoma) that would interfere with postoperative visual acuity. The mean postoperative follow-up time was 14.43 ±3.30 months (range of 12 to 16 months). After approval of the Human Ethics Committee of our school, the patients gave informed consent before inclusion in the study.

All patients received parabulbar anesthesia and were operated using the same technique. A 3.2-3.5 mm long temporal clear corneal incision was prepared. After continuous curvilinear capsulorhexis, hydrodissection, and hydrodelineation of the lens were done, phacoemulsification was performed using a bimanual technique with Oertli Orbit machine. The cortex was aspirated and the capsular bag expanded under sodium hyaluronate 3% (ENDOGEL®). The IOL was implanted in the capsular bag. The capsulorhexis had a diameter of approximately 4.5 to 5.0 mm and was centrally positioned on the optic, overlying the optic of the lens.

The Zaraccom F260 (Figure 1) is a foldable, single-piece IOL with optic and haptics of oligourethan metacrylate. The refractive index is 1.51. The diameter of the biconvex optic is 6.0 mm and the overall length, 12.5 mm. The lens has a smooth surface and a sharp edge. The haptics have a modified L design and an angulation of 0 degrees (Figure 2, 3).

Data were collected 1 day, 1 week, and 3, 6, and 12 months postoperatively. The main outcome criteria were visual acuity, anterior and posterior capsular biocompatibility and opasifications, intraoperative application properties, lens position and centralization, lens color and clarity, harmony of the lens with viscoelastic material, complications, and adverse effects. The visual acuity was evaluated with Snellen chart. Postoperative biomicroscopic examinations were performed by 1 observer with a slit-lamp (Nicon NS-1V, Japan) after pupil dilatation. First, the entire anterior and posterior IOL surfaces at the capsule were evaluated

under anterior illumination and retroillumination. Finally, the need for an Nd:YAG laser capsulotomy was noted (yes or no). The criteria for the necessity of capsulotomy were patient visual complaints or a VA of 20/25 or less attributable to central PCO at slit-lamp examination.

Results

The mean preoperative best corrected visual acuity (BCVA) was 0.26 ± 0.26 (range 0.001 to 1.0). One week after surgery, the mean BCVA was 0.49 ± 0.25. The final mean BCVA was 0.9 ± 0.28. Eighty-five eyes (74.6%) had no ACO, 25 (21.9%) had mild ACO, and 4 (3.5%) had anterior capsule fibrosis. Lens epithelial cells LEC's on the capsule-free anterior surface occurred in 6 eyes (5.3%). In 5 eyes (4.4%), PCO was occurred. The lenses were implanted by IOL implantation forceps or their implantation kits from 3.2-3.5 mm incisions easily. The all lenses were in the bag and centralized along the follow-up period. There were no change in color and clarity of the lenses. The lenses were well-adjusted with 3% sodium hyaluronate viscoelastic solution (ENDOGEL®). Any complications or adverse reactions were not seen associated with the lenses.

Discussion

We used a single piece foldable hydrophobic acrylic intraocular lens (Zaraccom F 260) for treating cataract patients over 18 years of age. Its biocompatibility, ACO and PCO scores were better than lots of the lenses in the literature. One week after the lens implantation, the mean BCVA was increased from 0.26 ± 0.26 to 0.49 ± 0.25. The final mean BCVA was reached to 0.9 ± 0.28. The rates of ACO, lens epithelial cells on the capsule-free anterior surface and PCO were 25.4%, 5.3% and 4.4%, respectively. Its implantation was easy and it

was compatible with the 3% sodium hyaluronate. We did not see any decentralization, color or clarity change, and complications or adverse reactions.

Schauersberger et al.[7] evaluated for the first time the uveal and capsular biocompatibility of 2 foldable square-edged IOLs (CeeOn 911A silicone IOL, Pharmacia and AcrySof IOL, Alcon) of different materials 3 years after surgery. Their results showed that a sharp-edged optic design was, to date, the most effective method of reducing the rate of PCO.

Caporossi et al.[8] evaluated the intraoperative and postoperative performance of the single-piece AcrySof SA30AL IOL in a series of patients after cataract surgery and IOL implantation. They concluded the single-piece AcrySof SA30AL IOL was good biocompatible, effective, safe, stable in the capsular bag and easily manipulated.

Lane et al.[9] compared a standardized battery of biomechanical laboratory tests to assess the performance of popular foldable IOLs (Alcon AcrySof® MA60BM, MA30BA, S®LI61U; Pharmacia & Upjohn CeeOn® 920). They found that AcrySof 1-piece SA30AL and SA60AT IOLs demonstrated superior biomechanical characteristics over other foldable IOL designs.

Sacu et al.[10] assessed and compared the development of PCO as well as the clinical outcome between the 1-piece and 3-piece Acrysof IOLs. Their study showed the 1-piece Acrysof caused slightly more regeneratory PCO than the 3-piece Acrysof in one year postoperatively, and the barrier effect of the 1-piece design was comparable to that of the 3-piece haptic design, with low PCO intensity in 2 years postoperatively.

Findl et al.[11] compared the long-term development of PCO as well as the clinical outcome between two 3-piece, open-loop, sharp-edge IOLs-namely, the acrylic Acrysof IOL and the silicone 911A IOL. In their study, for hydrophobic materials, edge design seemed to play a more important role in PCO inhibition than the optic material. It remained to be shown that this also held true for hydrophilic acrylic materials.

Wren et al.[12] investigated some of the factors that influence the development of PCO in patients implanted with a polyacrylic 5.5-mm optic IOL to ascertain why some patients still develop PCO. They concluded that PCO was reduced when the rhexis was in complete contact with the anterior IOL surface. In addition, they found PCO formation was related to surgical technique as well as IOL design. Their results support the trend to the use of larger optic IOLs to prevent PCO and also support the "capsule compression" theory of PCO prevention.

Nixon and Apple[13] evaluated the pattern of LEC ingrowth behind the intraocular lens (IOL) optic in patients implanted with the AcrySof SA60AT one-piece IOL. In their study, LEC migration beyond the edge of the IOL optic was displayed by 57.5% (23/40) of patients, and LECs migrated into the visual axis in 22.5% (9/40) of patients, leading to a visual acuity of <6/9 (20/30) in 10% (4/40) of patients. Their study demonstrated the optic-haptic junction of the Acry-Sof one-piece IOL was a point of weakness in the barrier effect of the square-edge IOL design that provides migrating LECs access to the posterior capsule.

Kugelberg et al.[14] conducted the effect of hydrophilic acrylic IOL (BL27, Bausch & Lomb) and hydrophobic acrylic IOL (AcrySof SA60AT, Alcon) on PCO after cataract surgery. At 1 year, they found 18.6% and 4.65% PCO with the BL27 and AcrySof SA60AT, respectively. They concluded the IOL surface seemed to exert an important influence on PCO development.

In summary, visual outcome of Zaraccom F 260 lens is comparable with those in the literature. We did not see any adverse reactions with its implantation. We found the lens is good capsular and uveal biocompatible, safe and easily implantable. More wide, multi-center and long-term studies may show its performance better. Foldable hydrophobic acrylic intraocular lens Zaraccom F 260 can be an alternative choice for the patients with cataract requiring lens replacement.

References

1- Amon M, Menapace R, Radax U, Freyler H. In vivo study of cell reactions on poly(methyl methacrylate) intraocular lenses with different surface properties. J Cataract Refract Surg 1996; 22:825-829.

2- Ravalico G, Baccara F, Lovisato A, Tognetto D. Postoperative cellular reaction on various intraocular lens materials. Ophthalmology 1997; 104:1084-1091

3- Hollick EJ, Spalton DJ, Ursell PG, Pande MV. Biocompatibility of poly(methyl methacrylate), silicone, and AcrySof intraocular lenses: randomized comparison of the cellular reaction on the anterior lens surface. J Cataract Refract Surg 1998; 24:361-366.

4- Abela-Formanek C, Amon M, Schild G, Schauersberger J, Heinze G, Kruger A. Uveal and capsular biocompatibility of hydrophilic acrylic, hydrophobic acrylic, and silicone intraocular lenses. J Cataract Refract Surg 2002; 28:50-61.

5- Amon M. Biocompatibility of intraocular lenses. (letter) J Cataract Refract Surg 2001; 27:178-179.

6- Maldonado-Codina C, Efron N. Impact of manufacturing technology and material composition on the surface characteristics of hydrogel contact lenses. Clin Exp Optom 2005; 88:396-404.

7- Schauersberger J, Amon M, Kruger A, Abela C, Schild G, Kolodjaschna J. Comparison of the biocompatibility of 2 foldable intraocular lenses with sharp optic edges. J Cataract Refract Surg. 2001; 27:1579-85.

8- Caporossi A, Casprini F, Tosi GM, Baiocchi S. Preliminary results of cataract extraction with implantation of a single-piece AcrySof intraocular lens. J Cataract Refract Surg 2002; 28:652-5.

9- Lane SS, Burgi P, Milios GS, Orchowski MW, Vaughan M, Schwarte E. Comparison of the biomechanical behavior of foldable intraocular lenses. J Cataract Refract Surg 2004; 30:2397-402.

10- Sacu S, Findl O, Menapace R, Buehl W, Wirtitsch M. Comparison of posterior capsule opacification between the 1-piece and 3-piece Acrysof intraocular lenses. Ophthalmology 2004; 111:1840-1846.

11- Findl O, Buehl W, Menapace R, Sacu S, Georgopoulos M, Rainer G. Long-term effect of sharp optic edges of a polymethyl methacrylate intraocular lens on posterior capsule opacification: a randomized trial. Ophthalmology 2005; 112:2004-8.

12- Wren SM, Spalton DJ, Jose R, Boyce J, Heatley CJ. Factors that influence the development of posterior capsule opacification with a polyacrylic intraocular lens. Am J Ophthalmol 2005;139:691-5.

13- Nixon DR, Apple DJ. Evaluation of lens epithelial cell migration in vivo at the haptic-optic junction of a one-piece hydrophobic acrylic intraocular lens. Am J Ophthalmol 2006; 142:557-62.

14- Kugelberg M, Wejde G, Jayaram H, Zetterstrom C. Posterior capsule opacification after implantation of a hydrophilic or a hydrophobic acrylic intraocular lens: one-year follow-up. J Cataract Refract Surg 2006;32:1627-31.

Figure 1. (Toker) The single-piece foldable hydrophobic acrylic intraocular lens Zaraccom F260.

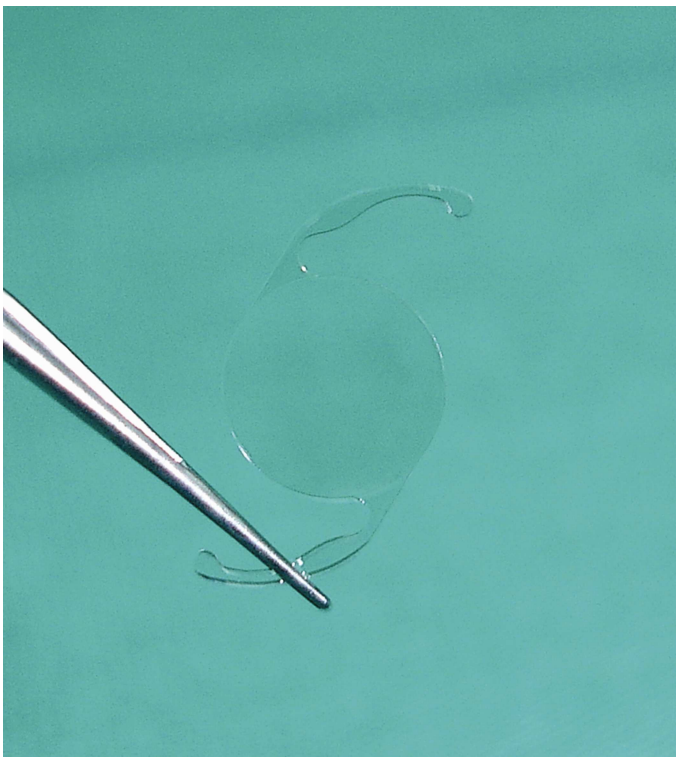

Figure 2. (Toker) The optic edge of the Zaraccom F260 lens blocked LECs ingrowth to behind the lens optic.

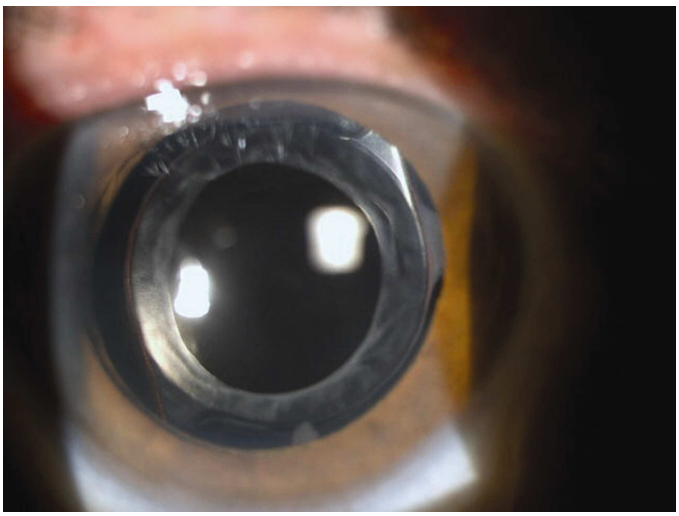

Figure 3. (Toker) Slitlamp retroillumination photograph of a Zaraccom F260 lens 1 year after implantation. No PCO appeared behind the lens optic.