

ThinOptX vs AcrySof: Comparison of visual and refractive results, contrast sensitivity, and the incidence of posterior capsule opacification

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PURPOSE. To evaluate the visual and refractive results, the changes in contrast sensitivity, and the incidence of posterior capsule opacification (PCO) after the implantation of UltraChoice 1.0 ThinOptX (ThinOptX Inc.) intraocular lens (IOL) and conventional acrylic foldable IOL (AcrySof MA30AC).

METHODS. Twenty-five patients were randomized into two groups prospectively. In Group 1, microincisional phacoemulsification and the ThinOptX IOL implantation were applied in one eye, and in Group 2, conventional phacoemulsification and the AcrySof IOL implantation were applied in the fellow eye. Uncorrected visual acuity (UCVA) and best-corrected visual acuity (BCVA), surgically induced astigmatism (SIA), contrast sensitivity, and the incidence of PCO were observed in the two groups and comparisons were made.

RESULTS. Mean follow-up period was 12.8 ± 1.5 months (range 11 to 14 months). In the last follow-up examination, UCVA and BCVA were significantly lower and the PCO scores were significantly higher in Group 1 ($p < 0.05$). Although SIA was lower in Group 1, the difference was not statistically significant. Contrast sensitivity in higher spatial frequencies was significantly lower in Group 1 in the 6th month and 12th month visits. Capsular contraction was seen in 3 eyes (12%) in Group 1 whereas there was no capsular contraction or phimosis in Group 2.

CONCLUSIONS. Long-term evaluation of the ThinOptX IOL concludes with an increased rate of PCO, a diminished resistance to the capsular contraction vs the AcrySof IOL, and a decrease in visual performance. The poor after cataract performance of this rollable lens shows that microphacoemulsification and ThinOptX IOL implantation is not as effective as conventional phacoemulsification and AcrySof IOL implantation in the long term. (*Eur J Ophthalmol* 2007; 17: 307-14)

KEY WORDS. Capsular phimosis, Contrast sensitivity, Microincisional cataract surgery, PCO, ThinOptX

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INTRODUCTION

Inserting intraocular lenses (IOL) through smaller corneal incisions has been an ongoing goal for surgeons performing anterior segment procedures. Smaller incisions would mean greater anterior chamber stability, less surgically induced astigmatism, and reduced time loss in healing and the risk of wound leakage and/or endophthalmitis (1, 2). Phacoemulsification and in the bag foldable IOL implanta-

tion through a clear corneal incision is the preferred method for cataract surgery (3). Different types of materials and shapes exist for IOLs with different specifications. A rollable hydrophilic IOL, UltraChoice 1.0 Rollable ThinOptX (ThinOptX Inc.), with a flexible plate haptic design, enables insertion through incisions smaller than 2 mm and phacoemulsification can be performed through an ultra-small incision with the sleeveless ultrasound tip (4-7).

In this study, we evaluated the visual and refractive results, the changes in contrast sensitivity, and the incidence of posterior capsule opacification (PCO) after the implantation of UltraChoice 1.0 Rollable ThinOptX and conventional hydrophobic acrylic foldable IOL (AcrySof MA30AC, Alcon Laboratories) in fellow eyes.

PATIENTS AND METHODS

Twenty-five patients (15 male, 10 female) who had a diagnosis of senile cataract in both eyes were prospectively enrolled in this study. Patients were randomized by using random number table first for right or left eye and then for the type of surgery: microincisional phacoemulsification and ThinOptX IOL implantation in one eye (Group 1) and conventional phacoemulsification and AcrySof IOL implantation in the fellow eye (Group 2). Patients with past or present ocular diseases were not included in the study. Before enrollment, each patient received a detailed description about the aim of the study and after a complete discussion of the predictable risks and benefits, all the patients signed a written informed consent. Mean follow-up period was 12.8 ± 1.5 months (range 11 to 14 months). Preoperative patient characteristics were as follows: mean age was 67.1 ± 7.1 years. There was no significant difference in cataract grading between the two groups. Mean keratometric reading was 43.23 ± 1.81 diopters in Group 1 and 43.74 ± 1.62 diopters ($p=0.32$) in Group 2. Mean intraocular pressures were found to be 15.1 ± 2.4 and 15.7 ± 2.1 mmHg, respectively, in Group 1 and Group 2 ($p=0.3$).

A thorough ophthalmic examination was performed prior to surgery. Uncorrected visual acuity (UCVA) and best-corrected visual acuity (BCVA) were measured according to the Snellen chart. Keratometric power was measured with Javal keratometry and corneal topography was evaluated with the EyeSys corneal topography instrument (EyeSys Technologies Inc., Houston, TX). The power of the IOL was calculated using Axis II (Quantel Medical, Bozeman, MT) and emmetropia was aimed.

Surgical technique

Group 1 (ThinOptX). Under topical anesthesia with proparacaine 0.5% a 1.5 mm clear corneal stab incision was performed in the upper temporal quadrant using a 15° knife. Anterior chamber was filled with Viscoat® (Alcon

Laboratories, Inc.). A second stab incision was performed in the upper nasal quadrant. Five mm continuous curvilinear capsulorhexis was completed using a special capsulorhexis forceps (art.116004, Optikon 2000, Rome) and hydrodissection was done. Bimanual microincisional phacoemulsification was performed using sleeveless ultrasound tip (30°, art.113209, Optikon 2000), irrigating chopper (art.114304, Optikon 2000), and Pulsar MS (Optikon 2000) phacoemulsification device was used in the first seven eyes and Sovereign® Whitestar™ (AMO, Inc., Santa Ana, CA) phacoemulsification device was used in the rest of the eyes (19 eyes). Following bimanual irrigation and aspiration, the upper temporal incision was enlarged to 2 mm. In the first five cases the IOL was removed from the container and placed in a bowl of balanced salt solution (BSS) that was approximately at body temperature. This was done to ensure the IOL was pliable and to facilitate the rolling process. Then it was held between the index finger and the thumb and rolled in a rubbing motion. It was then carefully inserted through the sub-1.4 mm incision. The tip of the haptic should have had a pointed shape to allow the lens to penetrate the clear corneal incision. The lens was carefully implanted in the capsular bag after the application of viscoelastic solution (Viscoat®). To ensure proper placement of the lens, the teardrop on the haptic should have pointed in a clockwise direction. The natural heat of the eye enabled the lens to open gradually. Viscoelastic solution (Viscoat®) was then removed from the capsular bag and the anterior chamber by using bimanual irrigation-aspiration probes and the incisions were hydrated. In the rest of the cases (20 eyes) the lens was implanted using an injection system. ThinOptX IOL was placed on the plastic plate between the two lines and then it was inserted into the injector. The tip of the injector was adapted to the corneal incision without inserting it into the eye. With the help of a piston the lens was implanted into the capsular bag and positioned with a Sinskey forceps. Viscoelastic solution (Viscoat®) was then removed by bimanual irrigation-aspiration and the incisions were hydrated.

Group 2 (AcrySof MA30AC). Two stab incisions were performed in the upper nasal and lower temporal quadrants for the right eyes and in the upper and lower temporal quadrants for the left eyes. A 3 mm diamond keratome was used to make the temporal clear corneal single planed incision. Anterior chamber was filled with the viscoelastic solution (Viscoat®) and a 5 mm capsulorhexis

was performed using an Ultrata forceps. Following hydrodissection, phacoemulsification was performed by Optikon 2000 phacoemulsification device using 30° microphaco tip in the first five eyes and Sovereign® Whitestar™ phacoemulsification device in the rest of the cases (20 eyes). After the phacoemulsification with stop and chop technique, the residual cortical fragments were removed by bimanual irrigation and aspiration. The incision was enlarged to 3.5 mm and AcrySof IOL was implanted after folding it in its folder. Two experienced surgeons performed all the operations in both groups.

Postoperative examinations were scheduled as follows: postoperative first day, first week, first month (3–5 weeks), third month (11–15 weeks), sixth month (24–28 weeks), and first year (47–56 weeks). Surgically induced astigmatism (SIA) was evaluated with vector analysis method. UCVA, BCVA, and keratometry readings were recorded. Biomicroscopic examination was done and intraocular pressure was measured by Goldmann applanation tonometer. Contrast sensitivity was measured by using F.A.C.T. 101 test (Stereo Optical Co., Chicago, IL) developed by Dr. Arthur Ginsburg. F.A.C.T. sine-wave grating chart tested five spatial frequencies (sizes) and nine levels of contrast. The patients determined the last grating seen for each row (A, B, C, D, and E) and reported the orientation of the grating: right, up, or left. The final correct grating seen for each spatial frequency was plotted on a contrast sensitivity curve. During the study, the hand-held near test model of the F.A.C.T. chart with

a card and a holder were held at a distance of approximately 40 cm from the patient. All the patients were examined in the same room under the same illumination conditions (68–240 cd/m²) following the assessment of the best spectacle correction for the target distance of 40 cm. At the end of the study, the mean values for each spatial frequency were calculated and the comparisons were made between the study groups. PCO was evaluated as described by Tetz et al (8). Anterior segment photographs were taken using a Nikon Coolpix 5000 camera and Pentacam Scheimpflug Imaging System. Intraoperative and postoperative complications were recorded.

Visual and refractive results were compared using Student *t*-test. Contrast sensitivity results and PCO scores were evaluated by Wilcoxon test. A *p* value less than 0.05 was considered statistically significant. All statistical analyses were done using SPSS software version 11.0 for PC (SPSS Inc., Chicago, IL).

RESULTS

There were significant differences in UCVA and BCVA between the two groups in the last follow-up examination (Tabs. I and II). The mean UCVA was found to be 0.56±0.24 in Group 1 and 0.71±0.23 in Group 2 (*p*=0.012). BCVA was found to be 0.73±0.32 in Group 1 and 0.91±0.14 in Group 2 (*p*=0.008).

TABLE I - POSTOPERATIVE UNCORRECTED VISUAL ACUITY (UCVA) IN SNELLEN LINES

UCVA	Group 1 (ThinOptX)	Group 2 (AcrySof)	<i>p</i> value
Postop first day	0.61±0.26	0.63±0.21	0.65
Postop first week	0.66±0.26	0.74±0.15	0.13
Postop first month	0.72±0.26	0.67±0.25	0.52
Postop third month	0.63±0.23	0.75±0.21	0.11
Postop sixth month	0.67±0.22	0.79±0.19	0.12
Postop first year	0.56±0.24	0.71±0.23	0.012

TABLE II - POSTOPERATIVE BEST-CORRECTED VISUAL ACUITY (BCVA) IN SNELLEN LINES

BCVA	Group 1 (ThinOptX)	Group 2 (AcrySof)	<i>p</i> value
Postop first day	0.74±0.26	0.74±0.21	0.99
Postop first week	0.84±0.16	0.9±0.13	0.39
Postop first month	0.90±0.17	0.87±0.19	0.54
Postop third month	0.94±0.09	0.91±0.14	0.63
Postop sixth month	0.84±0.15	0.87±0.15	0.50
Postop first year	0.73 ±0.32	0.91±0.14	0.008

TABLE III - SURGICALLY INDUCED ASTIGMATISM (SIA) IN DIOPTERS

SIA	Group 1 (ThinOptX)	Group 2 (AcrySof)	p value
Postop first day	0.65±0.31	0.72±0.09	0.78
Postop first week	0.67±0.35	0.75±0.17	0.62
Postop first month	0.66±0.30	0.77±0.15	0.88
Postop third month	0.54±0.28	0.56±0.29	0.72
Postop sixth month	0.44±0.36	0.49±0.03	0.58
Postop first year	0.46 ±0.28	0.50±0.18	0.54

TABLE IV - POSTERIOR CAPSULE OPACIFICATION (PCO) RESULTS

PCO	Group 1 (ThinOptX)	Group 2 (AcrySof)	p value
Postop third month	0.08±0.02	0.06±0.01	0.73
Postop sixth month	0.14±0.01	0.09±0.03	0.08
Postop first year	0.68 ±0.20	0.12±0.08	0.002

The postoperative induced astigmatism was found to be less in Group 1 throughout the follow-up, although the difference was not statistically significant ($p>0.05$) (Tab. III). PCO incidence was significantly higher in Group 1 in the 12th month examination and Nd:YAG laser capsulotomy was applied to two of them in the 8th and 14th months, respectively (Tab. IV). In Group 2, none of the patients required Nd:YAG laser capsulotomy. PCO was observed in only 1 eye (4%) and Nd:YAG laser capsulotomy was not necessary.

In the early postoperative examinations there was no significant difference between the contrast sensitivity scores of Group 1 and Group 2. However, contrast sensitivity in Group 1 was found to be significantly lower in higher spatial frequencies in the sixth and 12th months when compared to Group 2.

Complications

Capsular contraction was found in 3 eyes (12%) in Group 1 and one IOL (4%) was exchanged with a three-piece hydrophobic IOL because of the decentration and tilt of the IOL due to the capsular phimosis in the third month. No capsular contraction or phimosis was found in Group 2. Posterior capsule perforation was noted during microincisional phacoemulsification in one eye and this patient was excluded from the study. In one patient a macular hole in one eye and an epiretinal membrane in the fellow eye were established in the third month and this

patient was excluded from the study. In two eyes the ThinOptX IOLs were torn by the injector system during the insertion in the bag. These lenses were exchanged with the AcrySof IOLs in the same session and these patients were excluded from the study.

DISCUSSION

Phacoemulsification through an ultrasmall incision is a major development in cataract surgery and several authors reported successful results without significant complications (3-7, 9). Conventional phacoemulsification and foldable IOL implantation are performed through 3.0 mm corneal incisions. Ultrasmall sleeveless phacoemulsification allows us to emulsify the cataract through a 1.5 mm corneal incision which is enlarged to 2.0 mm to implant the rollable ThinOptX IOL. Dogru et al reported no significant differences in mean UCVA or BCVA between ThinOptX IOL and AcrySof IOL implanted eyes (7). However, in our study, both UCVA and BCVA were significantly lower in the ThinOptX IOL implanted eyes (Group 1). We also assessed postoperative induced astigmatism between the two groups and the SIA was found to be less in Group 1, although the difference was not statistically significant ($p>0.05$). According to Dogru et al, the mean induced astigmatisms at the last postoperative visit were $0.06 D \pm 0.50$ in the ThinOptX group and $0.25 D \pm 0.68$ in the AcrySof group. The difference was not statistically

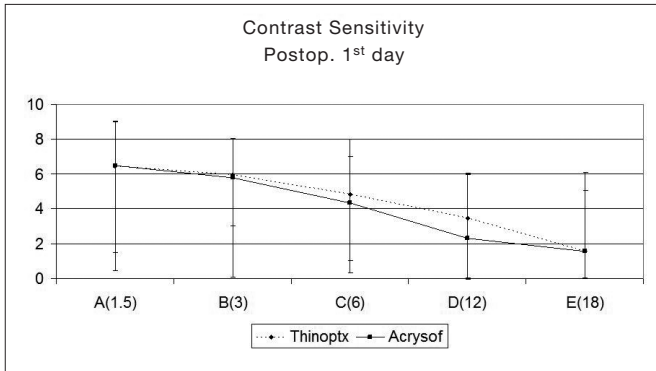


Fig. 1 - Contrast sensitivity scores, postoperative first day.

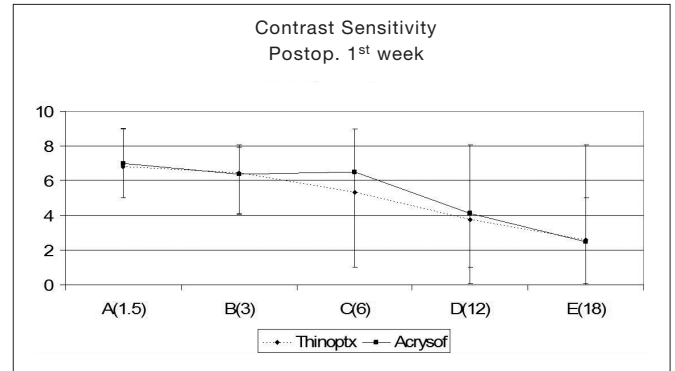


Fig. 2 - Contrast sensitivity scores, postoperative first week.

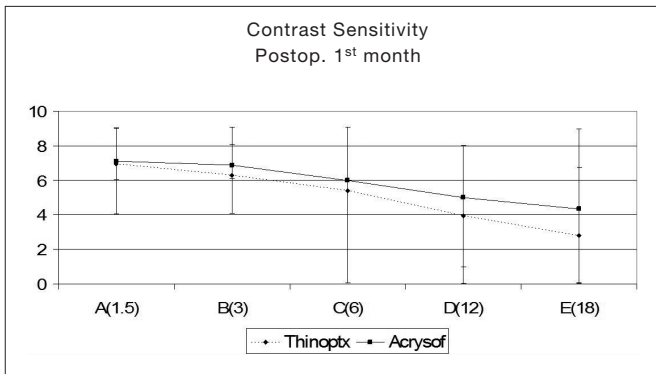


Fig. 3 - Contrast sensitivity scores, postoperative first month.

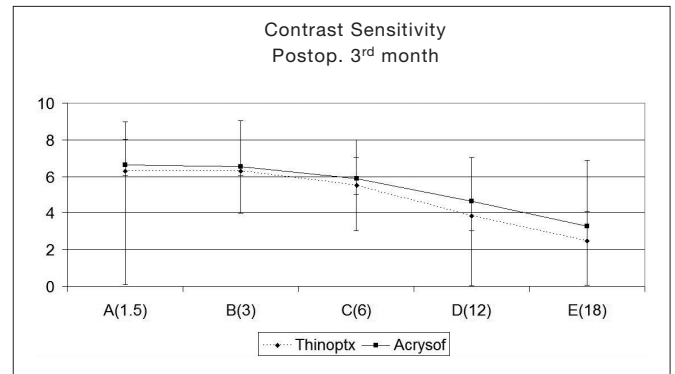


Fig. 4 - Contrast sensitivity scores, postoperative third month.

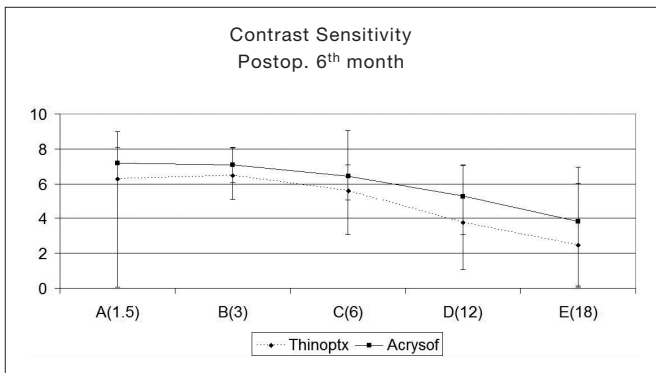


Fig. 5 - Contrast sensitivity scores, postoperative sixth month.

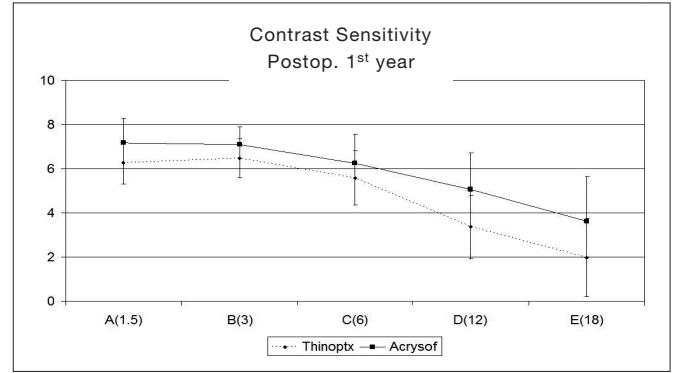


Fig. 6 - Contrast sensitivity scores, postoperative first year.

significant. The clear corneal microincision appears to have a minimal effect on corneal architecture, thus resulting in minimal astigmatic change. However, the authors also showed that the induced astigmatism did not vary between the two groups significantly. The contrast sensitivity between the two groups showed

no significant difference in the early postoperative period (Figs. 1–4). However, beginning from the sixth month, significantly lower contrast sensitivities in higher spatial frequencies (D, E) were observed in the ThinOptX IOL implanted eyes ($p=0.03$) (Figs. 5, 6). Diminished visual acuity and contrast sensitivity due to PCO have been reported in

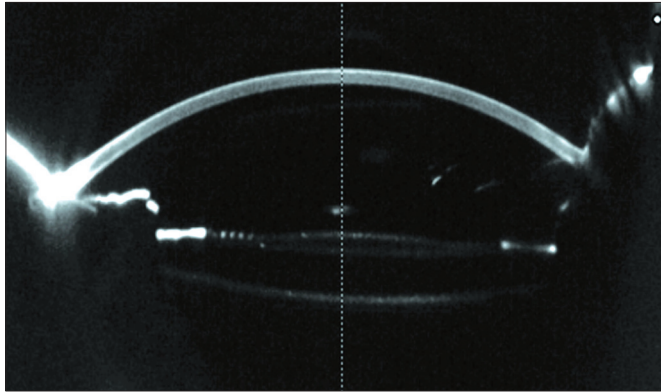


Fig. 7 - ThinOptX intraocular lens presenting no contact pressure on the posterior capsule (image by Pentacam Scheimpflug Imaging System).

the literature (22-24). In the last follow-up, the decrease in the contrast sensitivity was more significant. We assume that the diminished contrast sensitivity in Group 1 may be due to the increased light scattering because of PCO. PCO is the most common complication of cataract surgery despite the advances in surgical techniques and IOL design (10). Several factors contribute to PCO formation. Some of them are associated with surgical techniques such as sufficient aspiration of the cortical remnants or the capsulorhexis overlapping the optic of the IOL (11-14). The square edge design of the optic and the hydrophobic acrylic material are some other factors in PCO prevention related to the design and the material of the IOL (15-20). Plate haptic design and very thin, rollable structure of the ThinOptX IOL probably prevented the closure of the capsular bag and the formation of capsular bend. Nagamoto and coauthors demonstrated that the pressure on the posterior capsule which is maintained by the lens optic was effective in the prevention of PCO (21). The plate haptic design and the thin material of the ThinOptX IOL appeared not to have this contact pressure (Fig. 7).

Capsular fusion which results in capsular bending was disturbed at the haptic optic junction because of the plate haptic design of the ThinOptX IOL. In Group 1, it was an attention pointer that PCO started from the region where the haptics settled (Fig. 8). There was no statistically significant difference in PCO rates between the two groups in the 3th and 6th months. However, in the 12th month examinations, we observed significantly more PCO in Group 1 when compared to Group 2 ($p=0.002$). In addition to the increased PCO incidence in Group 1, three eyes in this

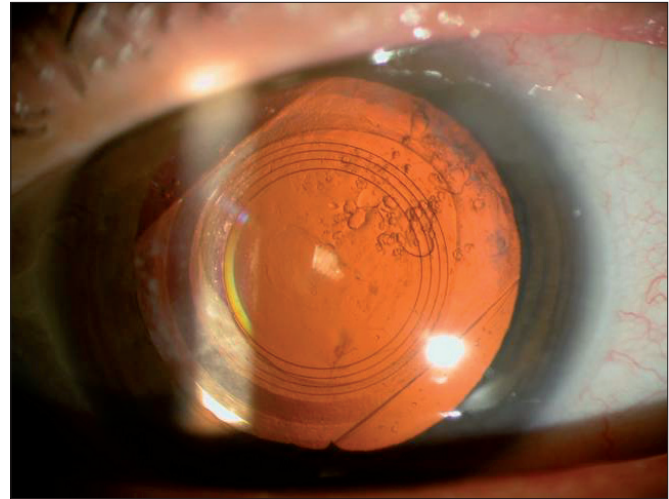


Fig. 8 - Posterior capsule opacification starting from the haptic region of ThinOptX intraocular lens.

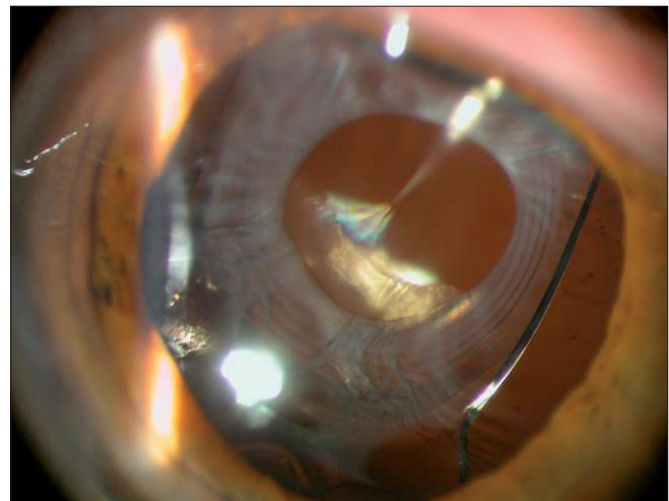


Fig. 9 - Capsular contraction in a ThinOptX intraocular lens implanted eye.

group developed excessive fibrosis prominent in the border of the capsulorhexis resulting in narrowing of the capsulorhexis space (rhexis phimosis). In one of these eyes excessive and asymmetric shrinkage of the capsule resulted in IOL decentration in spite of the centralized rhexis. In this patient the ThinOptX IOL was exchanged with a three-piece hydrophobic IOL in the postoperative third month (Fig. 9). In Group 2, there occurred no severe fibrosis in the border of the capsulorhexis.

Dislocation of the plate haptic IOLs into the vitreous after Nd:YAG laser treatment of PCO has been published (25-

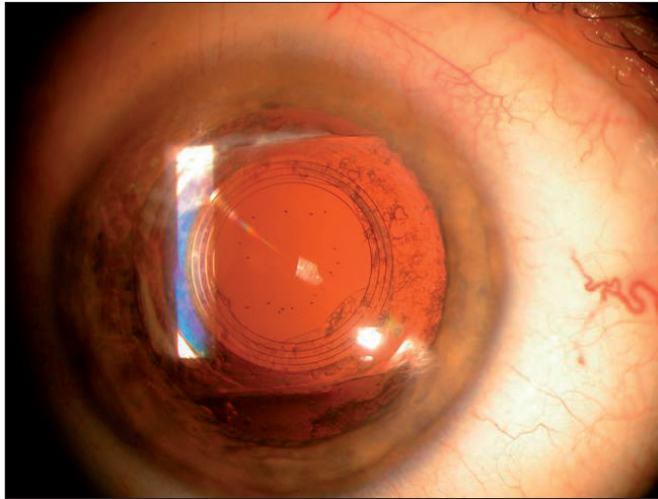


Fig. 10 - Nd:YAG laser spot damage on the surface of ThinOptX intraocular lens.

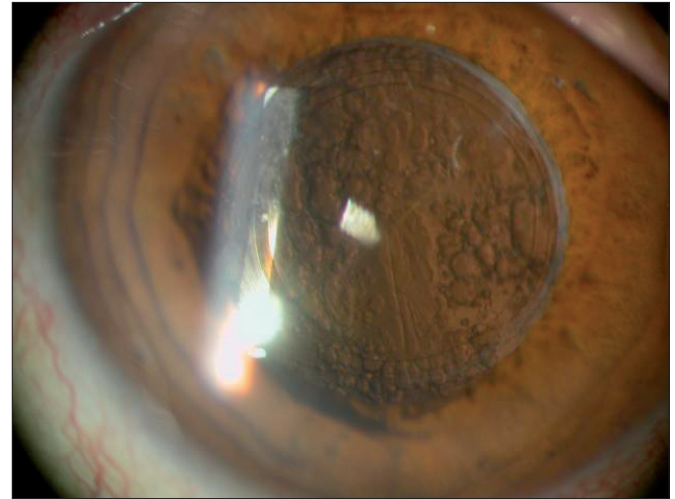


Fig. 11 - Severe posterior capsule opacification in a ThinOptX intraocular lens implanted eye.

27). In our series we did not observe any dislocation of the IOL after Nd:YAG laser capsulotomy in Group 1. However, the IOL surface was slightly damaged by the laser spots in one eye (Fig. 10).

In conclusion, the PCO incidence in the ThinOptX IOL implanted eyes was higher beginning from the third month. The difference increased in the sixth month and there was a significant difference in the last follow-up ($p=0.002$). Early PCO formation and high Nd:Yag laser capsulotomy incidence (8%) pointed out that the after cataract performance of these lenses was extremely low (Fig. 11). Not only the PCO incidence but also the incidence of contraction of capsulorhexis opening (rhexis phymosis) due to severe fibrosis of the anterior capsule was high.

These rollable IOLs, which were inserted through 2 mm

incisions, could not provide better results according to the surgically induced astigmatism when compared with the conventional acrylic foldable IOLs, which were inserted through 2.5 mm incisions. Also, they had an increased rate of PCO and diminished resistance to the capsular contraction than the AcrySof MA30AC IOL.

No author has a financial or proprietary interest in any material or method mentioned.

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