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Assessment of Aqualens (AH612AL) Intraocular Lens

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Abstract

Background: Cataract is the leading reason for blindness in all years old groups in North Africa and Middle East. Cataract was the leading reason for reversible blindness worldwide between 1990 and 2010, accounting for nearly half of all cases. The most common cataract surgery method is phacoemulsification with Intra Ocular Lens (IOL).

Aim: To assess commercially available, locally manufactured intraocular lenses Aqualens (anti hydro 612 lens, AH612AL) regarding quality, clinical biocompatibility, and complications.

Studied cases and techniques: This prospective, interventional research involved thirty eyes with senile cataracts. Patients were collected from the Ophthalmology Department, Faculty of Medicine, Al-Azhar University at a time from March 2021 to March 2022.

Results: This study included 30 eyes with senile cataracts operated by phaco-emulsification and implantation of IOL (Aqualens, AH612AL). There were 11 (36.7%) males and 19 (63.3%) females. The operated eyes were 16 (53.3%) right eye (OD) and 14 (46.7%) eyes were left (OS). The present research finds that there was no variation found among 48 h and 1 week and also 1 month regarding PCO grading with P value = 1.000 and 0.075; while there was a rise in the PCO grading at 3 and 6 months than 48 h postoperative with $P = 0.009$ and less than 0.001.a.

Conclusion: This research demonstrated that the optical quality of Aqualens, AH612AL IOL has satisfactory results and significant improvement in regard to the incidence of PCO formation, flare reaction, cell deposits, cystoid macular edema, aberrations, stability, and visual acuity.

Keywords: AH612AL, Food and drug administrations, IOLs, Premarket approval, Pseudoexfoliation

1. Introduction

In North Africa and the Middle East, cataract is the leading reason for blindness in all years old groups.¹ Cataract was the leading reason for reversible blindness worldwide between 1990 and 2010, accounting for nearly half of all cases.²

According to the Food and Drug Administration (FDA), Intra Ocular Lens (IOLs) are considered medical devices. FDA classifies all IOLs as Class 3 medical devices that require premarket approval (PMA).³

Biocompatibility is the ability of a prosthesis implanted in the body to exist in harmony with tissue without causing adverse conditions or reactions.⁴

A new concept IOL based on extended depth of focus technology was recently introduced basic idea

behind EDOF IOLs is to create a single elongated focal point in order to improve depth of focus or range of vision. EDOF IOLs have advantages for intermediate and near vision when compared with mono-focal IOLs.⁵

The aim of the work is to assess commercially available, locally manufactured intraocular lenses Aqualens (anti hydro 612 lens, AH612AL) regarding quality, clinical biocompatibility, and complications.

2. Studied cases and techniques

This prospective, interventional research involved thirty eyes with senile cataracts. Patients were collected from the Ophthalmology Department, Faculty of Medicine, Al-Azhar University at a time from March 2021 to March 2022.

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2.1. Study design

- (1) Type of the study: This is interventional Prospective study in which cataract surgery was done by same expert surgeon, using same phacoemulsification machine, method, materials and the same postoperative treatment regimen.
- (2) Subjects and Sample size: 30 cataractous eyes were operated. Patients were matching our inclusion criteria.

2.2. Inclusion criteria

Age between 50 and 70 years, Senile cataract, Nondiabetic, Significant cataract with best corrected visual acuity (BCVA) of less than 6/12 (0.5 decimal equivalent), Normal intraocular pressure and Pre-operative astigmatism less than 1.5 diopter.

2.3. Exclusion criteria

Complicated cataract, Traumatic cataract, Eyes with uveitis, Glaucomatous patients, History of previous ocular operations or other ocular pathologies, History of autoimmune diseases and Patients who refuse to participate in the study.

2.4. Ethical considerations

The study was conducted after approval of the protocol by Al-Azhar medical research Ethical committee. An informed written consent was obtained from all patients that contain the following; the aim, procedures and duration of the study explained in a simple way. The patients have the right to refuse participation without affecting the medical care expected to be offered to the patient. The patients have the right to withdraw from the study at any time without any penalty and without giving reasons. Confidentiality of data and results of all study population was preserved by ensuring anonymity of data and minimal access to data by research team only. The procedure was performed by one qualified experienced ophthalmic surgeon.

3. Methodology

Complete assessment was done for each patient.

3.1. Operative technique

Cataract surgeries were performed under local anesthesia with sedation.

3.2. Implantation of the IOL

Implantation was done using hydroimplantation. Characteristics of Aqualens (AH612AL) [MOH registration number: 30/2021/1].

3.3. Postoperative management

Medications: For 4 weeks, studied cases were given antibiotic (Gatifloxacin 0.3%) and steroid eye drops (Prednisolone acetate 1%).

Follow up intervals: Within 48 h, After 1 week, After 1 month, After 3, and After 6 months.

3.3.1. Postoperative evaluation

Studied cases were followed-up on to determine their BCVA. Reactions: including Inflammation/ infection. Optical aberrations using aberrometer (ZY wave, Bausch and LOMB, USA) (1 month postoperative). The postoperative total spherical aberration was measured using the same parameters used for preoperative evaluation. OCT Measurement of central macular thickness (Topcon DRI-OCT, Topcon, Japan), one month postoperatively (1 month postoperative). Posterior capsular opacification (PCO): severity was determined according to the grading described by Shakeel and Gupta⁶ (Table 1):

3.3.2. Stability

Was evaluated according to technique defined by Weinand and colleagues, Patients had slit-lamp photography in the immediate postoperative period and 1 month postoperatively (after mydriasis), photographs were assessed using image-editing features of Adobe Photoshop software. Two lines were drawn on the photo (Figs. 1–3): A horizontal reference axis was determined using two points that were clearly identifiable outside the limbus in both photos. Another line is drawn perpendicular to the base of lower IOL haptic towards base of other haptic, bisecting the IOL longitudinally. The angle between both lines was measured.

Table 1. PCO classification.⁶

Grade	Severity	Posterior capsular opacification
Zero	None	No evidence of Posterior capsular opacification
One	Trace	Few distinct epithelial pearls
Two	Mild	Several distinct epithelial pearls
Three	Moderate	Several epithelial pearls that have coalesced
Four	Severe	Thick epithelial pearl sheet

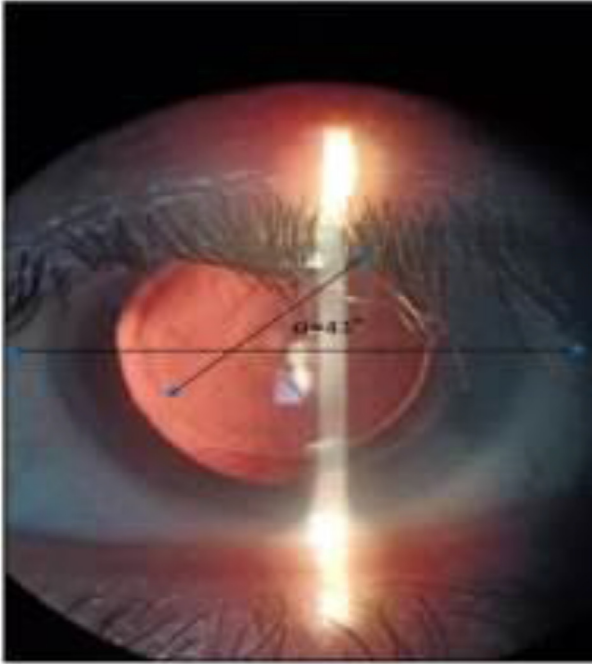


Fig. 1. The angle (θ) measures 43° immediately after Implantation.

3.4. Statistical data analysis

The phase of analysis of data: statistical package SPSS version 25 was used to analyze data. Kolmogorov-Smirnov test was used to define whether variables had normal distribution.

4. Results

This study included 30 eyes with senile cataract operated by phaco-emulsification and implantation

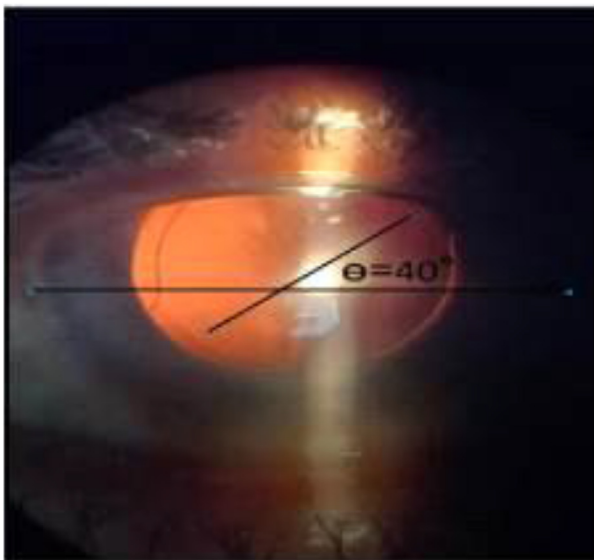


Fig. 2. The angle (θ) measures 40° 1 month after implantation.

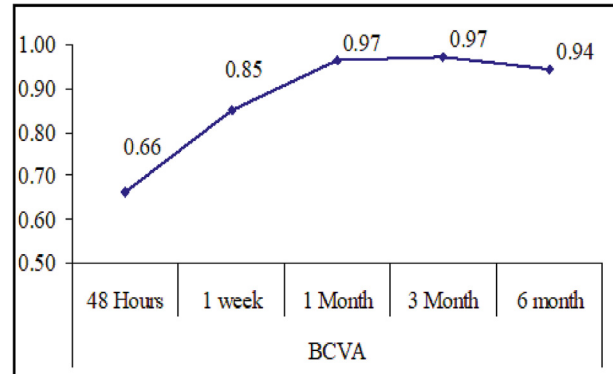


Fig. 3. Results for best corrected visual acuity at different interval.

of IOL (Aqualens, AH612AL). They were 11 (36.7%) males and 19 (63.3%) females, aged 58–70 years. The operated eyes were 16 (53.3%) right eye (OD) and 14 (46.7%) eyes were left (OS) (Table 2, Figs. 4 and 5).

Mean BCVA enhanced from 0.29 ± 0.09 preoperatively to 0.94 ± 0.08 postoperatively. Mean BCVA showed a statistically significant increase at 1 week, 1 month, 3, and 6 months than 48 h postoperative with P value less than 0.001, less than 0.001, less than 0.001, and less than 0.001 (Table 3, Fig. 3).

Percentage of patients with flare reaction significantly decreased at intervals 1 week, 1 month, 3, and 6 months than 48 h postoperative with P value = 0.020, 0.020, 0.020, and 0.020 (Table 4, Fig. 4).

Flare was of moderate intensity with clear iris and IOL details (grade: +1, +2).

Two patients presented with cells in anterior chamber (AC) at the first follow-up at 48 h (grade +1). Cells disappeared at 1 week and no cells were detected in the anterior chamber on further follow-up intervals. Results for cell in the AC were statistically insignificant (P value = 0.129), (Table 5, Fig. 5).

Spherical aberrations showed a statistically significant increase at 1 month postoperative (0.06 ± 0.09) than at preoperative (-0.49 ± 0.18) with a mean difference of 0.55 ± 0.20 and with P value less than 0.001 (Table 6, Fig. 6).

Table 2. Demographic data of cases.

	Number = thirty
Years old	
Range	58–70
Mean \pm SD	63.73 ± 3.7
Sex	
Female	19 (63.3%)
Male	11 (36.7%)
Eye	
OD	16 (53.3%)
OS	14 (46.7%)

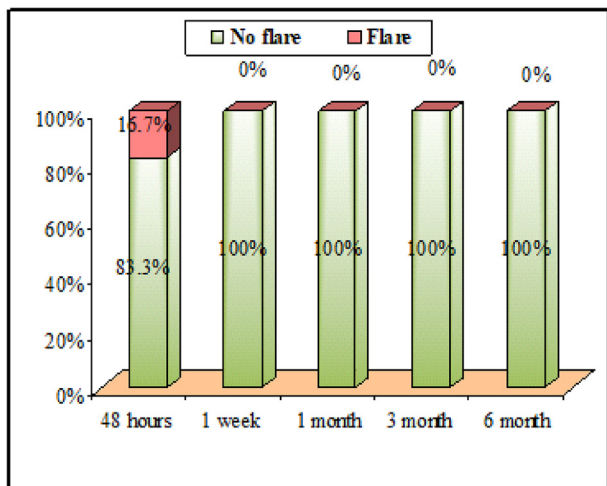


Fig. 4. Results for flare at different follow-up intervals.

5. Discussion

Several novel intraocular lens models have been advanced in recent years for therapy of cataract studied cases Son and colleagues.⁷

This thesis aims to review the possible advantages and disadvantages of using implanted Aqualens, AH612AL intraocular lenses.

Our study included only cases with visually significant cataract (BCVA <0.5), results showed that mean BCVA significantly increased postoperatively. Furthermore, BCVA progressively increased at 1 week, 1 month, 3, and 6 months than 48 h post-operative with *P*-value less than 0.001, less than 0.001, less than 0.001, and less than 0.001.

Table 3. Results for best corrected visual acuity at different intervals.

BCVA	Number = 30	Difference	<i>t</i> -test	<i>P</i> value
Preoperative				
Mean ± SD	0.29 ± 0.09	—	—	—
Range	0.1–0.33			
48 Hours				
Mean ± SD	0.66 ± 0.08	—	—	—
Range	0.5–0.8			
One week				
Mean ± SD	0.85 ± 0.11	0.19 ± 0.10	10.143	<0.001 (HS)
Range	0.6 – one			
1 Month				
Mean ± SD	0.97 ± 0.07	0.30 ± 0.07	23.127	<0.001 (HS)
Range	0.8 – one			
3 Months				
Mean ± SD	0.97 ± 0.06	0.31 ± 0.05	31.000	<0.001 (HS)
Range	0.8 – one			
6 Months				
Mean ± SD	0.94 ± 0.08	0.28 ± 0.08	20.149	<0.001 (HS)
Range	0.7 – one			
Repeated	139.115			
Measure test				
<i>P</i> value	<0.001 (HS)			

BCVA, best corrected visual acuity, HS, highly significant.

Nanavaty and colleagues⁸ at three to nine months, both unocular UCVA (*P* < 0.02) and binocular UCVA (*P* < 0.01) improved with TECNIS IOL. Both unocular and binocular defocus curves were wider at 3–9 months with TECNIS IOL among –0.50 and –3.00 diopters. Stifter and colleagues,⁹ reported no differences in best-corrected visual acuity before and after uneventful phacoemulsification surgery with hydrophilic IOL implantation.

Postoperative inflammation is one of the essential parameters for an IOL material evaluation. Titiyal and colleagues¹⁰ studied 72 eyes of

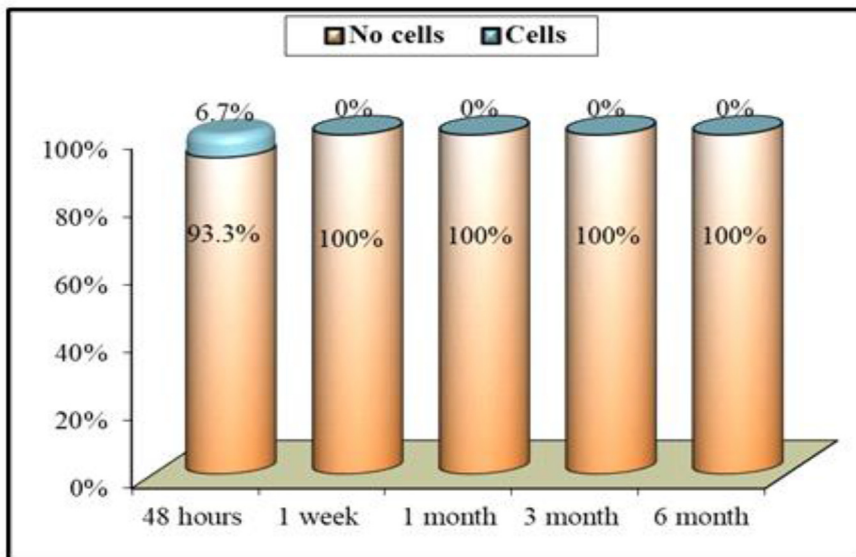


Fig. 5. Results for cells in the anterior chamber at different follow up intervals.

Table 4. Results for flare at different follow-up intervals.

	No flare	Flare	2	P-value	Sig.
48 h	25 (83.3%)	5 (16.7%)	–	–	–
1 week	30 (100.0%)	0	5.455	0.020	S
1 month	30 (100.0%)	0	5.455	0.020	S
3 months	30 (100.0%)	0	5.455	0.020	S
6 months	30 (100.0%)	0	5.455	0.020	S

P greater than 0.05: Non-significant; P less than 0.05: Significant; P less than 0.01: Greatly significant, 2: χ^2 test.

Table 5. Results for cells in the anterior chamber at different follow-up intervals.

	No cells	Cells	2	P value	Significance
48 h	28 (93.3%)	2 (6.7%)	–	–	–
1 Week	30 (100.0%)	0	2.303*	0.129	NS
1 Month	30 (100.0%)	0	2.303*	0.129	NS
3 Months	30 (100.0%)	0	2.303*	0.129	NS
6 Months	30 (100.0%)	0	2.303*	0.129	NS

P greater than 0.05: Nonsignificant; P less than 0.05: Significant; P less than 0.01: Greatly significant; 2: χ^2 test.

phacoemulsification with hydrophilic IOL (Vivonex XY1), and found that at 1 year, anterior chamber flare was 5.5 ± 0.9 Photons/milliseconds (ph/ms) and 2.2 ± 1.2 ph/ms. Magnitude of cellular reaction is also impacted by IOL material, inflammatory response throughout surgery, existence of preexisting inflammation, and postoperative treatment, according to researchers.

IGCDs with modern hydrophobic IOLs have been noted infrequently Samuelson and colleagues.¹¹

Jia and Li¹² it was discovered that customizing the selection of aspheric IOL implants enhanced mesopic contrast sensitivities at great spatial frequencies. Another study found that after cataract surgery, implantation of aspheric aberration-correcting monofocal IOL occurred in very low residual HOA and normal straylight Kretz and colleagues.¹³

Research by Savini and colleagues¹⁴ indicated interactive relationship among defocus and HOAs studied cases with both myopia and cataract benefit from positive spherical aberration, while studied cases with both hyperopia and cataract benefit from negative spherical aberration.

Gharaee and colleagues¹⁵ compared depth of focus after implantation of TECNIS and Akreos AO IOLs and discovered that specific residual spherical aberration can rise depth of focus after surgery.

Song and colleagues¹⁶ concluded that ocular vertical coma may be major HOA related to better near visual acuity in cases of aspheric IOL implantation. Even though corneal aberrations are major determinants of postcataract surgery ocular aberrations, internal optics aberrations can play important role in visual performance.

Chen and colleagues¹⁷ Optical Quality Analysis System was used to demonstrate that objective visual quality of aspheric IOLs is superior to that of spherical lenses. Numerous researches on visual quality of aspheric IOLs have been conducted. Meta-analysis and systematic review found that aspheric mono-focal IOL implantation resulted in less ocular spherical aberration and fewer ocular HOAs than spherical IOLs, and aspheric IOLs can provide better contrast sensitivity Schuster and colleagues.¹⁸

Macular edema is well-known posterior segment problem after cataract surgery. Hauser and colleagues¹⁹ found 10/16 eyes had CME longer than 6 months, and 1 longer than 12 months post-operatively which was both chronic and refractory.

Also, Chu and colleagues²⁰ mean incidence of postoperative edema was 1.17% in studied cases who did not have diabetes at period of surgery, whereas it was four-fold higher in studied cases with diabetes.

Clinical reports describe postphaco CME rates of 0.1%–2.35% in studied cases with risk factors and complicated surgery, whilst imaging-based examinations report rates ranging from 4 to 60% Scheers and colleagues.²¹

Pseudophakic macular edema is typically believed to be self-limiting condition with low visual morbidity, and surprisingly few researches that compare visual morbidity in eyes with and without PME have been published Yonekawa and Kim.²²

In large cohort research by Hecht and colleagues²³ on acrylic monofocal IOL by TECNIS showed that implantation of lower diopter IOLs were related to greater rates of PCO formation.

Numerous factors could account for greater rates of PCO observed with lower powered IOLs. ‘Barrier impact’ caused by IOL contact on posterior capsule was suggested by classical no space no cell theory. Theoretically, this barrier prevents epithelial cell

Table 6. Comparison between preoperative and one-month postoperative spherical aberrations among the studied patients.

Spherical aberrations	Preoperative	1 month post	Mean difference	Test value ^a	P value	Significance
Mean \pm SD	-0.49 ± 0.18	0.06 ± 0.09	0.55 ± 0.20	-4.763	<0.001	HS
Range	-0.66–0.17	-0.05–0.5				

P greater than 0.05: Nonsignificant; P less than 0.05: Significant; P less than 0.01: Highly significant.

^a Wilcoxon Rank test.

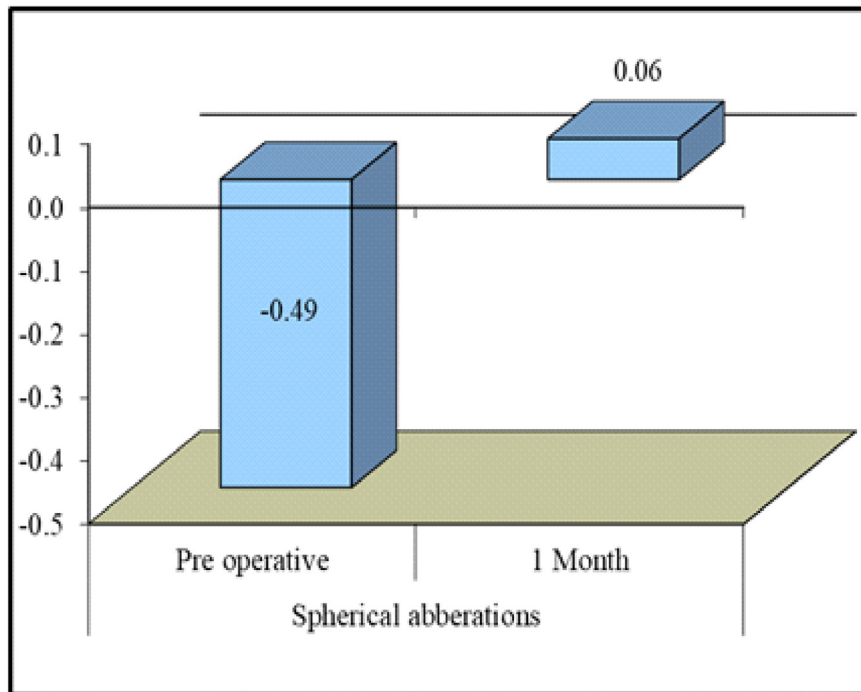


Fig. 6. Comparison between preoperative and one-month postoperative spherical aberrations among the studied patients.

migration onto central posterior capsule and inhibits PCO formation.^{3–9}

Zhao and colleagues²⁴ stated that, pooled analysis discovered that hydrophobic lenses had lower rate of Nd: Yttrium aluminium garnet (YAG) laser capsulotomy than hydrophilic lenses ($P = 0.029$).

Molecular and cellular mechanisms underlying efficiency variation among hydrophobic and hydrophilic intraocular lenses are not well understood Iwase and colleagues.²⁵

Sharp-edged IOLs are more likely to form PCO and have lower Nd: YAG ratio than round-edged IOLs. Capsulotomy with YAG Maedel and colleagues.²⁶

In another study, Weinand and colleagues²⁷ assessed stability of single-piece hydrophobic IOL within capsular bag, at end of surgery, eyes were photographed thru operating microscope to create small sequence of pictures of IOL, which was then converted into digital fixed-image. Digital fundus camera was used to photograph IOL 6 months after surgery. The angle of IOL rotation was then measured.

Lane and colleagues²⁸ new Clareon CNA0T0 IOL is mechanically comparable to AcrySof SN60WF IOL and may provide better mechanical and associated refractive stability than other IOLs tested, according to their *in vitro* comparative evaluation. Clareon C NA0T0 IOL had less axial displacement ($P < 0.005$) than enVista MX60, Tecnis ZCB00, and Vivinex iSert XY1 IOLs, as well as less optic tilt ($P < 0.005$) than enVista MX60 IOL.

Warlo and colleagues²⁹ over 3 month post-operative follow-up, 32% and 16% clinically relevant rotations were discovered. Till and colleagues³⁰ in eleven percent of one hundred eyes, rotation with toric plate-haptic IOLs was discovered to be clinically relevant.

We reported minimal rotation with a mean angle of 2.5°, eight (26.6%) patients had an angle of rotation of 1° or less. Only one patient had an angle of rotation of 6° (range 0.5–6°). The evaluated IOL design showed a good stability.

5.1. Conclusion

Our study demonstrated that the optical quality of Aqualens, AH612AL IOL has satisfactory results and significant improvement in regard flare reaction, cell deposits, cystoid macular edema, aberrations, stability and visual acuity.

Disclosure

The authors have no financial interest to declare in relation to the content of this article.

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Conflicts of interest

The authors declare no conflict of interest.

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