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Comparative Study between Anterior Chamber Iris Claw Phakic Iol and Posterior Chamber Phakic Iol (Icl) for Correction of Myopia

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ABSTRACT

Background: Compared to other refractive surgeries, implantation of phakic intraocular lenses (pIOLs) have more desirable results and are potentially reversible procedures due to the possibility of explanting these lenses. These methods usually do not require expensive or special surgical equipment and most ophthalmologists are able to perform these procedures; however disabilities resulting from pIOLs are more severe compared to corneal refractive surgery. Due to the potential risk of damage to anterior segment structures, especially corneal endothelial cell loss.

Aim of the Work: to compare between anterior chamber (AC) pIOL and posterior chamber (PC) pIOL in patients with myopia as regard:

1- Uncorrected and best corrected visual acuity (UCVA & BCVA).
2- IOP(Intra ocular pressure).
3- Endothelial cell count (ECC).
4- Postoperative inflammation and complications.

Patients and Methods: This prospective comparative study included 30 eyes of patients suffering from high myopia at Al-Hussein University Hospital from 2017 to 2018. The patients were divided into two groups:

Group (A): included (15) eyes where Polymethyl methacrylate (PMMA) iris-fixated AC pIOL were implanted (Artisan). Group (B): included (15) eyes where the PC pIOL were implanted (Implantable CollamerLens (ICL V4).

In this study we did pre and postoperative specular microscopy, pentacam and IOP measurement by applanation tonometer to evaluate endothelial cell count and IOP changes over 6 months. The main outcome measures were central corneal ECC, the percentage of corneal endothelial cell loss and IOP changes. Secondary outcome measures were UCVA, BCVA, manifest refraction, and complications.

Results: The mean pre-operative ECC in Group A was 3365±403 cell/mm² ranged from 2830 to 3846 cell/mm². In Group B, it was 3329±356 cell/mm² ranged from 2901 to 3989. Post operative mean ECC in group A was 3183±344 cell/mm² ranged from 2609 to 3686. In Group B, it was 3251±361cell/mm² ranged from 2432 to 3621 at 6 month after surgery. The mean percentage endothelial cell loss in group A was 5.4% While in group B, it was 2.3% at the end of the follow up period (6 months). The mean pre-operative IOP in group A was 15.63 ±1.74 mmHg ranged from 12 to 18.2 mmHg, while in Group B, it was 15.53 ±1.98 mmHg ranged from 13 to 20 mmHg. Post operative mean IOP in group A was 14.95±1.01 mmHg ranged from 12.5 to 16.2 mmHg, while in Group B, it was 14.69±1.20 mmHg ranged from 12.6 to 16.7 mmHg at 6 month after surgery. The mean pre-operative UCVA in Group A was 0.03 ± 0.011 ranged from 0.01 to 0.04, while in Group B, it was 0.06 ± 0.023 ranged from 0.01 to 0.083. And by the end of the 6th month after surgery, the mean UCVA was 0.39 ± 0.10 in Group A, while it was 0.5 ± 0.27 in Group B. The mean pre-operative BCVA in Group A was 0.3 ±0.12 ranged from 0.16 to 0.7, while in Group B, it was0.4 ± 0.22 ranged from 0.25 to 1.00 the mean BCVA at 6 month after surgery was 0.49± 0.12 in Group A, while it was 0.62 ± 0.23 in Group B. The mean pre-operative spherical error (SE) in Group A was -15.3 ± 2.68 D ranged from -11D to -20D, while in Group B, it was -13.72 ± 3.97D ranged from -7D to -20.25D. by the end of the 6th month after surgery, the mean post operative SE was-1.02 ± 0.53 in Group A, while it was -1.18 ± 0.67 in Group B.

Conclusion: Our study revealed that pIOLs implantation (AC IOLs or PC IOLs) in high myopes had excellent results including; stability of refraction for high myopes, reversibility, high optical quality, potential gain in visual acuity, preservation of corneal architecture, asphericity and accommodation the comparison between the two types of pIOLs proved that the ICL was superior over the Artisan as regards the effect on corneal endothelium and postoperative AC inflammation, and they were equal as regards predictability, efficacy and the effect on IOP.

Keywords: Phakic intraocular lenses, endothelial cell count, high myopia.

INTRODUCTION

High myopia represents a multiple management challenge. Surgical options such as refractive lens exchange are less desirable in younger patients as they result in the total loss of accommodation and a higher risk of retinal detachment. Another option is excimer laser treatment (effective in the correction of low-to-moderate myopia). However, high refractive errors are beyond the boundaries of safety and effectiveness of corneal surgery. Even with wavefront-optimized and wavefront-guided treatment, common concerns include lower predictability of the refractive outcome, postoperative refractive instability, and the risk of postoperative ectasia [(1)]. Thus, in the absence of contraindications, the safest and most effective procedure for treating young patients with moderate-to-high refractive errors and/or decreased corneal thickness is phakic intraocular lenses (pIOLs) implantation. This is a preferred technique, since it preserves accommodation and corneal architecture, is potentially reversible, and has outcomes that are more predictable, with faster recovery than excimer surgery [(1)].

Refractive surgery is classified into two categories: corneal based refractive surgery and lens based refractive surgery [(2)]. In corneal based refractive surgery, corneal reshaping using excimer laser has proven to be very useful in the correction of a wide spectrum of visual defects. However, common options like Laser assisted in situ keratomileusis (LASIK), Photorefractive keratectomy (PRK), Laser assisted

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subepithelial keratectomy (LASEK) and Epi-LASIK have shown their limitations for correction of higher myopia [3].

In lens based refractive surgery, refractive surgery is done either by altering the natural crystalline lens i.e clear lens extraction (CLE) [2], or by placing an intraocular lens inside the eye in front of patient's natural lens i.e phakic IOLs (pIOLs) [3]. pIOLs can be classified into the following three categories based on their position in the eye or their mechanism of fixation: Anterior chamber (AC) angle supported, AC iris-fixated, and posterior chamber PC [4]. The iris-claw or lobster-claw lens was first designed by Worst in 1977 for aphakic eyes. Later, in1986, Worst and Fechner modified this IOL to a biconcave anterior chamber lens for the correction of myopia. To increase the safety of this IOL and minimize the possibility of IOL-cornea contact, in 1991 the biconcave design was changed to a convex- concave model with a lower shoulder, a thinner periphery, and a larger optic diameter (5.0mm) to reduce photopic phenomena. This lens, called the Worst myopia claw lens, has been implanted successfully since then. In 1998, the name of the lens was changed to the Artisan-Worst lens, without a change in lens design. In 2002, AMO*(Abbott Medical Optics, Inc.)*acquired the global distribution rights of the Artisan, now known as the Verisyse lens [5].

Previously, it has been shown that these pIOLs display stable and predictable visual results. the effects of iris fixated pIOLs on endothelial cell loss have remained a matter of controversial debate [6]. However, the risk for cataractogenesis, pigment dispersion, and glaucoma seem to be the principal issue with PC pIOLs [7].

AIM OF THE WORK

The aim of the work was to compare between AC pIOL and PC pIOL in patients with myopia as regard:

1- Uncorrected and best corrected visual acuity (UCVA & BCVA).
2- IOP (Intra ocular pressure).
3- Endothelial cell count (ECC).
4-Postoperative inflammation & complications.

PATIENTS AND METHODS

This prospective comparative study included 30 eyes of patients suffering from high myopia at Al-Hussein University Hospital from 2017 to 2018. The study was approved by the ethical board of Al-Azhar University and an informed written constent was taken from each participant in the study. The patients were divided into two groups:

• **Group (A):** included (15) eyes where polymethyl methacrylate(PMMA) iris-fixated AC pIOL were implanted (Artisan).
• **Group (B):** included (15) eyes where the PC pIOL were implanted (Implantable CollamerLens (ICL V4).

In this study we did pre and postoperative specular microscopy, pentacam and IOP measurement by applanation tonometer to evaluate ECC and IOP changes over 6 months.

Patient's selection

Inclusion criteria:

- Age between 20 - 40 years old of either gender.
- Not suitable for LASIK/LASEK due to high degrees of myopia or thin corneas.
- Preoperative refractive error > -6 diopter (D) of spherical equivalent.
- Stable refraction for at least one year (< 0.5D change for >1year).
- AC depth (ACD) is more than 2.8 mm measured from corneal endothelium to the anterior lens capsule via Pentacam.
- ECC of 2800 cells/mm² or more.
- Horizontal whit to white (WTW) distance is more than 11mm in cases of ICL implantation.
- No other ocular pathology.

B) Exclusion criteria:

- Myopia other than axial myopia.
- Abnormal cornea such as keratoconus, opaque cornea or endothelial dystrophy.
- ECC less than 2800 cells/mm²
- Anterior segment pathology such as any form of cataract, pseudoexfoliation, pigment dispersion and severe iris atrophy.
- Abnormal pupil
- History and/or clinical signs of iritis or uveitis.
- Presence of anterior or posterior synechiae.
- Glaucoma or IOP greater than 21 mm.Hg.
- ACD less than 2.8 mm
- WTW distance less than 11 mm in cases of ICL.
- Posterior segment pathology such as retinal detachment, diabetic retinopathy, pre -existing macular degeneration or macular pathology.
- Diabetes mellitus.
- Previous ocular surgery.

Preoperative evaluation:

A complete history taking & ocular examination included: visual acuity, refraction, slit-lamp examination, indirect Ophthalmoscopy and specular microscopy.

-Visual Acuity:

UCVA & BCVA.

-Refraction:

Manifest and cycloplegic refraction were done, cycloplegic refraction is done one hour after instillation of 1% cyclopentolate eye drops.

-Slit Lamp Examination:

Anterior segment examination using the slit lamp was performed.

-Indirect ophthalmoscopy:

Fundus examination was done to assess the periphery as well as the central part of the retina.

- Applanation tonometry.

-Investigations:

(1) ACD (endothelium to anterior surface of crystalline lens) measurement, **keratometry** readings, **Pachymetry**, **WTW** distance,and **Mesopic pupillary** diameter using the Sirius Scheimpflug Analyzer (CSO, Costruzione Strumenti Oftalmici, Florence, Italy).

(2) Corneal ECC (central area):

Central area of the corneal endothelium was evaluated using specular microscopy. A non-contact specular microscopy was performed by Topcon SP- 1P(Topcon Medical Inc., Japan).

-Lens Power Calculation:

The manufacturers calculated the IOL power required to achieve emmetropia after they were provided with the patient's information.

The patient information consisted of the preoperative spherical equivalent (SE) refraction, keratometry readings, and ACD (anatomic ACD), Pachymetry and WTW.

The procedure:

For the pIOL implantation procedure, peribulbar anesthesia or general anesthesia was used.

Povidone iodine (Betadine) 5% was used to sterilize the eye, and povidone iodine 10% to sterilize the eyelids and surrounding skin.

A plastic sterile drape (Opsite) was applied to draw away the lashes, followed by the application of a wire speculum to separate the eyelids.

For Group A

- a 2-plane, 5.2 mm or 6.2 mm posterior corneal incision is centered at 12 o'clock and 2 vertical paracenteses directed toward the enclavation area are performed at 2 o'clock and 10 o'clock.
- The pupil should be constricted to protect the crystalline lens from contact with the pIOL or the instruments during surgery. This is achieved by injecting acetylcholine (Myochol) in the AC at the beginning of the procedure.
- After the AC is filled with a cohesive Ophthalmic Viscoelastic Device (OVD), the IOL is introduced and rotated 90 degrees into a horizontal position. The pIOL is fixated with an enclavation needle that has a bent shaft and a bent tip that pushes the iris into both claws.
- The needle is introduced through one paracentesis and holds the fold of iris while the pIOL is slightly depressed with the implantation forceps so the claws will automatically grasp the iris. Hands are then switched, and the same maneuver is performed through the other paracentesis.
- If the pIOL is not well centered, enclavation can be released by pushing in the central portion of the claw with the enclavation needle. A peripheral iridectomy(PI) is performed at 12 o'clock to prevent pupillary block. The viscoelastic is removed.
- The corneal wound is then sutured with interrupted 10-0 nylon Sutures or figure of eight suture.
- Subconjunctivally, Gentamycin 20 000u and Dexmathasone 2.5mg were injected.

For Group B

- The pupil should be dilated to implant the ICL in the ciliary sulcus
- Correct loading of the ICL in the cartridge and the injector is essential for correct and easy implantation
- Two paracenteses made by MVR 20G were performed at 12 o'clock and 6 o'clock.
- The AC is filled with a dispersive (Hydroxypropyl methyl cellulose 1.4%) or a cohesive low-viscous OVD injected through the side port to partially inflate the AC to protect the corneal endothelium and crystalline lens from surgical trauma.
- A clear corneal tunnel incision was done by an angled keratome 3.2 mm centerd temporal
- The cartridge is inserted bevel down, and the ICL is carefully injected slowly using the MicroSTAAR injector (STAAR Surgical)
- OVD was injected on top of the ICL
- Once the lens unfolds, the marks on the footplates are checked for proper orientation
- The haptics are gently pushed under the iris with a blunt spatula.
- Methacholine is injected into the AC to induce pupil constriction after removal of the OVD
- A peripheral iridectomy should be performed with scissors
- Finally, the wounds are hydrated.

Post-operative medication:

- Topical Prednisolone acetate 1% eye drops every two hours (while the patient is awake only) for one week then tapered gradually over six weeks.
- Topical Gatifloxacin 0.3% eye drops every two awaken hours for one week then four times per day for two weeks.
- Combined Tobramycin 3% with Dexamethasone phosphate 0.1% eye ointment once before sleep for one week.
- Actezolamide 500 mg tablet every 12 hours for 5 days.

Postoperative follow-up:

Initial postoperative examination was done on the first day postoperative followed by periodic follow-ups on the first week then after one month, three months and six months.

In each visit the following was done:

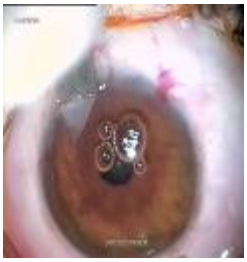
1- UCVA.
2- BCVA and residual refractive error.
3- Postoperative astigmatism.
4- Checking IOP using applanation Tonometer.
5- ECC will be done using the non contact specular microscope at the sixth month after implantation and compared with the preoperative data.
6- Slit lamp examination for assessment of:
Corneal status, Inflammation: iritis detection, IOL position and enclavation, pupil shape, vault evaluation and lenticular changes.
7- Retinal evaluation.

Statistical analysis

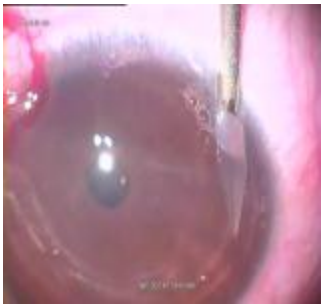
Recorded data were analyzed using the statistical package for social sciences, version 20.0 (SPSS Inc., Chicago, Illinois, USA). Quantitative data were expressed as mean± standard deviation (SD). Qualitative data were expressed as frequency and percentage.

The following tests were done:

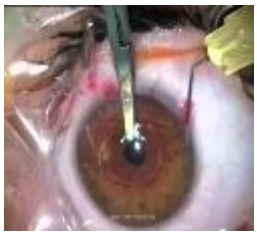
- Independent-samples t-test of significance was used when comparing between two means.
- Paired sample t-test of significance was used when comparing between related sample.
- A one-way analysis of variance (ANOVA) when comparing between more than two means.
- Chi-square (X2) test of significance was used in order to compare proportions between two qualitative parameters.
- The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered significant as the following:
- Probability (P-value)
  – P-value <0.05 was considered significant.
  – P-value <0.001 was considered as highly significant.
  – P-value >0.05 was considered insignificant.



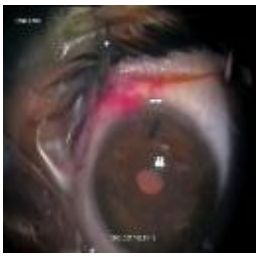
. **(A):** The corneal incision



(B): vertical paracenteses directed toward the enclavation area are performed at 2 o'clock.



(C): The pIOL is fixated with an enclavation needle

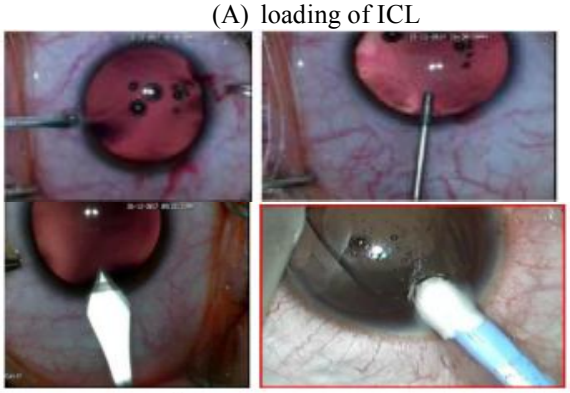


(D) peripheral iridectomy is performed at 12 o'clock

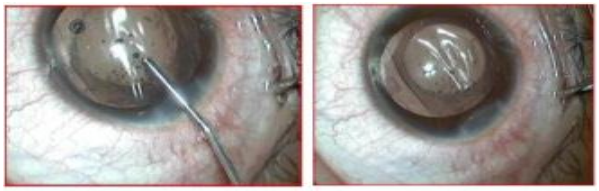
(E) The viscoelastic is removed.

Fig. 1: Implantation of Artisan implants**.**

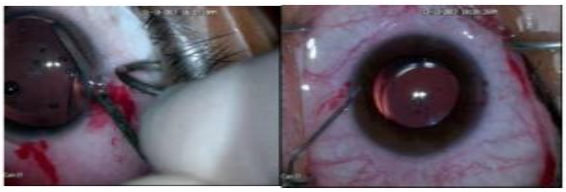
(A) loading of ICL



(B) Paracentesis
(C) Injection of OVD
(D) Corneal incision
(E) Injection of the ICL



(F) Injection of OVD on top of the ICL
(G) Unfolding of the ICL



(H) Implantation of the ICL in the ciliary sulcus & Injection of methacholine

(I) PI & Stromal hydration

Fig. 2: Implantation of ICL

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RESULTS

This study was conducted on 30 eyes of 18 patients divided into two groups, each included 15 eyes:

Group (A): In which the PMMA iris-fixated AC pIOL (ARTISAN) was implanted.

Group (B): In which the PC pIOL (ICL V4) was implanted.

Group A included male (10%) and 9 females (90%), the mean age of which was 23.50 years ± 3.41 ranged from 20 to 28 years.

Group B included 4 males (50%)and 4 females (50%), the mean age of which was 25.00 years ±4.81 ranged from 21 to 35 years.

Postoperative :

The mean UCVA was 0.39 (6/18) ± 0.10 in Group A, while it was 0.5 (6/12) ± 0.27 in Group B.

The mean BCVA was 0.49(6/12) ± 0.12 in Group A, while it was 0.62 (6/9) ± 0.23 in Group B.

The mean SE was -1.02 ± 0.53 in Group A, while it was -1.18 ± 0.67 in Group B.

The mean cylindrical error in Group A was -1.10±0.70 ranged from -0.25D to -3D, while in Group B, it was -1.07±0.56D ranged from -0.55D to -2 D.

The mean IOP in group A was 14.95±1.01 mmHg. ranged from 12.5 to 16.2 mmHg, while in Group B, it was 14.69±1.20 mmHg ranged from 12.6 to 16.7 mmHg at 6 month after surgery.

The mean ECC in group A was 3183±344 cell/mm² ranged from 2609 to 3686. In Group B, it was 3251±361cell/mm² ranged from 2432 to 3621 at 6 month after surgery.

The mean ACD in group A was 3.17±0.22 mm ranged from 2.88 to 3.52 mm, while in Group B, it was 3.25±0.27 mm ranged from 2.92 to 3.8 mm.

The mean corneal thickness in group A was 523.27±30.28 µm ranged from 469 to 577 µm while in Group B, it was 516.00±21.66 µm ranged from 477 to 549 µm .

Table (1): Preoperative patient characteristics.

Parameter	Group A		Group B	
	Mean ± SD	Range	Mean ± SD	Range
SE (D)	-15.35 ± 2.86	-20.00 – - 11.00	-13.72 ± 3.97	-7 – -20.25
ACD (mm)	3.17 ± 0.22	2.88 – 3.52	3.25±0.27	2.92 – 3.8
CCT (µm)	523.27 ± 30.28	469 – 577	516.00±21.66	477 – 549
ECC (cell/mm²)	3365 ± 403	2830 – 3846	3329±356	2901 – 3989
Cylinder (D)	-1.17 ± 0.70	-2.50 – -0.25	-1.54±0.59	-2.5 – -0.75

ACD: anterior chamber depth; **CCT**: central corneal thickness;
ECC: endothelial cell count ; **SE**: spherical equivalent

Four eyes were operated under local anesthesia (40%) while 6 eyes under general anesthesia (60%)in group A. while 3 eyes were operated under local anesthesia (37.5%) and 5 eyes under general anesthesia (62.5%)in group B.

Postoperative results:

In Group A, the mean pre-operative UCVA was 0.03 (1\60) ± 0.011 ranged from 0.01 (CF at 50cm) to 0.04 (2\60), while in Group B, it was 0.06 (4\60) ± 0.023 ranged from 0.01 (CF at 50cm) to 0.083 (5\60). The difference between the two groups was statistically significant (P<0.001).

Postoperative UCVA had statistically significant difference between both groups in all follow up periods (P = 0.045).

By the end of the 6th month after surgery, the mean UCVA was 0.39 (6/18) ± 0.10 in Group A, while it was 0.5 (6/12) ± 0.27 in Group B.

Table (2): Changes in the mean postoperative UCVA from the preoperative value.

UCVA	Group A (N=15)	Group B (N=15)	t-test	p-value
Pre-operative				
Mean±SD	0.031±0.011	0.066±0.023	5.317	<0.001
Range	0.010-0.040	0.010-0.085		
Post-operative				
Mean±SD	0.397±0.106	0.530±0.272	2.014	0.045
Range	0.160-0.600	0.250-1.000		
Mean diff.	0.356	0.464		
Paired sample t-test	13.301	6.252		
p-value	<0.001	<0.001		

In Group A, the mean pre-operative BCVA was 0.3 (6\18) ±0.12 ranged from 0.16 (6\36) to 0.7 (6\9), while inGroup B, it was0.4 (6\18) ± 0.22 ranged from 0.25 (6\24) to 1.00 (6\6). The difference between the two groups was statistically significant (P=0.007).

Post-operatively, the BCVA had improved from its pre-operative value in both groups starting from the 1st week after surgery.

Postoperative BCVA had statistically insignificant difference between both groups in all follow up periods (P = 0.069).

By the end of the 6th month after surgery, the mean BCVA was 0.49(6/12) ± 0.12 in Group A, while it was 0.62 (6/9) ± 0.23 in Group B.

Table (3): Changes in the mean postoperative BCVA from the preoperative value.

BCVA	Group A (N=15)	Group B (N=15)	t-test	p-value
Pre-operative				
Mean±SD	0.301±0.126	0.497±0.226	2.934	0.007
Range	0.160-0.700	0.250-1.000		
Post-operative				
Mean±SD	0.498±0.128	0.627±0.231	1.892	0.069
Range	0.300-0.800	0.300-1.000		
Mean diff.	0.197	0.130		
Paired sample t-test	4.248	2.554		
p-value	0.002	0.035		

Emmetropia was aimed in all eyes.(Table 4) shows that : In Group A, the mean pre-operative spherical error was -15.3 ± 2.68 D ranged from -11D to -20D, while in Group B, it was -13.72 ± 3.97D ranged from -7D to -20.25D. The difference between the two groups was statistically insignificant (P= 0.196).

And by the end of the 6th month after surgery, the mean post operative SE was-1.02 ± 0.53 in Group A, while it was -1.18 ± 0.67 in Group B.

postoperative spherical error had no statistically significant difference between both groups in all visits through out the follow up period (P= 0.457).

Table (4): Changes in the mean postoperative spherical error from the preoperative value

SE	Group A (N=15)	Group B (N=15)	t-test	p-value
Pre-operative				
Mean±SD	-15.35±2.68	-13.72±3.97	1.751	0.196
Range	-20 – -11	-20.25 – -7		
Post-operative				
Mean±SD	-1.02±0.53	-1.18±0.67	0.57	0.457
Range	-2.5 – -0.5	-3 – -0.5		
Mean diff. (%)	14.33	12.54		
Paired sample t-test	-19.697	-13.155		
p-value	<0.001	<0.001		

In Group A, the mean pre-operative cylindrical error was -1.17 ±0.70D ranged from -0.25D to -2.5D, while in Group B, it was -1.54 ± 0.59D ranged from -0.75D to -2.5D. The difference between the two groups was statistically insignificant (P= 0.147).

The corneal wound was oriented superiorly in Group A and temporally in Group B irrespective to the axis of astigmatism present.

Postoperative cylindrical error had no statistically significant difference between both groups in all visits through out the follow up period (P=0.854).

Table (5): Changes in the mean postoperative cylindrical error from the preoperative value.

Cylinder	Group A (N=15)	Group B (N=15)	t-test	p-value
Pre-operative				
Mean±SD	-1.17±0.70	-1.54±0.59	2.237	0.147
Range	-2.5- – 0.25	-2.5- – 0.75		
Post-operative				
Mean±SD	-1.10±0.70	-1.07±0.56	0.094	0.854
Range	-3 – -0.25	-2 – -0.55		
Mean diff.	0.07	0.47		
Paired sample t-test	-0.405	-1.184		
p-value	0.691	0.063		

In Group A, the mean pre-operative IOP was 15.63 ±1.74 mmHg ranged from 12 to 18.2 mmHg, while in Group B, it was 15.53 ±1.98 mmHg ranged from 13 to 20 mmHg. The difference between the two groups was statistically insignificant (P= 0.884).

Postoperative IOP had statistically insignificant difference between both groups (P>0.05).

Table (6): Changes in the mean postoperative IOP from the preoperative value.

IOP	Group A (N=15)	Group B (N=15)	t-test	p-value
Pre-operative				
Mean±SD	15.63±1.74	15.53±1.98	0.147	0.884
Range	12-18.2	13-20		
After 1 day				
Mean±SD	17.42±1.35	16.63±1.74	1.372	0.181
Range	13.4-17.12	12-18.2		
After 1 weeks				
Mean±SD	16.65±0.90	17.61±2.10	1.627	0.115
Range	13.8-17.2	10.4-18		
After 1 months				
Mean±SD	15.45±1.01	16.05±1.24	1.453	0.157
Range	12.6-16.2	12.6-16.9		
After 3 months				
Mean±SD	14.43±1.14	14.78±1.15	0.837	0.409
Range	12.3-16.5	12.9-16.6		
After 6 months				
Mean±SD	14.95±1.01	14.69±1.20	0.642	0.526
Range	12.5-16.2	12.6-16.7		
Mean diff. between pre-operative and after 6 months	0.260	0.840		
Paired sample t-test	0.642	1.405		
p-value	0.526	0.171		

The mean pre-operative ECC in Group A was 3365±403 cell/mm² ranged from 2830 to 3846 cell/mm². In Group B, it was 3329±356 cell/mm² ranged from 2901 to 3989 cell/mm². The difference between the two groups was statistically insignificant (P = 0.798). Postoperative ECC had no statistically significant difference between both groups through out the follow up period (P= 0.602). The mean percentage endothelial cell loss in group A was 5.4% at the end of the follow up period (6 months). It seems that surgical trauma together with close proximity of the pIOL (Artisan) to the endothelium are the main causes of the reduction of ECC.

While in group B, it was 2.3% at the end of the follow up period (6 months). Here, it seems that only surgical trauma is the main cause of the decrease in ECC. There was statistically high significant difference between the two groups in percentage endothelial cell loss (P <0.001), with more loss in group A.

Table (7): Changes in the mean postoperative ECC from the preoperative value.

ECC	Group A (N=15)	Group B (N=15)	t-test	p-value
Pre-operative				
Mean±SD	3365±403	3329±356	0.067	0.798
Range	2830-3846	2901-3989		
Post-operative				
Mean±SD	3183±344	3251±361	0.528	0.602
Range	2609-3686	2432-3621		
Mean diff. (%)	182 (5.4%)	78 (2.3%)	14.419	<0.001 (HS)
Paired sample t-test	1.330	0.596		
p-value	0.194	0.556		

Patient compliance and satisfaction:

Group A: Patient satisfaction was encountered in 14 eyes (93%) with only one eye (7%) where the patient was not satisfied with the quality of vision. Although this patient achieved UCVA of 0.25 (6\24) and BCVA of 0.67 (6\9), he had residual cylindrical error of -2.5D and spherical error of -1.5D that might be the cause of the complaint, so cycloplegic refraction is mandatory in all cases of pIOLs. Night glare was complained of in three eyes (20%) after 1month of the surgery that was minimized to only 1 eye (6%) after 3months. This was related to pupil dilatation size in darkness rather than pupil ovalization.

Group B: Patient satisfaction was encountered in all eyes (100%) Night glare was complained of in two eyes (13%) till one month after surgery that was minimized to only one eye (6%) after two months. This was related to slightly central PI.

Complications:

Anterior uveitis occurred in 3 eyes (20%) of group A after surgery all responded well to topical and oral steroids, Slight pupil ovalization was reported in 1 eye (6%) in group A which were visually insignificant and not accompanied by any other problem, Iris-tissue depigmentation and atrophy at the enclavation site occurred in (13%) 2 eyes at the last follow-up. Crystalline lens opacities, retinal detachment, and pupillary block were not observed in both groups.

DISCUSSION

The results we got in our study concerning effectiveness, predictability, stability and improvement in visual acuity were similar to many previous studies of pIOLs.

After 6 months follow up, all eyes (100%) had UCVA of 0.25 (6\24) or better six months after surgery, the recorded levels of UCVA and BCVA in patients with high myopia due to myopic chorioretinal degeneration must be considered.

Regarding final refraction; 90 % of eyes were within ± 1.50 D of emmetropia, only one eye in group A (3%) had residual cylindrical error of -2.5 D and spherical error of -1.5D that might be due to improper preoperative cycloplegia, so cycloplegic refraction is mandatory in all cases of pIOLs. The refractive results were stable and the BCVA improved one to two lines from the preoperative values.

Regarding glare and halos; night glare was complained in group A (Artisan) in three eyes (20%) after 1 month of the surgery that was minimized to only 1 eye (6%) after 3 months. This might be attributed to pupil dilatation in darkness rather than pupil ovalization.

In group B (ICL), it was complained in two eyes (13%) till one month after surgery that was minimized to only one eye (6%) after two months.

By the end of the follow up period; glare and halos were not complained by any patient in both groups This was the same explanation as **Maroccos *et al.*** [8] who reported significantly less glare and halos with the Artisan pIOL than with other pIOLs, especially the 6.0 mm optic. This was attributed to the larger optic (6.0 mm versus 5.0 mm) and the fixation of the IOL to the iris, which causes less pupil dilation. Therefore, the 6.0 mm optic iris-fixated pIOL seems to be preferable to the 5.0 mm optic.

In the ICL FDA study, a larger incidence of glare and halos, approximately 8.5%, was reported. The authors concluded that the incidence of glare and halos decreased or remained unchanged from before the operation after ICL surgery [9].

Regarding the cylindrical error; our results reported no significant increase in postoperative cylindrical error with both Artisan and ICL. For ICL We attributed this to the small incision of 3.2 mm required for ICL implantation.

For Artisan: The corneal wound was oriented superiorly (at 90º) irrespective to the axis of astigmatism present

Because the PMMA iris claw IOL (Artisan/ Verisyse) is not foldable, it requires an incision that approximately equals the optic diameter (5.0 or 6.0 mm), which may induce surgically induced astigmatism (SIA).

According to **Kohnen *et al.*** [10], SIA after the 5.0 to 6.0 mm incisions is less than one might expect. **Menezo *et al.*** [11] reported no significant increase in postoperative astigmatism. Similar results were reported by **Menezo *et al.*** [11], after AC pIOL. Moreover, a decrease in the preoperative cylindrical error in 8 eyes (53%) in group A (Artisan) and in 10 eyes (66%) in group B (ICL) in our study occurred when the incision was coinciding with the axis of the steepest meridian. On the other hand, the SIA after ICL implantation was 0.45D [12].

The major statistically significant finding in our study was the decrease in the endothelial cell count (ECC) in both groups. The total endothelial cell loss was 5.4 % in group A (Artisan) and 2.3% in group B (ICL) at 6 months postoperative. There was statistically highly significant difference between the two groups in percentage endothelial cell loss (P <0.001), with more loss in group A This might be attributed to the damage of the corneal endothelium by direct close contact between the Artisan and the inner surface of the cornea either during implantation or from postoperative changes in Artisan position with leaning forward or eye rubbing. Moreover, chronic postoperative subclinical inflammation, which was more with the Artisan, might cause direct toxicity to the endothelium and led to further damage. However the less decrease in the ECC in the ICL group was only attributed to direct trauma to the endothelium during surgery.

Coullet *et al.* [13] reported a decrease of 9.4% and 9% in endothelial cell counts following Artisan and Artiflex implantation after 1year, respectively.

Doors *et al.* [14] described a decrease of 3.3% 12 months after after Artisan/Artiflex implantation.

Karimian *et al.* [15] reported a decrease of 10.1 % corneal endothelial cells after three years following implantation of Artisan /Artiflex pIOL.

Bouheraoua *et al.* [6] found that the endothelial cell loss was 6.27% at 1 year after Artisan pIOLs implantation.

In a recent study done on **Guerra *et al.*** [1], the mean endothelial cell loss was 2.68 % at 12 months after implantation of Verisyse pIOL.

As for ICL; a more endothelial cell loss of 5.2% - 5.5% was documented after 12 months by **Jiménez-Alfaro *et al.*** [7]. Moreover; ***ICL in Treatment of Myopia (ITM) Study Group*** [16] reported an endothelial cell loss of 8.4-9.7%, three years postoperative. Researchers therefore considered surgery to be the cause of the early corneal endothelial cell loss for both types of pIOL.

Factors leading to corneal endothelial cell loss after pIOL implantation, were studied by many authors who reported a yearly corneal endothelial cell loss of 1.0% for a mean minimum distance of 1.43mm between the edge of the pIOL and the corneal endothelium; the loss was 1.7% for a mean minimum distance of 1.20mm and 0.2%for a mean minimum distance of 1.66mm. They also expected that a critical corneal endothelial cell level of 1500 cells/mm2 would be reached 18 years after Artisan/Artiflex implantation [14].

Regarding Pigment Dispersion/Lens Deposits: two cases of inflammatory cell deposits on the IOL surface had been reported in the present study of group A. This might be due to the fact that the optic of the Artisan has an anterior vault to prevent iris chaffing Pigment cells are occasionally visible on the pIOL optic in the early postoperative period from surgical trauma. Iris pigment defects at the site of enclavation as a possible source of pigment dispersion [10].

Similar results were described by **Stulting *et al.*** [17] reported a long-term incidence of 6.6 – 6.9% pigment dispersion after Artisan implantation

No cases of neither pigment dispersion nor lens deposits in Group B had been reported in our study. This might be due to the Collamer of the ICL inhibits protein adhesion and deposition.

However, if the distance between the crystalline lens and PC pIOL is increased, the PC pIOL is closer to the iris with the consequent risk for pigment dispersion [10].

Regarding chronic postoperative subclinical AC inflammation in our study has been a major concern in 30% of eyes in group A (Artisan). This was because this pIOL is fixated directly to the iris tissue and causes pressure or shear forces when the eye is moving or patients rub their eyes. This may lead to injury or increased permeability of the iris vessels with breakdown of the blood–aqueous barrier and chronic release of inflammatory mediators, on the other hand; no cases of chronic intraocular inflammation have been reported in group B (ICL).

Similarly; **Moshirfar *et al.*** [18] reported elevated flare levels after Artisan.

On the other hand; **Groβ *et al.*** [19] reported no elevated flare levels after Artisan.

Regarding pupil ovalization one case (6%) of slight occurred after Artisan implantation in group A which might be due to slight unequal enclavation, while,No any case of pupil ovalization was reported with ICL group B.

Stulting *et al.* [17] report an incidence of 13.0% of asymptomatic oval pupil one day postoperative, after iris fixated pIOL

Regarding postoperative decentration of pIOL had not occurred in any case of both groups. Postoperative decentration is possible in AC pIOLs if the enclavation is not sufficient. This can lead to difficulties if the pupil itself is decentered and the optical axis is not in the middle of the pupil.

Regarding pIOL rotation or dislocation; no cases of Artisan IOL rotation or dislocation had occurred .

As for ICL; no cases of dislocation nor rotation had occurred in our study due to accurate WTW measurement which was done using the Scheimpflug photography.

Regarding IOP elevation after Artisan were reported in our study, this might be due to the anterior chamber angle which is not generally thought to be affected by the haptics of the iris-claw AC pIOL.

On the contrary; **Yamaguchi *et al.*** [20] reported that after implantation of an Artisan/Verisyse pIOL, partial narrowing of the AC angle of more than 5º occurred in the area where the pIOL haptics pinched the iris. This did not affect IOP.

Due to the position of the PC pIOL, the iris may be pushed forward and cause acute pupillary block glaucoma. The diameter of PC pIOLs is involved in this pathophysiological process [7]. Many authors stated that, a peripheral iridectomy or iridotomy was necessary to prevent acute pupillary block glaucoma [21].

On the other hand, **Kamiya *et al.*** [12]; did not report a statisticaly significant IOP increase after ICL implantation.

Regarding cataract formation although; one of the most common expected complications after pIOLs is cataract formation, yet; we did not report any case of cataract formation after Artisan or ICL over the follow up period. For Artisan it attributed to its insertion in the AC over a miotic pupil and its far location from the crystalline lens which was also explained by **Kohnen *et al.*** [10].

On the Contrary; **Chen *et al.*** [22] reported that the incidence of cataract was 8.5% for the ICL pIOL and 1.1% for the myopic Artisan/Verisyse pIOL while no cataracts with the Artiflex pIOL. Also, **Stulting *et al.*** [17] reported a nuclear cataract rate of 3% after implantation of an iris-fixated pIOL. **Sanders *et al.*** [9], stated that 0.6% developed significant lens opacity in the ICL's FDA trial.

While **Azar and Ghanem** [23] stated that metabolic disturbances induced by the implant might also be partially responsible for cataract formation. However, a longer follow up is needed as it may detect more cases of cataract.

No cases of RD occurred in our study, with both types. Mostly this was due to thorough preoperative and postoperative fundoscopic investigation.

On the contrary; **Stulting *et al.*** [17] reported a RD rate of 0.3% per year after Artisan/Verisyse implantation. However; this was similar to RD rates that had been reported in the highly myopic population that did not have refractive surgery [24]. While ***ITM study group,*** [16] found only three eyes of RD .

The present study revealed the ICL vault (distance from the anterior lens surface and the center of ICL optic from the posterior surface) was within the ideal range [from ½ CCT to 1 ½ CCT (250 µm to 750µm)] in 15 cases (100%)

Other complications of iris-fixated pIOL implantation are ischemic blown pupil (Urrets-Zavalia syndrome), early postoperative hyphema, and ischemic optic neuropathy [25]. Another rare complication is implantation of a pIOL with incorrect power. Due to the aim of the surgery is to correct ametropia as precisely as possible, this complication should not occur with current formulas.

CONCLUSION

Our study revealed that pIOLs implantation (AC IOLs or PC IOLs) in high myopes had excellent results including; stability of refraction for high myopes, reversibility, high optical quality, potential gain in visual acuity, preservation of corneal architecture, asphericity and accommodation. Moreover, correction is not limited by corneal thickness or topography. However, selection between these two types of pIOLs depends on some criteria including; ACD and pupil size.

ACD less than 2.8mm measured from the endothelium is considered a limitation for both Artisan and ICL. So we recommend ICL implantation in eyes with ACD 2.8 mm or more.

Pupil size; which acts as an important factor in preventing postoperative glare and halos, Artisan having a larger optic (6.0mm), is recommended in eyes with larger mesopic pupil diameter. However, a preoperative mesopic pupil larger than 5.0mm should be considered a limitation to both Artisan and ICL pIOLs.

Some precautions that should be made to avoid unnecessary complications of pIOLs. Among these precautions is; Preoperative Endothelial Cell Count (ECC) measurement, using specular microscopy, is obligatory. Patients with endothelial damage or ECC below 2000 cell/mm2 should not receive a pIOL especially the Artisan IOL accurate preoperative white to white measurement using the Scheimpflug photography or a caliber is mandatory to avoid implantation of undersized or oversized ICL and to prevent postoperative rotation or decentration of the pIOL, fundoscopic examination is required to rule out retinal changes or vitreoretinal pathologies and to perform prophylactic laser

photocoagulation if required. Last but not least; a peripheral iridectomy is mandatory to prevent pupillary block glaucoma. Performing an "intraoperative" peripheral iridectomy for both types of pIOL is better than a preoperative Nd:YAG which might be small and insufficient.

The present work studied the effects of both PMMA iris-fixated AC pIOL (Artisan) and PC pIOL (ICL) and compared them together. In both types; the surgery was safe, effective, predictable and had a low complication rate. It also provided rapid visual rehabilitation and long term stability.

Hence, the comparison between the two types of pIOLs proved that the ICL was superior over the Artisan as regards the effect on corneal endothelium and postoperative AC inflammation, and they were equal as regards predictability, efficacy and the effect on IOP.

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