Implantable collamer Lens [ICL] in myopia correction

INTRODUCTION

Many patients with high myopia cannot see well with glasses, and their thickness may cause psychological problems. Others cannot tolerate contact lenses. So these patients need other solutions for their myopia **[1] .**

The field of phakic IOLs has experienced tremendous evolution in recent years. The increased knowledge on anterior segment anatomy and the availability of better imaging technologies along with improved IOL designs and surgical techniques have led to higher success rates with these lenses. Compared to corneal refractive surgery, phakic IOLs compete favorably for the correction of high ametropias, with excellent predictability, efficacy, safety, and quality of vision [2] **.**

Compared to laser corneal surgery or crystalline lens exchange surgery, correcting moderate and high ammetropias with phakic IOLs not only allows maintenance of accommodation, but also offers a better quality of vision, some reversibility of the procedure and easy management of postoperative residual error**.** Moreover, they maintain the original shape of the cornea, thus not altering optical qualities of the cornea [2,3]**.**

Since 1986 when Fyodorov first implanted a phakic IOL in the prelenticular space to correct high myopia, several posterior chamber phakic IOLs of his derivation have been developed. Results with phakic IOL materials and designs used to date suggest that both biocompatibility with an adequate spacing from sensitive intraocular structures are required for improved safety in all patients[3,4].

For implantation of a phakic IOL in the prelenticular space, we would ideally desire materials that would allow permeability of nutrients and circulation of aqueous humor, and would not cause crystalline lens trauma [5].

The Implantable collamer Lens (ICL) is another type of Phakic. Intraocular Lens which is manufactured from a soft foldable polymeric material called Collamer. The cornea is actually comprised of collagen and so this material provides excellent biocompatibility and superior optical capability. It is readily implanted behind the iris by gently folding it and injecting into the anterior chamber through a tiny incision only3.0mm in length placed by the surgeon at the clear edge of the cornea [6] **.**

The ICL offers vision correction that's sharper, clearer and has greater depth and dimension than other procedures. The main advantage of the ICL over traditional corrective laser eye surgery is that patients may experience significant improvement in quality of vision after the lens is implanted [7] **.**

When compared to the results of corneal refractive surgery, the ICL may produce superior vision quality as evidenced by fewer higher order aberrations. Patients experience a nearly immediate visual recovery [7]**.**

Vault: Ideal ICL vault is approximately 500 μm, which is roughly one corneal thickness. There are concerns about high vault (1000 μm) leading to angle crowding and resulting in angle closure or synechiae formation. High vault may also increase iris chaffing and pigment dispersion, resulting in pigmentary glaucoma. Furthermore, low vault (125 μm) may also cause ICL contact with the crystalline lens and increase the risk of cataract formation over time.[8]

AIM OF THE WORK

The aim of the work is to assess the outcome of Implantable collamer Lens [ICL] in moderate and high myopia correction

PATIENTS AND METHODS

This study was conducted in accordance with the principles of the Declaration of Helsinki and was approved by the Ophthalmoogy department councils in Fayoum and mIsr university for Science and Technology . Written informed consent was obtained from all patients after the nature and possible consequences of the study were explained.

This **prospective** study includes (30) eyes (12 patients unilateral, 9 patients bilateral) with moderate and high myopia.

The surgeries were done by 1 surgeons.

The period of this study was 12 months after ICL implantation

This study had started since 2013 and ended by 2016. The follow up period was 12 months. Patients were examined after one day, one week, 1,3,6,12 months after ICL implantation.

The surgical procedures and follow up were done at Fayoum University hospital and Misr University Hospital.

All patients were fully examined preoperatively including : history taking , assessment of uncorrected visual acuity (UCVA) and best spherical corrected visual acuity (BCVA) for far and near , Manifest and Cycloplegic refraction , Slit lamp examination and fundus biomicroscopy , Intraocular pressure (IOP) measurement using Goldmann applanation tonometer, Mesopic pupillary diameter, White to White diameter, Keratometry (K) readings, Endothelial Cell Density (ECD) measurement using the Specular Microscope, Pentacam to measure anterior chamber depth (ACD),corneal topography and corneal thickness and Calculation of IOL power (Biometry) using the formula provided by the manufacturer.

Inclusion criteria:

1- Age between 17 years old and 38 years old, either male or female.
2- Myopia between -4 D and -30D with or without astigmatism.
3- Stable refraction for at least 3 years.
4- Anterior chamber depth of 2.8 mm or more measured from corneal endothelium to the anterior lens capsule .
5- A patient's ability to comply with the standardized postoperative follow-up visits would be taken into consideration.

Exclusion criteria:

1- Anterior segment pathology such as any form of cataract, pseudoexfoliation, pigment dispersion and severe iris atrophy.
2- Abnormal cornea such as opaque cornea or endothelial dystrophy.
3- History and/or clinical signs of iritis or uveitis.
4- Glaucoma or IOP greater than 21 mmHg.
5- Posterior segment pathology such as retinal detachment, diabetic retinopathy, preexisting macular degeneration or macular pathology.

All cases were done under general anesthesia or peribulbar anesthesia performed by anestheologist using a mixture of lidocaine hydrochloride 20 mg/ml (Xylocaine 2%) and hyaluronidase 1.500 IU/ampoule (Hyalase). The pupil was dilated by topical application of a combination of tropicamide 1%, and phenylephrine hydrochloride 10 % . A corneal incision was opened using keratome 2.4 mm with 2 side ports using MVR 20G. Loading the ICL(STAAR Surgical) into the MicroSTAAR injector (STAAR Surgical) and then injected and repositioned in

place. Toric ICL was used in cases of astigmatism more than 2 D. The corneal wound was hydrated and eye patched .

The postoperative treatment was as follows:

1. *Actezolamide* 500 mg tablet every 6 hours for first days.
2. Topical *Prednisolone acetate 1%* eye drops 5 times/day for one week then tapered gradually over 2 weeks.
3. Topical *Gatifloxacin 0.3%* eye drops 5 times/day for one week then tapered gradually over 2 weeks. 5 times/day for one week then tapered gradually over 2 weeks.
4. Topical NSAID twice daily for one week

Initial postoperative examination was done on the first day postoperative followed by periodic follow-ups on the first week then after one month then every three months for 12 months.

In each visit the following will be done:

1- UCVA and BCVA.

2- Slit lamp examination for assessment of:

a) Corneal status: presence of stromal odema, epithelial odema, striate keratopathy or not.
b) Inflammation: iritis detection (Aqueous flare and cellular reaction) with the room light dimmed.
c) IOL position.
d) Pupil shape.
e) Lenticular changes.

3- Retinal evaluation.

4- Checking IOP using Goldmann Applanation Tonometer.

6- Pentacam starting from the third month after implantation: The main parameters that will be measured and compared are anterior chamber depth, keratometry (k) readings, corneal topography, corneal thickness and mesopic pupillary diameter .

7- Endothelial Cell Density (ECD) at 6month and 12 month

Statistical analysis:

Data were statistically described in terms of mean ± standard deviation (± SD), and range, or frequencies (number of cases) and percentages when appropriate. Comparison of IOP over the study period was done using repeated measure analysis of variance through a general linear model analysis with subsequent paired *t* tests. Correlation between various variables was done using Pearson moment correlation equation for linear relation in normally distributed variables and Spearman rank correlation equation for non-normal variables. *p* values less than 0.05 was considered statistically significant. All statistical calculations were done using computer program SPSS (Statistical Package for the Social Science; SPSS Inc., Chicago, IL, USA) release 21 for Microsoft Windows (7).

RESULTS

This study was conducted on 30 eyes of 21 patients in which the PC pIOL (Implantable Collamer Lens [*ICL*] by STAAR Surgical) was implanted.

It include 11 males (37%)and 19 females (63%), the mean age of which was 28.2 years ±6.01 ranged from 18 to 37 years.

All patient had UCVA of less than 0.05 (3/60) before surgery. The mean pre-operative UCVA was 0.03 (2\60) ± 0.01 ranged from 0.01 (CF at 30cm) to 0.05 (3\60).
The mean post-operative UCVA improved in the first week to 0.49 (6/12) ± 0. 234 then 0.482 (6/12) ± 0. 215 in first month , 0.492 (6/12) ± 0. 236 in 6th month, and 0.498 (6/12) ± 0. 233 in 12th month as shown in table 1 There is ***statistically significant difference*** between pre-operative and post-operative UCVA measured in all visits ***(P < 0.05) as shown in table 1.***

The mean pre-operative BCVA was 0.432 (6\24) ±0.236 ranged from 0.1 (6\60) to 1.0 (6\6). The mean post-operative BCVA improved at first week to 0.59 (6\12) ± 0.205 then 0.620 (6\12) ± 0.209 at first month , 0.623 (6\12) ± 0.217 at 6 months and 0.640 (6\12) ± 0.233 at 12 month. There is ***statistically significant difference*** between pre-operative and post-operative BCVA measured in all visits ***(P < 0.05) as shown in table 1.***

Table (1): Mean (pre-operative and post-operative) visual acuity

	UCVA		***BCVA***	
	Mean	***P value***	***Mean***	***P value***
pre-operative	0.03 (2\60) ± 0.01		0.432 (6\24) ±0.236	
1st week	0.49 (6/12) ± 0. 234	0.000	0.59 (6\12) ± 0.205	0.000
1st month	0.482 (6/12) ± 0. 215	0.000	0.620 (6\12) ± 0.209	0.000
6th month	0.492 (6/12) ± 0. 236	0.000	0.623 (6\12) ± 0.217	0.000
12th month	0.498 (6/12) ± 0. 233	0.000	0.640 (6\12) ± 0.233	0.000

UCVA did not reach the expected VA (target) in 6 eyes (20.0%) though out the study as shown in table 2

Table (2): Expected UCVA (target)

	1st week		**first month**		**six month**		**12 month**	
	Frequency	**Percent**	**Frequency**	**Percent**	**Frequency**	**Percent**	**Frequency**	**Percent**
Above	14	46.7	17	56.7	16	53.3	17	56.7
Below	6	20.0	7	23.3	7	23.3	7	23.3
Target	10	33.3	6	20.0	7	23.3	6	20.0
Total	30	100.0	30	100.0	30	100.0	30	100.0

The mean pre-operative spherical error was -12.8 ± 4.486D ranged from -6.0D to -22D.
The mean post-operative spherical error improved at first week to -0.32 ± 1.77 , then -1.07 ± 1.39 at first month , -0.91 ± 1.51 at 6th months and -0.82 ± 1.30 at 12th months as shown in table 3 . There is *statistically significant difference* between pre-operative and post-operative ***Spherical error*** at all visits *(P < 0.05).*

Table (3): Mean error (pre-operative and post-operative).

	Spherical error		Cylindrical error	
	mean	***P value***	***mean***	***P value***
pre-operative	-12.8 ±4.48D		-2.84 ±1.68	
1st week post operative	-0.32 ± 1.77	0.000	-1.97 ± 1.36	0.030
1st month post operative	-1.07 ± 1.39	0.000	-1.95 ± 1.39	0.021
6th month post operative	-0.91 ± 1.51	0.000	-2.10 ± 1.05	0.032
12th monyh post operative	-0.82 ± 1.30	0.000	-1.99 ± 1.17	0.026

The mean pre-operative cylindrical error was -2.84 ±1.68D ranged from -1D to -7D.
The mean post-operative cylindrical error improved at first week to -1.97 ± 1.36, then -1.95 ± 1.39 at first month , -2.1 ± 1.05 at six months and -1.99 ± 1.17 at 12 months as shown in table 3 . There is *statistically significant difference* between pre-operative and post-operative cylindrical ***error*** at all visits *(P < 0.05).*

• The mean pre-operative IOP was 13.43 ±2.67 mmHg ranged from 10 to 21 mmHg. Which increased to 20.57 ± 5.26 in the first visit then decresed to 16.83 ± 5.71 , 14.67 ± 3.33 and 14.00 ± 1.83 in the following visits . that there is ***statistically significant difference*** between pre-operative and post-operative IOP at 1st week, 1st month, 6rd month ***(P < 0.05)*** and no ***statistically significant difference*** between pre-operative and post-operative IOP at 12th month ***(P > 0.05) as shown in table 4***

Table (4): Mean Intraocular pressure (IOP) and ECC (pre-operative and post-operative)

	Mean IOP	***P value***	***Mean ECC***	***P value***
pre-operative	13.43 ±2.67		2918.63±427	
1st week post operative	20.57 ± 5.26	0.000		
1st month post operative	16.83 ± 5.71	0.001		
6th month post operative	14.67 ± 3.33	0.036	2721.2 ± 538.5	0.023
12th month post operative	14.00 ± 1.83	0.219	2554.30 ± 412.1	0.000

The mean pre-operative Corneal Endothelial Cell Count (ECC) was 2918.63±427 cell/mm² (ranged 2170 -3897 cell/mm²) that decrease at six month to 2721.2 ± 538.5 cell/mm² (ranged 1950 to 3567 cell/mm²) while at the end of study at 12 month reached 2554.30 ± 412.1 cell/mm² (ranged 1747 -3314 cell/mm²) which is statistically significant difference between pre-operative and post-operative ECC at 6th month and 12th month (P < 0.05).
The mean percentage endothelial cell loss was 6.39% at the end of the follow up period (6 months) and 12.91% at the end of the follow up period (12 months)

The ***ICL*** vault (distance from the anterior lens capsule and the center of ICL optic from the posterior surface) was within the ideal range [from ½CCT to 1½ CCT (250 μm to 750μm)] in 23 cases. Five cases were above 1½ CCT (790-1180 μm) (Fig. 1) these eyes have normal IOP and two cases were below ½ CCT (130,140 μm) (Fig. 2) these eyes don't develop anterior sub capsular cataract postoperative in the 12 month postoperative follow up

The mean vault at six month was 549.63 ± 246.07 μm (ranged from 130-1140 μm) while the mean vault at 12 month was 549.63 ± 246.07 μm (ranged from 130 -1180 μm)
Using Pearson Correlation between vault , IOP and between vault, ECC show that there is no ***statistically significant correlation*** between vault and IOP at 6th month and 12th month ***(P > 0.05)*** and no ***statistically significant correlation*** between vault and ECC at 6th month and 12th month ***(P > 0.05) as shown in table 5-7***

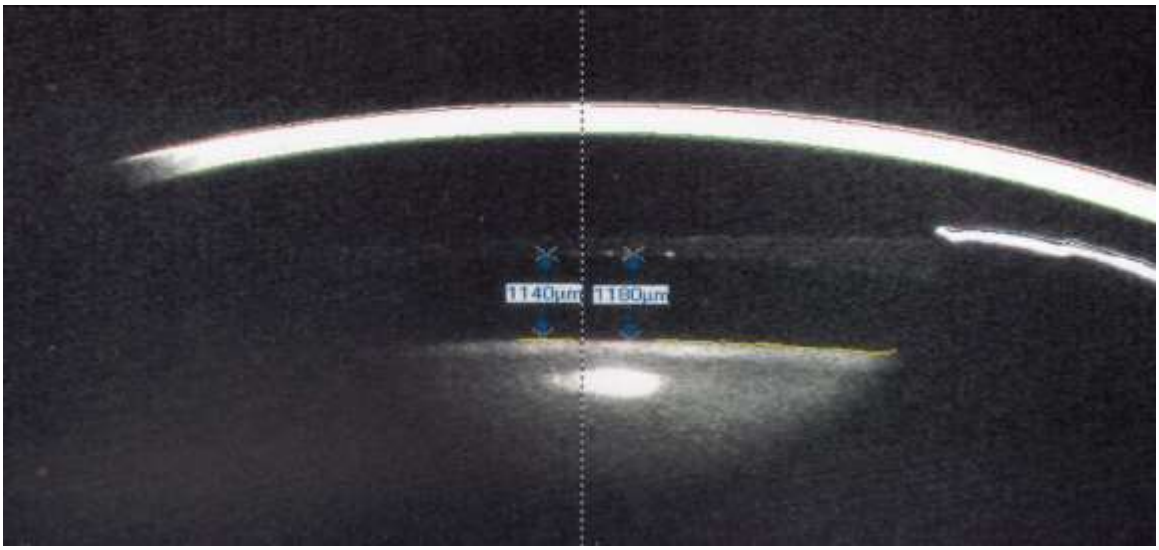


Fig. (1): High vault

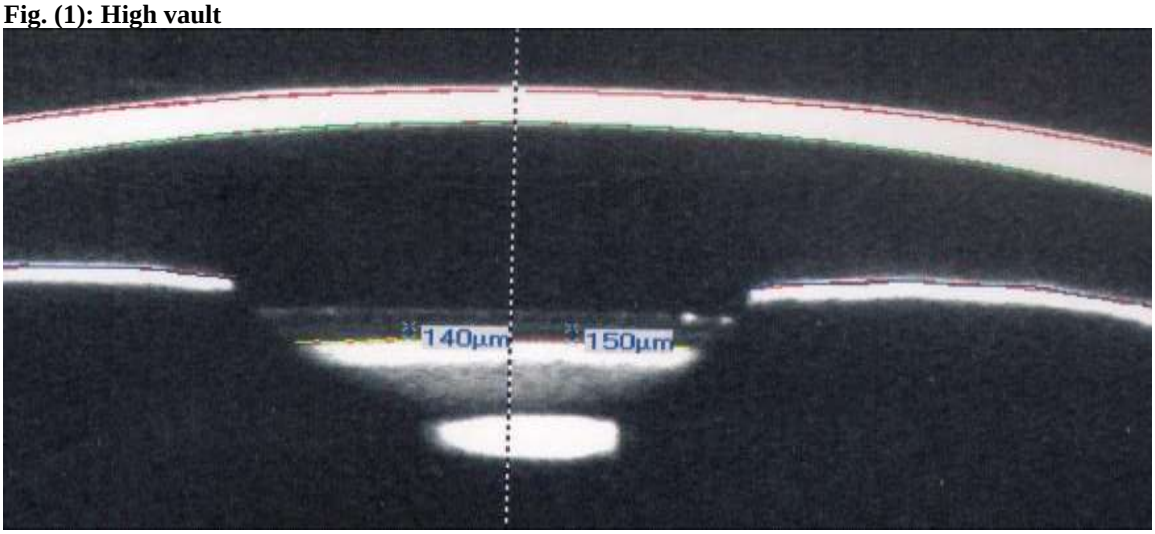


Fig. (2): Low vault

Table (5): Correlation between (vault and IOP) (vault and ECC) at 6and 12months

		Vault-6m	Vault-12m
IOP	Pearson Correlation	0.122	0.059
	p value	0.522	0.758
	N	30	30
ECC	Pearson Correlation	0.321	0.318
	p value	0.084	0.087
	N	30	30

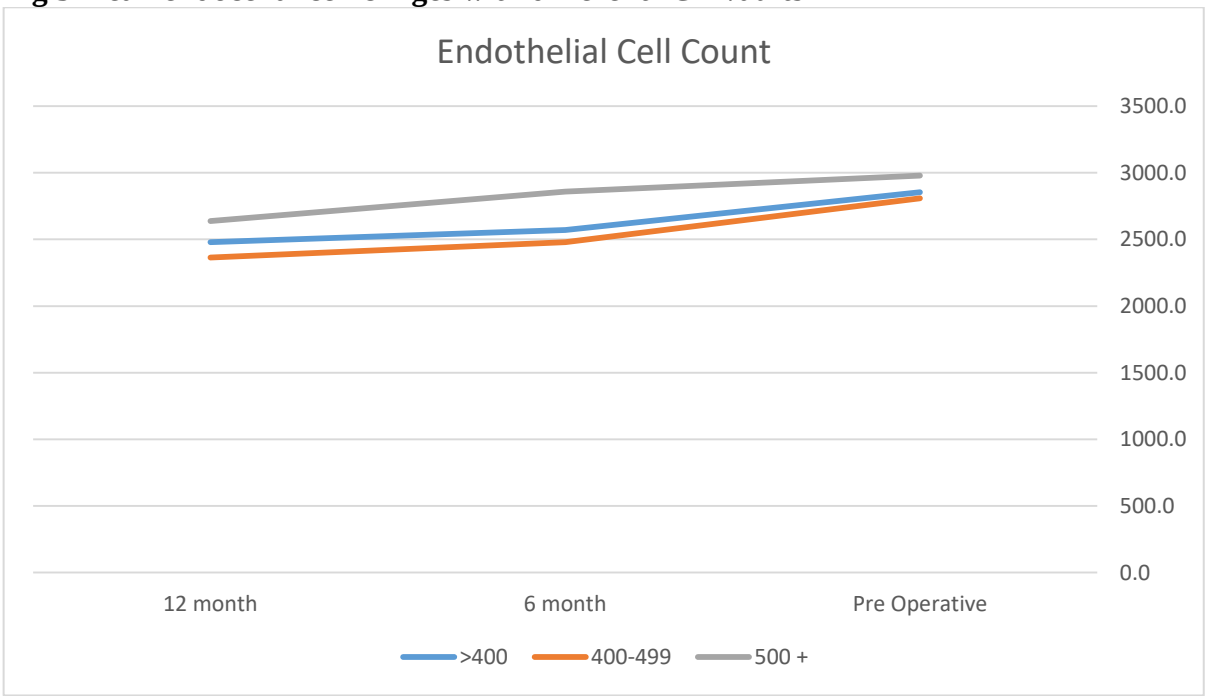
Table (6): analysis of ECC and Vault

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
ECCpre - ECC_A6m	197.4333	450.8368	82.3112	29.0881	365.7786	2.399	29	.023
ECCpre -ECC_B12m	364.3333	295.4039	53.9331	254.0277	474.6390	6.755	29	.000
ECC_A6m - ECC_B12m	166.9000	384.2018	70.1453	23.4367	310.3633	2.379	29	.024
Vault6m - vault_A12m	0.0000	10.2183	1.8656	-3.8156	3.8156	0.000	29	1.000

Table (7): correlatin and statistical analysis between ECC and Vault

	vault (Binned)											
	< 400.0				400.0 - 499.0				500.0+			
	Mean	St.Dv	Minimum	Maximum	Mean	St.Dv	Minimum	Maximum	Mean	St.Dv	Minimum	Maximum
ECCpre	2854.2	417.1	2296.0	3567.0	2807.8	529.0	2170.0	3462.0	2978.8	426.4	2462.0	3897.0
Vault6m	276.7	90.3	130.0	360.0	420.5	21.3	400.0	450.0	724.5	164.3	520.0	1140.0
ECC_A6m	2570.4	421.8	1950.0	3279.0	2479.3	450.5	2050.0	3087.0	2857.9	592.8	2000.0	4567.0
vault_A12m	276.7	90.3	130.0	360.0	420.5	21.3	400.0	450.0	724.5	173.4	517.0	1180.0
ECC_B12m	2479.9	433.4	1747.0	3111.0	2363.3	475.3	1830.0	2967.0	2638.6	389.6	1935.0	3314.0

Fig 3 mean endocelial cell chnges with different ICL vaults



Post-operative Complications:

1) Corneal status:

28 eyes (93%) had a clear cornea in the 1st week postoperative. 2 eyes (7%) had mild edema. by the end of the 1st month postoperative, all corneas (100%) were clear.

2) Uveitis:

We have clinical signs of AC inflammation in 5 eyes (18%) by the end of the 1st week after surgery and we have 1 eye developed endogenous endophthalmitis at 5th day (resolved at end of 2nd week after intraviteral injection and control of septic focus). Clinical signs of AC inflammation had disappeared in all eyes (100%) by the end of the 1st month after surgery.

3) Pupil irregularity:

Pupil irregularity was reported in only one eye (3%) in which visually insignificant and was not accompanied by any other problem.

4) Crystalline lens opacities:

No cases were reported in the 12 month follow up

5) Retinal detachment and Pupillary block:

These complications were not observed in any case.

6) IOL position:

No complication was observed in IOL position in any case

DISCUSSION

The ICL demonstrate reversibility, high optical quality, and potential gain in visual acuity in myopic patients due to retinal magnification; also they are not limited by corneal thickness or topography **[4].**

The drawbacks of ICLs are: anterior subcapsular cataract formation, chafing of the posterior iris and ciliary processes with pigmentary dispersion syndrome, damage to the zonules with dislocation of the IOL in the vitreous, pupillary block glaucoma and malignant glaucoma, chronic uveal inflammation, and macular edema [9] **.** No causative relationship between ICL implantation and retinal detachment has been established **[6].**

For ICLs to be clinically acceptable, they must achieve a high standard of efficacy, predictability, stability and safety. UCVA is the main index used to assess the effectiveness of a refractive procedure[10]**.** The results we got in our study concerning effectiveness, predictability, stability and improvement in visual acuity were similar to many previous studies of ICLs.

After 12 months follow up, The mean post-operative UCVA was 0.498 (6/12) ± 0. 233 ranged from 0.1 (6/60) to 0.9 (6\6). UCVA had reached the expected VA (target) in 6 eyes (20%) and 17 eyes (56.7%) above the target and 7 eyes (23.3%) below target (due to residual astigmastism not corrected by ICL).

The refractive results were stable from 1st week and the BCVA improved from the preoperative values (pre operative mean BCVA 0.432 and 12th months post operative mean BCVA 0.640). Similarly; in a United States FDA study, the ITM study group showed that the ICL had good safety, efficacy and functional results with a low complication rate [7,11]. But Moya et al [12] reported 9% of patients lost more than two lines of vision on the eye chart with glasses.

Regarding glare and halos were complained in three eyes (10%) till one month after surgery that was minimized to only one eye (5%) after two months. This was related to high IOP. By the end of the follow up period; glare and halos were not complained by any patient. This due to control IOP and relatively small mesopic pupil diameter (3.0mm) of almost all selected subjects (the optic diameter ICL 4.5-5.0mm). This was the same explanation as **Senthil et al[13];** who reported no glare and halos after implantation of the ICL in 60 myopic eyes. As for glare reported in ICL; **Menezo et al.[14] , Edelhauser et al [15] and** Chen et

al[8] attributed it to decentration of pIOL greater than 1.0mm. 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[11]**.**

Regarding the cylindrical error; our results reported statistically significant difference between pre-operative and post-operative cylindrical error at pot operative visits (pre operative mean cylindrical error -2.84 and 12th months post operative mean cylindrical error -1.99). Decrease in postoperative cylindrical error this occurred when the incision was coinciding with the axis of the steepest meridian. This was also reported by **Maloney et al[16] and Kamiya et al** reported that the cylindrical error after ICL implantation was 0.45D **.[17].**

No cases of neither pigment dispersion nor lens deposits in had been reported in our study. The Collamer of the ICL inhibits protein adhesion and deposition. However, if the distance between the crystalline lens and ICL is increased, the ICL is closer to the iris with the consequent risk for pigment dispersion[18]**.** Pigmentary reaction was frequently associated with elevated IOP as reported by **Sánchez-Galeana et al [18,]** . Also, **Zaldivar et al [3]** reported that two of 124 eyes showed IOL-related IOP spikes and one of these eyes, with a decentered ICL, had excessive pigment deposition on the ICL surface.

No cases of chronic intraocular inflammation have been reported. Only 5 eyes have clinical signs of AC inflammation at the 1st week and these Clinical signs of AC inflammation had disappeared in all eyes (100%) by the end of the 1st month after surgery.

The ITM study **group[11]** did not detect any long-term inflammation two to three years after ICL implantation **.** Pupil irregularity was reported in only one eye (3%) in which visually insignificant and was not accompanied by any other problem.

There is statistically significant difference between pre-operative and post-operative IOP at 1st week, 1st month, 6th month ($P < 0.05$) and no statistically significant difference between pre-operative and post-operative IOP at 12th month ($P > 0.05$). On the other hand; **Menezo et al [14], and Kamiya et al[17] ;** did not report a statisticaly significant IOP increase after ICL implantation. Cases of elevated IOP in the early postoperative period that were probably related to steroid medication had been found by **Hoyos et al[19], Kodjikian et al[20] and Pineda-Fernández et al [21]**

Due to the position of the ICL, the iris may be pushed forward and cause acute pupillary block glaucoma. The diameter of ICL is involved in this pathophysiological process[22] . Many authors [3,22] stated that, a peripheral iridectomy or iridotomy was necessary to prevent acute pupillary block glaucoma**.** Similarly; preoperative iridotomies become non-permeable over time because they are too small or the haptic of the ICL blocks them. This may cause acute pupillary block glaucoma. A second iridotomy has to be performed in these cases[15] **.** Malignant glaucoma after ICL implantation is rare and has only been described by **Kodjikian [20]** ICL explantation had to be performed. Thereafter, IOP normalized without medical treatment.

In our study; postoperative decentration of ICL had not occurred . Dislocations due to blunt ocular trauma were described by **Maloney et al[16]** . No cases of ICL dislocation or rotation had occurred in our study except one eye due to accurate WTW measurement which was done using the IOL master and by using a caliber while the patient was laying supine which was also advised by **Menezo [14].**

Trindade [23]and AlSabaani [4] reported exchanging an ICL because of oversized length. Malpositioning with a very large vault and under correction occurred because the ICL

was too long. The ICL was exchanged for a smaller ICL with higher power. In a study with a 12-month follow-up, UBM showed ICL rotation in 11% of eyes. Although there was no decentration of the optic, the authors [24] suggest that the diameter of the ICL was too small .

Although; one of the most common expected complications after ICL is cataract formation, yet; we did not report any case of cataract formation. This was explained by **Zaldivar et al[3]** who clarified that the reason why these cataracts develop is depends mainly on the space (vault) between the IOL and the natural lens. When this space is too narrow or even nonexistent (the IOL touching the natural lens) the aqueous humor cannot flow freely around the lens, causing changes in metabolism responsible for the opacities. The metabolic disturbances induced by the implant might also be partially responsible for cataract formation[25]. However, a longer follow up is needed as it may detect more cases of cataract[25].

The same study by **Zaldivar et al [3]** concluded that none of 124 eyes developed lens opacities due to ICL implantation. Nevertheless, one eye developed peripheral lens opacification at the position where Nd:YAG iridotomy which was performed preoperatively[3,26] **.** On the Contrary; **Chen et al[27]** reported that the incidence of cataract was 8.5% for the ICL. **Sanders et al[28]**, stated that 0.6% developed significant lens opacity in the ICL's FDA trial**.** On the other hand, **Gonvers et al[29];** found that the incidence of ICL-induced anterior subcapsular cataract was 27%. Also, these anterior subcapsular opacities were described by Trindade etal[48] and recently by Mayo et al[12] reported 13.88% of patients developed clinically relevant cataracts and many more developed milder cataracts.

Risk factors for cataract include experience of the surgeon, older patient age, preexisting lens opacities **[30]** and excessive postoperative use of steroids [25]. No cases of RD occurred in our study. The study by **Hassaballa and Macky[25]** concluded that none of 26 eyes developed RD due to ICL implantation. Mostly this was due to thorough preoperative and postoperative fundoscopic investigation. On the contrary; Stulting et al[30] reported a RD rate of 0.3% per year after ICL implantation. However; this was similar to RD rates that had been reported in the highly myopic population that did not have refractive surgery [31]. While Panozzo and Parolini [32] recorded four cases of RD after ICL and ITM study group[11] found only three eyes of RD .

The ICL vault (distance from the anterior lens capsule and the center of ICL optic from the posterior surface) was within the ideal range [from ½CCT to 1½ CCT (250 µm to 750µm)] in 23 cases. Two cases were below ½ CCT (130,140 µm) these eyes don't develop anterior sub capsular cataract postoperative till now and five cases were above 1½ CCT (790-1180 µm) these eyes have normal IOP. Similar to our study; El Danasoury, [33] found that the ICL sits away from the corneal endothelium and he concluded that ACD of 2.7mm from the endothelium to the anterior surface of the crystalline lens is estimated as the lower limit for safe ICL implantation.. Also, in the study of Ki-Hwan et al[34] in the UBM method group, ICL vault was within the ideal range in all 13 eyes (100%) at one and six months postoperatively, whereas in the conventional method group, 10 eyes (58.8%) showed ideal vault at one month postoperatively (P=0.01) and 9 eyes (52.9%) showed ideal vault at six months postoperatively (P=0.01). Other studies illustrated that there was a contact between ICL and the posterior surface of the iris using the UBM [22-24].

Moya et al [12] reported Endothelial cell density decreased by 19.75%. while in our study. The mean percentage endothelial cell loss was 6.39% at the follow up visit (6 months) and 12.91% at the end of the follow up period (12 months)

Moreover, anteroposterior movement of the ICL during iris contraction or accommodation led to intermittent central contact **[22,23,30].** Another rare complication is

implantation of a ICL 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 **[4,5]**

CONCLUSION

Our study revealed that ICLs implantation in moderate to 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.

The measurmentr of white to white and centration of ICL is important in the potoperative Vault results

In order to avoid implantation of undersized or oversized ICL and to prevent postoperative rotation or decentration of the pIOL, accurate preoperative white to white measurement using the IOL master or a caliber is mandatory.

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