# Long term safety and efficacy of iris claw versus scleral fixated intraocular lens for management of ectopia lentis

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**Short title:** Iris claw versus scleral fixated intraocular lens for management of ectopia lentis

**Abstract**

**Propose:** to compare between iris claw anterior chamber intraocular lens (ACIOL) and scleral fixated posterior chamber (PCIOL) regarding long term safety and efficacy in cases with ectopia lentis.

**Patients and methods:** This cohort study was conducted at Mansoura Ophthalmic Center, faculty of medicine, Mansoura University. It included 59 eyes of 34 patients who underwent surgery for ectopia lentis with IOL implantation (30 eyes with scleral fixation IOL & 29 eyes with Iris claw ACIOL) in the period from May 2010 to January 2014. All cases were subjected to history taking, full ophthalmological examination (visual acuity, cyclorefraction, anterior and posterior segment examination), endothelial cell density (ECD), central macular thickness (CMT). Regular follow up visits were scheduled to assess the efficacy and complication of each approach.

**Results:** Visual acuity and refraction showed significant improvement after surgery in both groups without significant difference. Endothelial cell density decreased significantly in both groups compared to the preoperative values. Moreover, the scleral fixation group showed significant increase in macular thickness compared to its preoperative values. However, no significant difference was detected between the two groups. Lens displacement occurred in 4 and 11% of cases in both groups respectively.

**Conclusion:** Both iris claw ACIOL and scleral fixated PCIOL are safe and effective techniques in the management of ectopia lentis.

**Keywords:** ACIOL, PCIOL, IOL, ectopia lentis.

## INTRODUCTION

Ectopia lentis is partial displacement of the crystalline lens of the eye. It might be congenital or acquired (50% traumatic)[1]. However the underlying pathophysiology is the same in the form of zonular disruption or dysfunction that affect the degree of lens displacement[2].

Although it is a rare entity, it is considered the most common congenital anomaly of the lens that might be sporadic or associated with diseases like Marfan syndrome, Weil-Marchesani syndrome, and homocystinuria[3].

Visual disturbances are the commonest presentation including; eye redness and pain (due to trauma or secondary glaucoma), diminished distance visual acuity (due to myopia or astigmatism), decreased near vision (due to loss of accommodation), and monocular diplopia[4].

Treatment of ectopia lentis is challenging. It varies from optical correction of refractive errors,[3] pharmacological mydriasis,[5] partially occlusive contact lenses,[6] LASER pupilloplasty using iris photocoagulation, and LASER zonulysis using Nd- YAG LASER[7] to surgical intervention. However, the optimal surgical technique is still under debate. Multiple available options includes intracapsular cataract extraction or lensectomy, and anterior chamber open loop IOL, iris claw ACIOL, posterior iris fixated IOL, in the bag PCIOL or scleral fixated PCIOL[8].

Scleral suture fixation of PCIOL is more commonly used in the correction of aphakic eyes without sufficient capsular support and some scholars accept it as the mainstream operation method for this kind of patients[9].

In cases of lens removal with no capsular support, iris claw ACIOL implantation has been used more commonly over the last two decades[10,11]. Many studies have evaluated the primary outcome of such techniques. However, they did not emphasis its long-term effect. This study was aiming to compare between iris claw ACIOL and scleral fixated PCIOL regarding long term safety and efficacy in cases with ectopia lentis.

**PATIENTS AND METHODS**

This cohort study was conducted at Mansoura Ophthalmic Center, faculty of medicine, Mansoura University on 34 patients who underwent surgical correction of ectopia lentis by pars plana lensectomy, anterior vitrectomy and secondary IOL implantation (either scleral fixated PCIOL or iris claw ACIOL) from May 2010 to January 2014.

Preoperative data, postoperative follow up to 6 months were retrieved from patient files. Patients diagnosed preoperatively with ectopia lentis bisecting pupil, ectopia lentis with monocular diplopia, ectopia lentis with anisometropia and high refractive or astigmatic error, ectopia lentis associated with cataract, or impending lens dislocation were included in the study. Patients with incomplete preoperative data, history of surgery less than 7 years, missed follow up, those having preoperative corneal surface irregularities, anterior or posterior lens dislocation, posterior segment pathology interfering with the visual outcome, glaucoma, or uveitis were excluded from our study.

The whole study group was divided into two groups; group A: included 30 eyes underwent scleral fixated PCIOL, while group B: included 29 eyes underwent Iris claw ACIOL.

At the scheduled follow up visits (1, 2, 3, 4, 5, 6, 7) years postoperatively, all cases were subjected to thorough ophthalmological examination (including uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), slit lamp biomicroscopy, direct and indirect ophthalmoscopy, and refraction), endothelial cell density (ECD) by Tomey specular microscope (EM- 3000, Erlangen, Germany), and measurement of central macular thickness (CMT) using OCT Topcon spectral domain optical coherence tomography (3D OCT-1000,Tokoyo, Japan). An informed consent was obtained from all the patients involved in the study.

**Statistical analysis**

IBM's SPSS statistics for windows (version 25, 2017) was used for statistical analysis of the collected data. Shapiro-Wilk test was used to check the normality of the data distribution. All tests were conducted with 95% confidence interval. P (probability) value $< 0.05$ was considered statistically significant. Quantitative variables were expressed as mean and standard deviation while categorical variables were expressed as frequency and percentage. Independent sample T and Mann Whitney tests were used for inter-group (between subjects) comparison of parametric and non-parametric continuous data with no follow up readings respectively. Repeated measures ANOVA or linear mixed model with unstructured co-variance and maximum likelihood (ML) were used for analysis of longitudinal data (follow-up readings) according to the fulfillment of their assumptions. Bonferroni adjustment of p value was applied for the model used. Fisher exact and Chi square tests were used for inter-group comparison of nominal data using the crosstabs function. A survival analysis was conducted using Kaplan-Meier graph to assess the median duration for lens displacement in the treated patients. Reading from both groups were compared using the log rank test.

**RESULTS**

This study was carried out on 59 eyes of 34 patients with ectopia lentis, including 18 males (53%) and 16 females (47%), The mean age of the studied patients was $11.51 \pm 4.94$ years Table (1). 30 eyes with scleral fixated PCIOL (group A) and 29 eyes with iris claw ACIOL (group B).

Eighteen patients had bilateral different surgical technique while 7 patients had bilateral same surgical technique, 4 in group (A) and 3 in group (B). The remaining 9 patients had unilateral surgical technique.

Types of ectopia lentis are shown in Table (1), including simple, familial, and traumatic ectopia lentis, ectopia lentis et pupillae, Marfan syndrome, and Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency.

**Table (1):** Demographic data and types of ectopia lentis among studied patients.

| **Patients total number = 34** | | |
|---|---|---|
| **Age** | 11.51 ± 4.94 | |
| **Gender** | **Male** | 18 (53 %) |
| | **Female** | 16 (47 %) |
| **Type** | **EL et pupillae** | 1 (3 %) |
| | **Familial** | 8 (23 %) |
| | **G6pd** | 2 (6 %) |
| | **Marfan** | 13 (38 %) |
| | **Simple** | 6 (18 %) |
| | **Traumatic** | 4 (12 %) |

Throughout the scheduled follow up visits, both groups showed a significant improvement compared to the preoperative values ($p > 0.05$). Moreover, there was no significant difference between the two groups regarding the degree of improvement ($p < 0.05$) as demonstrated in Table (2) and figure (1).

**Table (2):** Preoperative and follow-up values of visual acuity in study groups.

| **VA** | **Group (A) (n= 30)** | **Group (B) (n= 29)** | **95% CI** | **p** |
|---|---|---|---|---|
| **Preoperative** | 0.07 ± 0.023 | 0.07 ± 0.026 | -0.012, 0.014 | 0.89 |
| **6 months** | 0.46 ± 0.228* | 0.54 ± 0.234* | -0.192, 0.040 | 1.00 |
| **1 year** | 0.47 ± 0.225* | 0.54 ± 0.234* | -0.182, 0.049 | 0.26 |
| **2 years** | 0.47 ± 0.231* | 0.54 ± 0.234* | -0.188, 0.045 | 0.23 |
| **3 years** | 0.48 ± 0.233* | 0.54 ± 0.234* | -0.188, 0.045 | 0.23 |
| **4 years** | 0.48 ± 0.233* | 0.53 ± 0.238* | -0.188, 0.045 | 0.23 |
| **5 years** | 0.48 ± 0.237* | 0.53 ± 0.238* | -0.188, 0.045 | 0.23 |
| **6 years** | 0.48 ± 0.237* | 0.54 ± 0.238* | -0.188, 0.045 | 0.23 |
| **7 years** | 0.47 ± 0.235* | 0.54 ± 0.238* | -0.192, 0.040 | 1.00 |

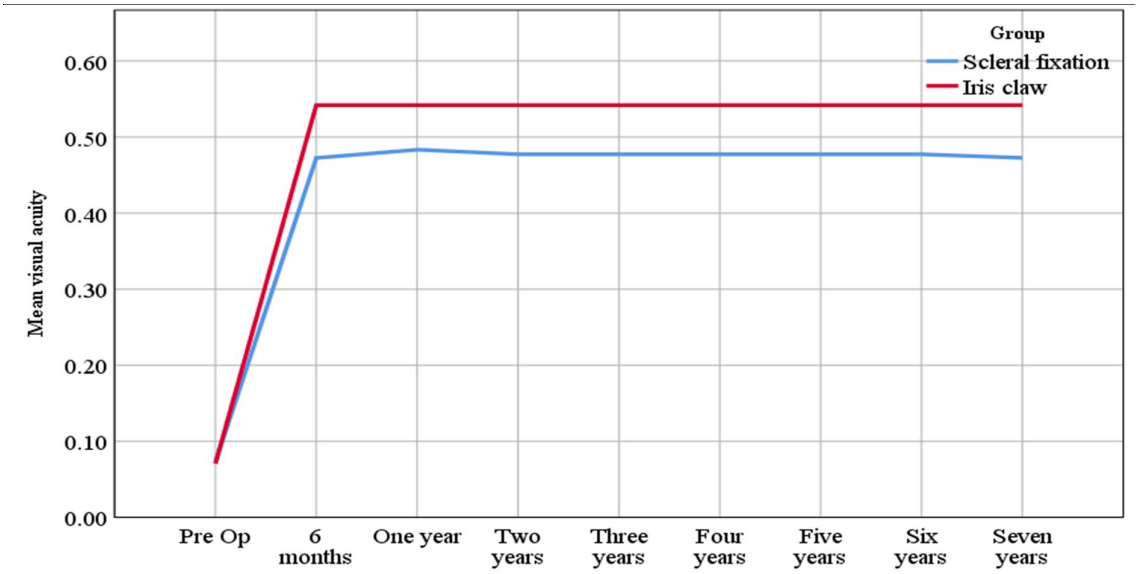


**Figure (1):** Chart showing visual acuity changes in study groups.

Both study groups showed a significant refractive improvement when compared to the preoperative values. However, no significant difference was detected between the two groups. Table (3) and figure (2) illustrate these data.

**Table (3):** Preoperative and follow-up values of refraction in study groups.

| Refraction | Group A (n= 30) | Group B (n= 29) | 95% CI | p |
|---|---|---|---|---|
| **Preoperative** | -7.34 ± 1.906 | -7.78 ± 1.760 | -0.618, 1.511 | 0.40 |
| **6 months** | -0.22 ± 1.338* | -0.19 ± 1.361* | -0.726, 0.656 | 0.92 |
| **1 year** | -0.24 ± 1.348* | -0.21 ± 1.371* | -0.731, 0.662 | 0.92 |
| **2 years** | -0.53 ± 1.319* | -0.47 ± 1.420* | -0.715, 0.698 | 0.98 |
| **3 years** | -0.78 ± 1.415* | -0.72 ± 1.498* | -0.726, 0.764 | 0.96 |
| **4 years** | -0.33 ± 1.361* | -0.24 ± 1.384* | -0.759, 0.636 | 0.86 |
| **5 years** | -1.00 ± 1.423* | -0.99 ± 1.454* | -0.746, 0.714 | 0.97 |
| **6 years** | -0.31 ± 1.375* | -0.24 ± 1.410* | -0.768, 0.628 | 0.84 |
| **7 years** | -0.60 ± 1.343* | -0.60 ± 1.470* | -0.699, 0.714 | 0.98 |

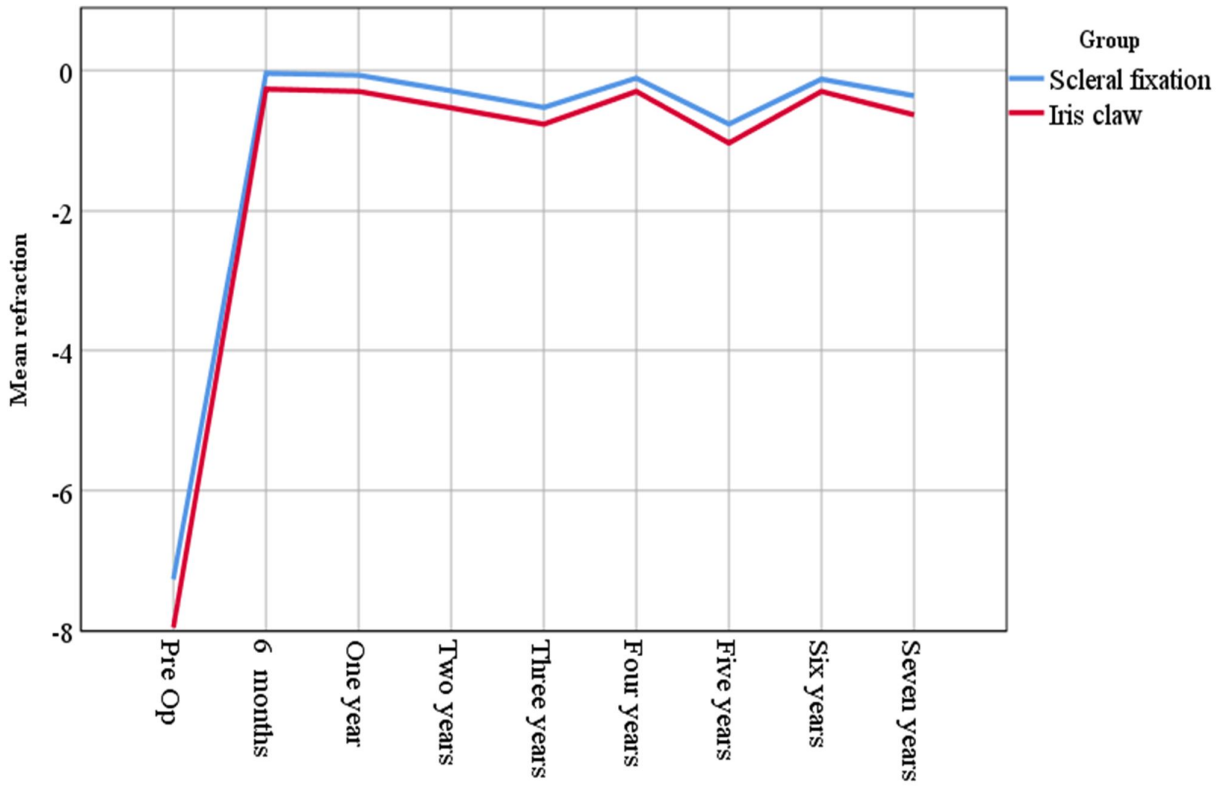


**Figure (2):** Chart showing refraction changes in study groups.

There was no significant difference between the two groups regarding CMT before or after operation. Nevertheless, the scleral fixation group showed significant increase compared to its preoperative value, and that significant increase was evident 1-month after operation and extended throughout the following visits as illustrated in Table (4) and figure (3).

**Table (4):** Preoperative and follow-up values of CMT in study groups.

| CMT | Group A (n= 30) | Group B (n= 29) | 95% CI | p |
|---|---|---|---|---|
| **Preoperative** | 189.20 ± 16.58 | 197.17 ± 24.10 | -18.53, 2.59 | 0.136 |
| **1 Day** | 188.20 ± 20.70 | 194.55 ± 19.66 | -16.70, 3.99 | 0.224 |
| **1 Week** | 196.43 ± 20.43 | 197.76 ± 25.05 | -13.01, 10.36 | 0.821 |
| **1 month** | 204.03 ± 22.70* | 198.90 ± 28.44 | -8.02, 18.29 | 0.438 |
| **3 months** | 205.37 ± 17.86* | 200.48 ± 23.83 | -5.88, 15.64 | 0.367 |
| **6 months** | 203.20 ± 15.73* | 200.31 ± 22.17 | -6.93, 12.71 | 0.558 |
| **1 year** | 205.33 ± 20.96* | 195.55 ± 28.05 | -2.87, 22.43 | 0.127 |
| **2 years** | 204.48 ± 19.84* | 199.10 ± 23.48 | -5.33, 16.82 | 0.303 |
| **3 years** | 204.57 ± 19.30* | 200.69 ± 23.92 | -7.89, 14.17 | 0.571 |
| **4 years** | 205.71 ± 21.97* | 194.46 ± 32.11 | -4.62, 23.40 | 0.185 |
| **5 years** | 205.33 ± 22.97* | 196.29 ± 22.91 | -2.84, 20.17 | 0.137 |
| **6 years** | 204.41 ± 20.71* | 199.07 ± 26.68 | -6.92, 17.21 | 0.397 |
| **7 years** | 206.04 ± 21.11* | 193.63 ± 30.82 | -2.85, 24.04 | 0.120 |

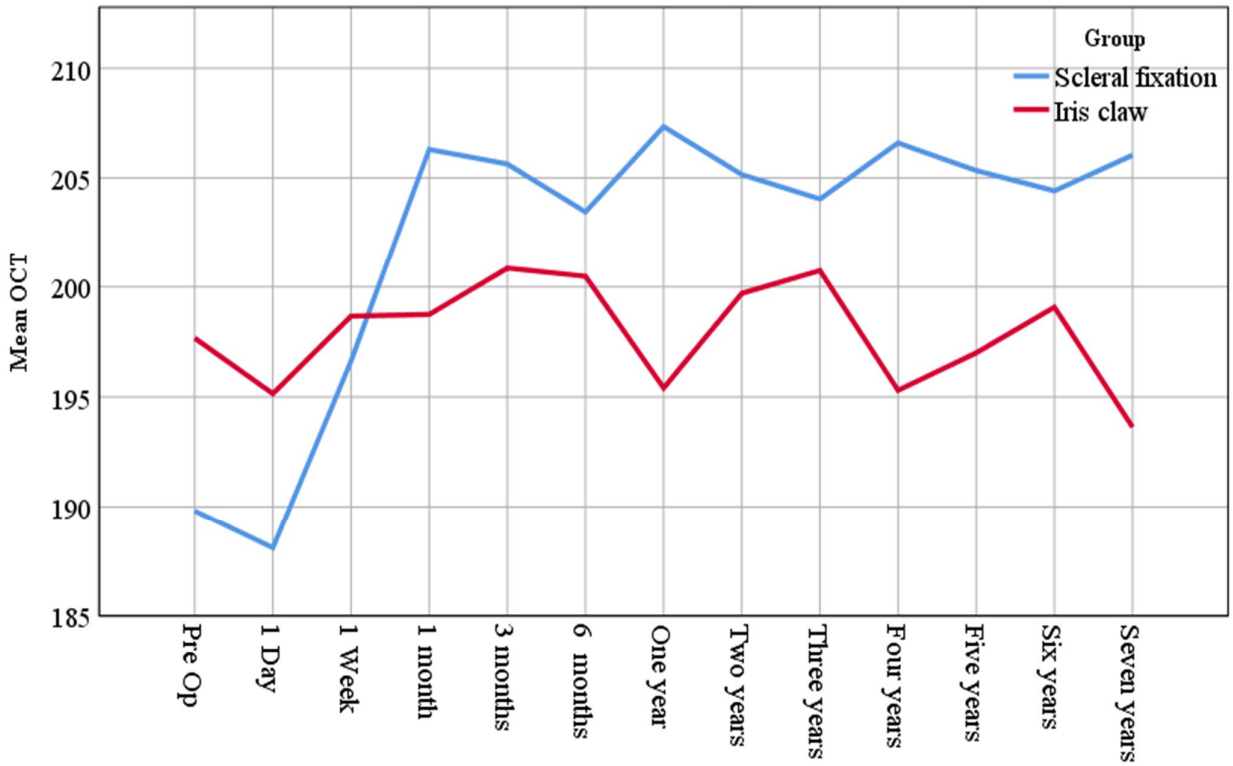


**Figure (3):** Chart showing CMT changes in the study groups.

Endothelial cell density showed a significant decrease in both study groups compared to their preoperative values ($p < 0.05$). However, no significant difference was detected between the two groups regarding that parameter ($p > 0.05$). These data are illustrated at table (5) and figure (4).

**Table (5):** Preoperative and follow-up values of ECD in both groups.

| ECD | Group A (n= 30) | Group B (n= 29) | 95% CI | p |
|---|---|---|---|---|
| **Preoperative** | 3217.37 ± 329.50 | 3244.93 ± 294.52 | - 187.777, 132.649 | 0.732 |
| **1 Day** | 3088.93 ± 383.27* | 3150.41 ± 341.40* | -247.558, 124.597 | 0.511 |
| **1 Week** | 3095.43 ± 374.85* | 3115.79 ± 341.40* | -204.136, 163.416 | 0.825 |
| **1 month** | 3052.10 ± 393.74* | 3046.31 ± 425.21* | -203.949, 215.529 | 0.956 |
| **3 months** | 3082.83 ± 388.68* | 2999.66 ± 410.85* | -121.554, 287.911 | 0.420 |
| **6 months** | 3053.63 ± 379.09* | 2989.69 ± 412.86* | -138.900, 266.788 | 0.531 |
| **1 year** | 3034.77 ± 381.21* | 2984.38 ± 412.15* | -152.801, 253.576 | 0.622 |
| **2 years** | 3018.10 ± 377.86* | 2993.59 ± 417.96* | -193.128, 215.048 | 0.915 |
| **3 years** | 2982.11 ± 376.02* | 2976.72 ± 407.54* | -199.779, 199.870 | 1.000 |
| **4 years** | 2951.00 ± 379.28* | 2961.46 ± 406.34* | -241.419, 164.647 | 0.707 |
| **5 years** | 2915.78 ± 381.28* | 2957.18 ± 413.23* | -266.432, 142.229 | 0.545 |
| **6 years** | 2884.26 ± 383.76* | 2970.56 ± 418.84* | -299.571, 110.498 | 0.360 |
| **7 years** | 2856.63 ± 381.33* | 2976.52 ± 405.35* | -329.873, 70.998 | 0.201 |

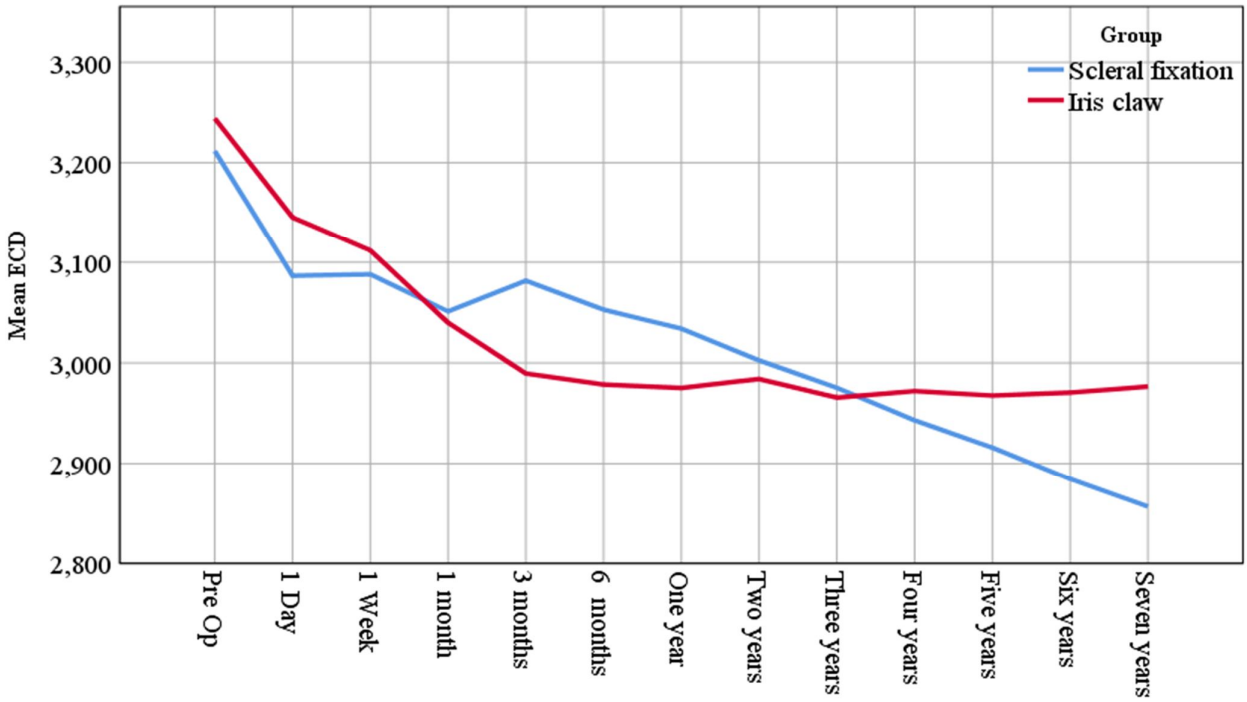


**Figure (4):** Chart showing endothelial cell density changes in the study groups.

one case out of 30 in group (A) and 3 out of 29 in the group (B) showed displacement of the implanted IOL at 39, 17, 22 and 32 months respectively. No significant difference was found regarding the incidence of lens displacement (3% vs 10%, 95% CI -0.06, 0.21, p 0.61) or its timing (95% CI -8.69, 11.94, p 0.18) in both groups. A survival analysis was conducted using Kaplan Meier's long rank test to determine the median period for lens displacement. Survival analyses are shown in table (6).

**Table (6):** Comparing both groups regarding lens displacement.

| Group | Median | $\chi^2$ | p |
|---|---|---|---|
| **Group A** | More than 7 years | 1.12 | 0.29 |
| **Group B** | More than 7 years | | |

P is significant when < 0.05.

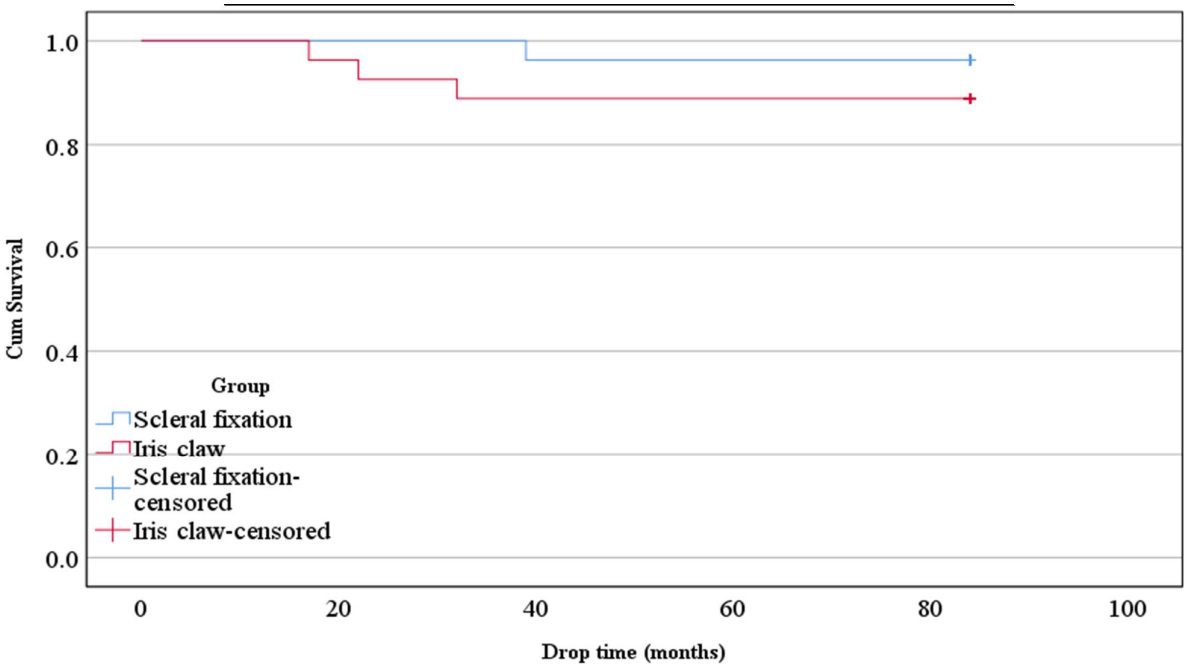


**Figure (5):** Kaplan Meier survival analysis.

## DISCUSSION

Management of ectopia lentis presents two main challenges. The first one is the removal of the crystalline lens with preservation of the capsular bag avoiding corneal endothelium damage and vitreous disturbance; the second challenge is correction of aphakia with favorable and long-standing outcome[2].

The choice of the intraocular lens, include anterior chamber open loop IOL, iris claw ACIOL, in the bag PCIOL, posterior chamber scleral fixated or posterior iris fixated IOL depends on the clinical and surgical situation[1].

This study was conducted at Mansoura Ophthalmic Center aiming to compare between iris claw and scleral fixated IOL regarding safety and efficacy in cases with ectopia lentis. we included a total of 59 eyes of 34 patients who were divided into two groups; group (A) which included 30 eyes who underwent pars plana lensectomy, anterior vitrectomy, scleral fixated PCIOL, and group (B) included the remaining 29 eyes who underwent pars plana lensectomy, anterior vitrectomy, iris claw ACIOL. There was no significant difference between the two groups regarding demographics and general characteristics.

To the best of our knowledge, there is a paucity of studies conducted comparing these two surgical techniques in such cases.

Another Egyptian study conducted at Zagazig University comparing the same approaches in aphakic cases included a total of 42 subjects who were divided into 2 equal groups; 21 cases for each group[12]. However, that study was conducted for aphakic cases not ectopia lentis as the current study.

In our study, throughout the scheduled follow up visits, both groups showed a significant improvement in BCVA compared to the preoperative values ($p > 0.05$). Moreover, there was no significant difference between the two groups regarding the degree of improvement ($p < 0.05$). It increased from 0.07 in both groups before operation up to 0.47 and 0.54 after 7 years in the scleral fixated and iris claw IOL groups respectively.

In another study, BCVA was significantly improved in both groups after surgery. Although there was significant

improvement in the scleral fixation group on the first post-operative day ($p = 0.0002$), subsequent assessment revealed no difference between the two groups till 3-month follow up ($p > 0.05$)[12]. The results of that study agree with our findings.

Farrahi and his associates[13] found that the iris claw IOL group had better BCVA results compared with the scleral fixated IOL group at final follow-up ; BCVA of 20/40 or greater was present in nine (75%) iris claw cases versus five (38%) scleral fixation cases. However, the study was carried on fewer numbers of patients than our study.

Another study evaluated iris claw lenses for aphakic cases. After 6 months, authors reported that 80% of patients had visual acuity of 20/40 or better[14].

Luk and colleagues[15] reported that visual acuity improved or remained unchanged in 72.1% of cases after scleral fixation, while the remaining 27.9% reported poorer visual acuity compared to their preoperative values.

In the current study, there was no statistically significant difference between the two groups regarding CMT before or after operation. Nevertheless, the scleral fixation group showed statistically significant increase compared to its preoperative value, and that significant increase was evident 1-month after operation and extended throughout the following visits. However, that increase was clinically insignificant.

Various studies reported a wide variation in the incidence of cystoid macular edema (CME) with IOLs. The incidence CME of after scleral fixated PCIOL was 0% to 7.6%[16,17] and after iris claw ACIOL was 7.7% in a study carried out by De Silva et al.[18] with a chronic CME incidence of 0.8%.

It has been reported that CME is the leading cause of poor visual outcome after implantation of posterior chamber lenses. This is always attributed to the initial pathology, which is present in the eye before fixation. In a previous study, CME was detected in 19.1% of cases of the iris-claw group, while it was present in 9.5% of scleral fixated IOL group[12].

Hazar and his colleagues[19] reported that CME occurred in 8.3 and 3.2% of cases in the iris claw and scleral fixated IOL groups respectively.

Furthermore, Farrahi et al.[13] reported that one case (8.3%) developed CME in the scleral fixated IOL group, while no cases developed that complication in the iris claw IOL group.

In the current study, ECD showed a statistically significant decrease in both study groups compared to their preoperative values ($p < 0.05$). However, no significant difference was detected between the two groups regarding that parameter ($p > 0.05$). It decreased from 3217.37 and 3244.93 down to 2856.63 and 2976.52 in scleral fixated and iris claw IOL groups respectively. This was similar to scholar that demonstrated ECD ranges from 3160 to 3727 cells/mm$^2$ at the age of 7.5 years, from 2695 to 3342 cells/mm$^2$ at the age of 13 years[20].

Another study has confirmed our findings as there was no significant difference between the two groups for 1 year after surgery[9].

Most studies confirm the initial endothelial loss and the long-term stability of ECD, with a 8.3% to 9% endothelial cell loss after 5 years[21]. The initial loss of endothelial cells after implantation can be explained by intraoperative trauma to the endothelium by operating instruments or the optic itself[22]. However, those studies were carried on phakic iris claw ACIOL and their results cannot be applied on the aphakic iris claw ACIOL.

In the current study, 1 case out of 30 in group (A) and 3 out of 29 in group (B) showed displacement of the implanted IOL at 39, 17, 22 and 32 months respectively. No significant difference was found regarding the incidence of IOL displacement (3% vs 10% - $p = 0.61$) or its timing ($p = 0.18$) in both groups.

In the previously mentioned Egyptian study, no cases of IOL dislocation were recorded in both study group[12]. This could be explained by the short term follow up period scheduled in that study (3 months) compared to ours.

On the other hand, another study reported that IOL dislocation occurred in 1.7% of cases,[18] while other authors reported that the same complication occurred in 8.7% of cases after iris claw IOL implantation[23].

Ohta et al.[24] reported that dislocation occurred in 5% of cases following intrascleral fixation, whereas it occurred in 18% of cases following IOL suture fixation.

More studies should be conducted on a larger sample size regarding the same perspective in the future.

In conclusion, based on our findings, it appears that both scleral fixated and iris claw IOL having a long-term safety and efficacy in management of ectopia lentis.

**DATA AVAILABILITY**

All data are included in this article.

**ACKNOWLEDGEMENT**

None

**Conflict of Interest**

Authors declare no conflicts of interest.

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**Ethics declarations**

**Conflict of interes**t

Walid M Gaafar, Dina Abd Elfattah, Sara A Gawad, Adel Ellayeh, Rania M Bassiouny. all authors have no conflicts of interest that are directly relevant to the content of this review.

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