

Comparative study between iris – claw and scleral – fixated intraocular lens in patients with aphakic eye

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虹膜夹型与巩膜固定型人工晶状体在无晶状体眼患者中的疗效比较

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摘要

目的: 分析无晶状体患者虹膜夹型人工晶状体 (ICIOL) 与巩膜固定型人工晶状体 (SFIOL) 在视力、手术时间及术后并发症方面的疗效。

方法: 前瞻性研究。共纳入 2018-10/2020-02 在我院门诊就诊的 60 例 60 眼无晶状体眼患者。将所有患者分为两组, 每组各 30 例。组 I 患者行 ICIOL 植入术, 组 II 患者行 SFIOL 植入术。筛除既往有眼部病变和视网膜手术史患者。术前、术后随访 9mo。

结果: 随访 9mo 后, ICIOL 组中 26 例 (87%) 患者, SFIOL 组中 24 例 (80%) 患者达到最佳矫正视力 (BCVA, LogMAR) 为 0.50~0.00。两组 BCVA 均值具有可比性。ICIOL 组手术时间较 SFIOL 组更短 ($P < 0.01$)。SFIOL 组并发症明显增多, 而 ICIOL 组的并发症较少。

结论: 两组的视觉结果具有可比性。在无晶状体矫正中, ICIOL 并发症少, 手术时间短, 是较 SFIOL 更好的手术方式。

关键词: 无晶状体; 后囊; 白内障; 虹膜夹型人工晶状体; 巩膜固定型人工晶状体; 疗效比较

Abstract

• **AIM:** To analyze the efficacy of iris-claw intraocular lens (ICIOL) and scleral-fixator intraocular lens (SFIOL) in terms of visual outcomes, surgical time, and postoperative complications in the aphakic patients.

• **METHODS:** This study was a prospective study with 60

aphakic eyes of 60 patients who attended our outpatient department from October 2018 to February 2020. These patients were divided into two groups and each with 30 patients. Patients in Group I were underwent ICIOL whereas patients in Group II underwent SFIOL implantation. Patients with pre-existing ocular pathologies, previous history of retinal surgery of the eye were excluded. The preoperative and postoperative evaluation was done for the follow up period of 9mo.

• **RESULTS:** Twenty-six (87%) patients in the ICIOL group and 24 (80%) patients in SFIOL group had best corrected visual acuity (BCVA, LogMAR) with 0.50–0.00 after 9mo follow up. The mean of BCVA (LogMAR) was comparable in both the groups. The surgical time in ICIOL was significantly less than the SFIOL group ($P < 0.01$). Complications related to sutures were significantly more in the SFIOL group. Complications found in the ICIOL group were very mild and harmless.

• **CONCLUSION:** The visual outcome was comparable in both groups. ICIOL with fewer complications and requiring less surgical time was found to be a better alternative to SFIOL in the correction of aphakia.

• **KEYWORDS:** aphakia; posterior capsule; cataract; iris-claw intraocular lens; scleral-fixated intraocular lens; efficacy comparison

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INTRODUCTION

Extracapsular cataract surgery is meant for implantation of the posterior chamber intraocular lens (PCIOL) in the posterior capsular bag. However, the implantation of PCIOL is not advisable in case of weak or no capsular support. In such situations, the iris-claw intraocular lens (ICIOL) or scleral-fixated intraocular lens (SFIOL) remains the treatment of choice.

The lens capsule is an elastic membrane that contains a crystalline lens. The thickest part of the capsule is located near the equator and the thinnest part of the capsule is located at the posterior pole^[1]. Extracapsular cataract surgery which is preferred surgery nowadays involves implantation of PCIOL in the intact posterior capsular bag. However, the implantation of PCIOL is not advisable in case of weak or no capsular support. In such cases, anterior chamber IOL, ICIOL, and SFIOL are

the different types of IOL used for providing better visual acuity to the patient^[2-5]. The technique for fixation of ICIOL behind the pupil was reported by Andres Mohr in 2002^[6]. This procedure takes less surgical time, preserves the anatomy of the anterior segment of the eye concerning the position of the natural crystalline lens, and also has added cosmetic benefit with the low-risk method of surgery. There are also few disadvantages of ICIOL such as dislocation, deformation of the pupil, and iris atrophy^[5]. SFIOL provides a good visual outcome but it is associated with certain complications such as retinal detachment, decentration and tilting of IOL, cystoid macular edema, and a difficult learning curve^[5-6].

SUBJECTS AND METHODS

It was an interventional prospective comparative study. Aphakic patients that presented to our outpatient department and the aphakic patients of our operation theatre (OT) at Hind Institute of Medical Sciences were included in our study during the study period from October 2018 to February 2020. Sixty patients were included in our study and were allotted into two groups by simple randomization method. Patients were asked to pick up a slip from a bowl, accordingly, they were assigned to Group I and Group II, with 30 patients in each group. Patients of Group I were operated and ICIOL was implanted in them whereas in patients of Group II SFIOL was implanted. The period of our study was limited to 2y, the sample size was taken as 60. The study was done after obtaining ethical clearance from the Ethics Committee of the Hind Institute of Medical Sciences. Adult patients aged between 25-75 years with aphakia resulting in secondary to surgery or trauma, in whom visual acuity was improving more than LogMAR 0.80 with aphakic correction were included in the study. Patients with pre-existing ocular pathology were excluded from the study. Preoperative evaluation of patients including visual acuity, aphakic correction, slit-lamp examination, IOP measurement, and detailed fundus examination was done. Preoperative biometric values were also considered in aphakia patients, and IOL power was calculated computing 'A' constant of the IOL being used in the surgery. ICIOL was used with 'A' constant 115 and SFIOL was used with 'A' constant of 118.5. Both the surgical procedures were done under local anesthesia. Two different surgeons, an expert in either technique performed the surgeries. Anterior vitrectomy was performed in both groups in all the patients.

In the ICIOL technique, intraoperative miosis was achieved using 0.2 mL of 0.5% intracameral pilocarpine. Holding the optic with ICIOL holding forceps, both the haptics are tucked behind the iris one after the other. Viscoelastic was injected at each stage to maintain the anterior chamber. In SFIOL, two scleral flaps (partial thickness) 2 mm posterior to the limbus was made at the 3 o'clock and 9 o'clock positions, 180° apart. A double arm 100 proline suture was used with a straight needle. The needle was guided out of the eye through the base of the opposite scleral flap using a 26 g bent needle introduced

through the scleral bed. A limbal section was made and the sutures were taken out of the eye and cut into two halves. One-piece, polymethyl methacrylate lens with bigger optic was used for the scleral fixation surgery. After introducing the IOL into the posterior chamber, the sutures were tied. The suture knots were buried and the scleral flaps were sutured. Subconjunctival gentamicin and dexamethasone 0.5 cc was injected at the end of both the procedures. Postoperative patients of both the groups were started on topical antibiotics with steroid combination, one drop 2 hourly for the first 2d and gradually tapered over the subsequent follow ups. Postoperative examination and evaluation were done on 1, 7d, 1, 3, 6, and 9mo. Best corrected visual acuity (BCVA) was done in the 6mo and rechecked at 9mo. The visual acuity evaluated on Snellens was converted into logarithm of the minimum angle of resolution (LogMAR) units for the statistical analysis. The results were analyzed using the software Statistical Package for the Social Sciences (SPSS) version10 (IBM statistics, Chicago, USA), including the Chi-square test and *t*-test. $P < 0.05$ was considered as statistically significant value for our study.

RESULTS

Out of 60 patients included in our study, 41 (68%) were males, and 19 (32%) females. The mean age of the patients was 64.3 years, with most of the patients between 60-70 years. According to age and sex of the patients matching of both the groups was done. The most common cause for aphakia among patients in our study was complicated cataract surgery. Three patients had traumatic nucleus drop and two patients had to post-cataract surgery IOL drop. The majority of patients had a vision of 1/60 to 2/60 on Snellen, as shown in Figure 1. The mean time is taken for Group I (ICIOL) was less 29 ± 4 min when compared to Group II 41 ± 3 min, and it was found to be statistically significant. At postoperative 9mo, 47% of patients had vision better than LogMAR 0.30 in Group I, whereas, in Group II, 40% of patients had vision better than LogMAR 0.30.

In both groups, about 80% of patients had BCVA of 0.47 LogMAR at 9mo (Figure 2). On comparing postoperative visual outcomes between both the groups, no statistically significant difference was found.

Complications associated with both the procedures are as shown in Table 1. At 1d postoperative, both the groups had common complications, but pupil irregularity (oval-shaped) was seen more significantly in Group I. On 7d postoperative, striate keratopathy persisted in ten patients in Group I because of anterior chamber (AC) reaction. These patients were started topical steroid medication every 2h, which was later on tapered and stopped. Keratopathy was retained in two patients of Group I even after 9mo follow up. One patient of Group I got one of the haptics released from the iris. It was again tucked in and was followed up. Problems related to sutures such as erosion of scleral flap and suture exposure

Table 1 Postoperative complications in both groups

Parameters	Group I	Group II	Total	P
Pigment dispersion	8	0	8	0.029
IOL related	0	4	4	0.49
Striate keratopathy	2	0	2	0.31
Suture related	0	8	8	0.029
Raised IOP	0	2	2	0.31
Irregular pupil	8	0	8	0.029
Cystoid macular edema	0	2	2	0.31
Mean surgical time taken, (min)	29±4	41±3	-	<0.05
Mean endothelial cell count preoperative, (cells/mm ²)	1851±301	1868±267	-	>0.05
Mean endothelial cell count 9mo postoperative, (cells/mm ²)	1792±421	1824±397	-	>0.05

IOL; Intraocular lens; IOP; Intraocular pressure.

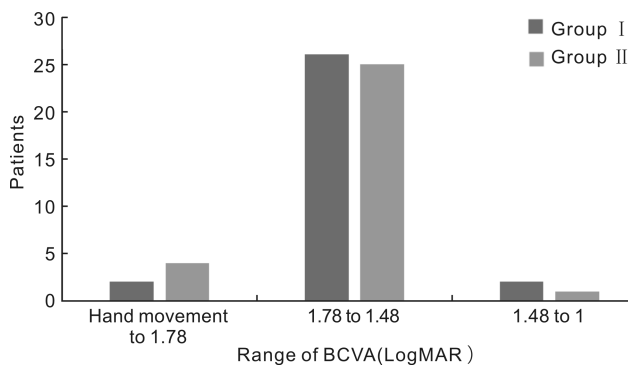


Figure 1 Preoperative best corrected visual acuity (LogMAR).

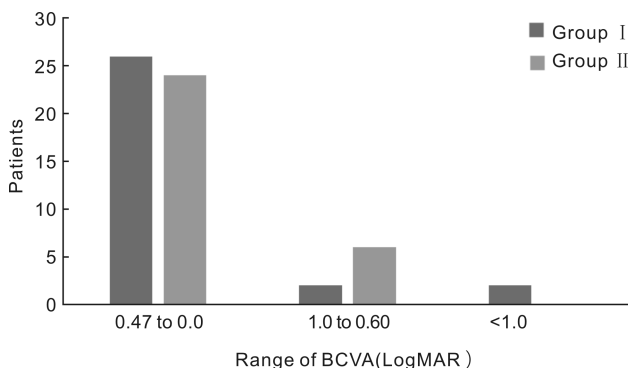


Figure 2 Best corrected visual acuity (LogMAR) after 9mo follow up.

resulted in tilting of IOL which caused astigmatism of more than 3 dioptres in 4 patients of Group II. Table 1 describes all postoperative complications encountered from 1wk to 9mo in both groups. At the end of the follow up period of 9mo, pupil irregularity (oval shape) and pigment dispersion were seen as statistically significant in Group I, whereas in Group II, eight patients had a suture-related complication, which was statistically significant. At the follow up after 9mo, the mean endothelial count was decreased in both the groups. However the difference in endothelial cell count was found insignificant.

DISCUSSION

In cases of aphakia with inadequate or weak posterior capsular support, anterior chamber intra ocular lens (ACIOL) or SFIOL are used^[7], preventing the patients from aphakic glasses. However, still there is debate on IOL of choice in

such aphakic patients. From several years, there have been repeated discussions on the best modality for secondary IOL implantation, which offers the minimum complication rate and best possible visual acuity over several years^[8-9]. Each of the available modalities has its risks and complications. Trans-scleral fixation of posterior chamber IOLs is a technically demanding modality with a relatively high risk of intraoperative and postoperative complications. It requires dissection into the conjunctiva and the sclera^[10]. ACIOL implantation, although technically easier, is associated with several complications related to the IOP, iridocorneal angle, and the endothelium of the cornea^[11]. Fixation of an ICIOL has the advantage of true posterior chamber implantation, with a deeper anterior chamber and a safe distance from the corneal endothelium. ICIOL has a lower intraoperative and postoperative complication rate than anterior chamber or scleral fixation IOL^[12-13]. The mean surgical time taken for ICIOL in our study was 29±4min, whereas it was 12±4.71min in the study by Mahajan *et al*^[14]. The mean surgical time for SFIOL in our study was 41±3min and was 30.9±5.81min reported by Mahajan *et al*^[14]. The mean surgical time was more in our study because of the anterior vitrectomy procedure, however, this was found to be statistically significant. Twenty-six patients (87%) of the ICIOL group and 24 patients (80%) of the SFIOL group got BCVA >6/18 at 9mo. The mean postoperative BCVA in terms of LogMAR of our study was similar and comparable to the postoperative BCVA with Mahajan *et al*^[14] and Farrahi *et al*^[15]. The mean BCVA of ICIOL and SFIOL in Mahajan *et al*^[14] was 0.41±0.32 and 0.45±0.37, respectively. In a study done by Farrahi *et al*^[15], the mean BCVA was 0.44±0.24 and 0.61±0.25 for ICIOL and SFIOL, respectively, whereas, in our study, BCVA was 0.32±0.3 for ICIOL and 0.34±0.24 for SFIOL group. In another study was done by Gonnermann *et al*^[16] on ICIOL, the mean BCVA of 0.38±0.31 was found which is comparable to our results. Even though our results were better than the above studies, but the difference in results was not statistically significant in both the groups. On 1d postoperative, striate keratopathy and anterior chamber

reaction were present in some patients of both the groups, which gradually resolved over subsequent follow ups. Pupil irregularity was observed in eight patients (26.6%) of the ICIOL group, and it remained the same till the last follow up the day after 9mo, no such complication was found in any patient of the SFIOL group. This was comparable to a study done by Mahajan *et al*^[14] as they found irregular pupils in five patients of the ICIOL group and one patient in the SFIOL group. This complication can occur as a result of asymmetrical and tight fixation of the haptic. It was less as compared to a study conducted by Gonnermann *et al*^[16]. Baykara *et al*^[13] who found persistent pupil irregularity after posterior ICIOL implantation in 12.7% of eyes. The initial secondary rise of IOP was seen in one patient of the ICIOL group. This got controlled with control of inflammation at the end of the 1wk. Six patients of the SFIOL group had elevated IOP at 1d postoperative. Two patients in the SFIOL group had elevated IOP at 9mo follow up. On examination, there was an angle recession noted on gonioscopy as they were the case of aphakia secondary to trauma. Secondary glaucoma secondary to angle recession was treated with topical antiglaucoma medication. Apart from them, no other patient in the SFIOL group had raised IOP unlike four cases in the study done by Mahajan *et al*^[14]. Pigment dispersion was noted in eight cases in the Group I (ICIOL), which was more when compared with the study done by Forlini *et al*^[17] who found four cases in 320 eyes which is lesser. The explanation given for its fewer occurrences of pigment dispersion was the vaulted design of the Artisan aphakic lens and its inverted position which provides adequate space between the pigment epithelium layer of iris and the optical zone of the lens. However, it was not associated with a secondary rise in IOP. One patient had disinsertion of ICIOL at 1mo follow up, and it was repositioned back and followed up. Similarly, subluxation was noted in one patient in the study by Mahajan *et al*^[14] and a similar finding was seen by Gonnermann *et al*^[16] who found a dislocation rate up to 8.7%. Three cases of spontaneous disinsertion of one haptic occurred in the study by Forlini *et al*^[17]. Suture-related complications in Group II such as erosion of conjunctiva and IOL tilt were seen in eight cases of our study which is the same as that found in the study by Mahajan *et al*^[14]. Cystoid macular edema was found in two patients in the SFIOL group and was treated with steroids. CME in the SFIOL group remained the same at 9mo follow up. Cystoid macular edema (CME) was not found in the ICIOL group but it was seen in two cases of SFIOL group in the study by Mahajan *et al*^[14] whereas in a study by Gonnermann *et al*^[16], the incidence of postoperative cystoid macular edema was 8.7% after 6.7mo. However, this CME rate was higher than 4.1% and 4.8% seen in the study by Mohr *et al*^[18] and Wolter-Roessler *et al*^[19] respectively. The incidence of CME in ICIOL is lower than the rate after implantation of scleralfixated PCIOLs (5.8%–33%)^[20-21]. Studies done on

safety and efficacy of ICIOL implantation in pediatric age group concludes good efficacy and acceptance of ICIOL in children^[22-24]. However, a comparative study between anterior and posterior chamber ICIOL regarding influence on outcomes concluded posterior chamber ICIOL to have an upper edge on anterior chamber ICIOL^[25-27]. In the current scenario posterior chamber retro-pupillary ICIOL is an accepted modality to treat aphakia with no or inadequate posterior capsular support^[28-32]. Moreover in microspherophakia with aphakia also ICIOL is being used successfully^[33]. Even newer techniques of sutureless SFIOL implantation is also in practice to avoid suture related complications^[34]. However, in the future, more studies on larger sample sizes are required to reach any conclusion.

The visual outcome after ICIOL implantation behind the pupil was found to be comparable with that of the SFIOL. However, ICIOL had a shorter surgical period with fewer complication rates. Therefore, ICIOL can be a good alternative to SFIOL in aphakic eyes with inadequate or weak posterior capsular support. Shorter duration of study and smaller study group is one of the limitations of this study. In future study with follow up of 2y or more is required which can give more conclusive and reliable results.

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