Iris-Claw Intraocular Lens and Scleral-Fixated Posterior Chamber Intraocular Lens Implantations in Correcting Aphakia: A Meta-Analysis

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PURPOSE. A meta-analysis to compare iris-claw intraocular lens (IC-IOL) and scleral-fixated posterior chamber intraocular lens (SF-PCIOL) implantations in correcting aphakia without sufficient capsular support.

METHODS. Eligible studies were collected through PubMed, Web of Science, Embase, and the Cochrane library. The pooled relative risks (RR), pooled standardized mean difference (SMD), and their 95% confidence interval of the eligible studies were then calculated. Seven studies met our inclusion criteria, involving 232 and 158 eyes in IC-IOL and SF-PCIOL groups, respectively.

RESULTS. The pooled SMD of the mean postoperative corrected distance visual acuity (CDVA) (logMAR) was −0.25. The pooled RR of the eyes achieving 20/40 or better postoperatively was 1.16. The pooled SMD of the surgical time was −2.97. The pooled RR of the surgical complications was 0.86. The pooled RR of IOL dislocation, retinal detachment (RD), and ciliary macular edema (CME) between the two groups were 0.22, 0.63, and 0.64.

CONCLUSIONS. Implantation of IC-IOL has a more simple procedure and shorter learning curve than SF-PCIOL implantation in correcting aphakia without sufficient capsular support.

Keywords: IC-IOL, SF-PCIOL, SMD, PubMed, CDVA

Many reasons can lead to an aphakia without sufficient capsular support for a posterior chamber intraocular lens (PC-IOL), such as intraoperative complications during phacoemulsification,1–4 intracapsular cataract extraction (ICCE),5,6 ocular trauma,7 and lens dislocation caused by various reasons (e.g., Marfan Syndrome,8,9 congenital or secondary weakness of zonules, etc.). It has always been the focus of ophthalmologists to choose an appropriate treatment to handle these issues. During the past decades, many ways have been tried to treat these diseases. At present, visual rehabilitation of these patients includes spectacles, contact lenses (CLs), and primary or secondary IOL implantation. Spectacles are rarely used for visual rehabilitation of aphakia, because of the poor visual field and relative peripheral refractive error, and many patients are unsatisfied with the inconvenience and thickness of the glasses.10,11 or just use over the period before secondary IOL implantation.12 Patients with anisometropia are thought to not be suitable for spectacles. Contact lenses are considered the most common treatment, as it is easy to get and effective to rehabilitate visual acuity of the aphakia. Therefore, CLs have been widely accepted.13,14 Complications in wearing CLs15 are always caused by poor maintenance, overexerted wearing, and wearing in a polluted environment. Several corneal and conjunctival complications are also common, such as conjunctivitis, especially giant papillary conjunctivitis,16 corneal vascularization, corneal edema, corneal abrasions, chronic endothelial dysfunction, and relatively tricky microbial keratitis. The major problem associated with CL-wearing is corneal hypoxia.

Most ophthalmologists agree that IOL implantation is the most appropriate treatment for visual rehabilitation and correction of aphakia. There are a variety of options17 for the correction of these aphakic patients lacking of adequate capsular support, such as angle-supported anterior chamber IOLs (ACIOLs); IC-ACIOLs; and SF-PCIOLs. The angle-supported ACIOLs have been used for decades and improved with many designs. However, with a high rate of conditions such as endothelial cell loss,18 secondary glaucoma, and severe uveitis,6,19 they are fading out from the field gradually. The IC- or lobster-claw (IC-IOL) (a biconvex PMMA IOL) was presented by Worst et al. in 197220 and was first used to treat myopia. Then many modifications were incorporated to this lens over time. Artiflex, Verisyse, and Artisan were designed and brought into the market for visual rehabilitation, and also used to correct aphakia with satisfactory results.21 One of the latest versions of IC-IOL designed for aphakia is the convex/concave model (Artisan Aphakia Model 205; Ophitec BV, Groningen, The Netherlands). According to the position of IOL fixation, IC-IOLs are classified into anterior chamber IOLs and retropupillary IC-IOLs.22,23 The implantation of an IC-IOL is a time-saving surgery with low intrusiveness, and the operation technique is much easier than the implantation of a SF-IOL. The implantation of a retropupillary IC-IOL combines the advantages of a PCIOL and a short operation time as well as...
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an easy operation technique; both advantages were accepted
by many surgeons.24–26 However, there are still some concerns
over corneal endothelial stability and late dislocation, and it is
also limited by the conditions of the iris as well as the anterior
chamber depth (ACD). Implantation of SF-PCIOL27 more
closely simulates the normal physiologic and anatomic position
of the crystalline lens, and so is considered to be implanted
first in patients suffering from aphakia when the eye conditions
allow. However, it requires experienced surgeons with skillful
surgical techniques and a long operation procedure. Therefore,
most surgeons consider the IC-IOLs first, and the SF-PCIOLs are
an acceptable alternative in the cases of correcting aphakia
without sufficient capsular support. Many complications may
associate with both kinds of surgeries, such as lens tilt and
decentration, hypotony, secondary glaucoma, hyphema, vitre-
ous hemorrhage, suprachoroidal hemorrhage, choroidal effu-
sion, CME, RD, and even endophthalmitis.28 Several previous
studies compared the outcomes of the two kinds of surgeries
directly when patient’s capsular support was lacking,29–31 but
there was no consensus of opinion. Thus, the present meta-
analysis aimed to compare the clinical efficacy, safety, and
complexity between both IOLs implantations in correcting
aphakia without sufficient capsular support.

**Materials and Methods**

**Search Strategy**

We searched appropriate articles by systematic queries in the
PubMed, Web of Science, Embase, and the Cochrane Library,
up to May 24, 2014. The terms of search strategy were “iris
fix*” OR “iris-claw” OR “artisan” OR “iris-clip” OR “verisyse”
OR “iris suture” combined with “scleral fix*” OR “transscleral
fix*” OR “intracorneal fix*” OR “transscleral suture*” OR “sulcus
fix*” OR “transscleral sulcus fix*” OR “scleral suture fix*”, with no language restriction but restricted to clinical
studies. The titles and abstracts were scanned firstly to exclude
the clearly irrelevant studies. Then the full texts of the
remaining articles were read to determine whether they
contained information on our topic of interest.

**Study Selection**

Two researchers (JW, GL) independently read all the publica-
tions to determine whether the studies can be included when
they met all the criteria as follows: (1) case control study,
cohort study, and randomized control trial (RCT) published as
an original article that associated an IC-IOLs and SF-PCIOLs
implantation without adequate capsular support; (2) any
causes result in absence of capsular support to implant a
IOL; (3) reported the change in visual acuity and complication;
and (4) reported the data that can evaluate the odds ratio (OR)
or RR with their corresponding 95% CIs.

**Qualitative Assessment**

Articles were reviewed for quality using a modified version of
the Quality Index Scale (QIS; Downs & Black). The quality
index was initially developed to systematically rate the
research quality of randomized and nonrandomized studies of
healthcare interventions. The Downs and Black checklist in
this study consisted of 26 items distributed between 5
subsccales: reporting (9 items); external validity (3 items);
confounding (6 items); power (1 item); and bias (7 items). The
quality index scale has good reliability and validity for
measuring the methodological quality of health research. A
higher score indicates a better quality of the study. Our meta-
analysis included both randomized controlled trials (RCTs) and
non-RCTs, so the quality index (also called Downs and Black
quality method) that is used for the RCTs and non-RCTs was
used as the qualitative assessment in our study.32 Of this study,
the QIS of the seven articles can be divided into four
subgroups, including subgroup with QIS (n = 26–28); QIS (n
= 20–25); QIS (n = 15–19); and QIS (n = ≤14). The articles
with QIS ≤14 have been excluded from this study.

**Data Extraction**

The two researchers (JW, GL) independently extracted the
relevant data from the included studies, and the conflict was
resolved by discussion or by the final decision of a senior
researcher (WX). The extraction information included were as
follows: the first author of the study, the year of publication,
the country of the study conducted, the study period, the
number of studied eyes with either of the two types of IOLs
implanted, the mean age of the patients in the two groups, the
mean follow-up time, the study design, the visual acuity, and
the intra- or postoperative complications of each IOL
implantation. Then the two researchers analyzed the data
and evaluated the effects. The data in this study were extracted
from the original studies with the least number of modifications
as possible. In the final analysis, these data were
converted to the form that can be compared with each other.

**Data Analysis**

The relative risks were used to estimate the result of the
complications and the number of eyes achieving 20/40 or
better; a P value < 0.05 or a 95% CI not including value 1 was
considered significant. We used the mean postoperative CDVA
(logMAR) and surgical time to calculate the pooled SMD; a P
value < 0.05 or the 95% CI not including value 0 was
considered significant.

The data from all studies were analyzed based on the fixed-
effects model with the Mantel-Haenszel method first when
heterogeneity was negligible. If the heterogeneity was not
negligible (I² > 25%), a random-effects model with the Mantel-
Haenszel method was applied.33 We used the latter model,
because in our meta-analysis, the heterogeneity of the seven
studies included that these patients were from different clinical
centers with different criteria and causes (e.g., lacking enough
capsular support, different sample size, different length of
follow-up, different outcome analysis, etc.). The heterogeneity
between all studies was examined using Q-statistic and I²
score.34,35 The null hypothesis was that the studies were
homogeneous unless rejected for less than 0.05 in a P value for
heterogeneity or greater than 25% in I².

The Egger’s36 and Begg’s tests37 were then performed to
evaluate the publication bias, and P < 0.05 for either Egger’s or
Begg’s test was considered reaching a significant level of
publication bias. Sensitivity analyses were also performed to
exclude the study that may contribute the heterogeneity. We
used commercial statistical software (Stata/SE 12.0; Stata Corp.,
College Station, TX, USA) for all data analysis in this study.

**Results**

After searching the databases, 434 articles met our interest.
Among them, 134 were duplicate references, and 6 animal
experiments were excluded. A total of 266 articles were
excluded after reviewing the titles and abstracts. Ultimately,
after reading the full text of the remaining articles, we
excluded another 21 articles that were: reviews of the
operation of IC-IOLs and SF-PCIOLs without clinic data, case
reports, letters to the editor, or articles with no relevant results

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### TABLE 1. Characteristics of Studies Included in the Meta-Analysis

<table>
<thead>
<tr>
<th>Author/Year</th>
<th>Country</th>
<th>Types</th>
<th>Period</th>
<th>Eyes</th>
<th>Mean Follow-up Time, mo</th>
<th>Mean Age, y</th>
<th>Causes</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazar30/2013</td>
<td>Turkey</td>
<td>Retrospective study</td>
<td>2008–2011 (IC-IOL 35 and retropupillary PCIOL 55)</td>
<td>20/40</td>
<td>11.7</td>
<td>Marfan syndrome or Operative complications, or Trauma</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td>Farrahi39/2012</td>
<td>Iran</td>
<td>Prospective study</td>
<td>2008–2010</td>
<td>25/20</td>
<td>12/13</td>
<td>Marfan syndrome or Operative complications, or Trauma</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Menezo40/1996</td>
<td>Spain</td>
<td>Retrospective study</td>
<td>1989–1994 Primary group, 34/13; Secondary group, 14</td>
<td>20/40</td>
<td>14</td>
<td>Marfan syndrome or Operative complications, or Trauma or Iatrogenic or Unknown</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>Hara41/2011</td>
<td>Japan</td>
<td>N/A</td>
<td>2009–2011</td>
<td>20/40</td>
<td>11/21</td>
<td>Marfan syndrome or Operative complications, or Trauma</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>Saleh31/2013</td>
<td>France</td>
<td>Retrospective study</td>
<td>2009–2011</td>
<td>20/40</td>
<td>18</td>
<td>Trauma</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>Teng29/2014</td>
<td>China</td>
<td>Prospective study</td>
<td>2008–2012</td>
<td>20/40</td>
<td>12</td>
<td>Trauma</td>
<td>12</td>
<td></td>
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</tbody>
</table>

ECCE, extracapsular cataract extraction; N/A, data not available; PPV, pars plana vitrectomy.

We used the surgical time to estimate the complexity of the procedure. A longer surgical time indicates a more complex procedure. A longer surgical time can be an indicator of a more difficult operation. In the seven enrolled studies, only 5 studies provided data for calculating the SMD of the mean postoperative CDVA (logMAR). Table 2 shows the clinical data of the mean postoperative CDVA (logMAR) of these five studies. Subsequent data analysis indicated no difference between the IC-IOL and SF-PCIOL groups (SMD = −0.23, 95% CI −0.49 to 0.03, \( P = 0.32, \lambda = 14.9\%\); Fig. 2A). In the five studies, one study just provided the mean postoperative week 1 CDVA (logMAR) but did not provide the final follow-up result. So we omitted this study of Hara et al. to obtain the final results (SMD = −0.20, 95% CI −0.51 to 0.12, \( P = 0.32, \lambda = 14.9\%\)). The follow-up time of the other four studies was about 1 year. There was no statistically significant difference on the publication bias (Begg’s test, \( P = 0.73\); Egger’s test, \( P = 0.14\)).

The number of eyes achieving 20/40 or better postoperatively was also an analysis of our interest, and four out of the seven studies provided available data of eyes of 20/40 or better postoperatively. The patients in the study of Menezo et al. were divided into primary and secondary implantation groups, so we considered the data of eyes of 20/40 or better postoperatively were from independent studies (Table 3). We thought that the result could be used to estimate the surgical efficacy of the IC-IOL implantation and SF-PCIOL implantation. There was no significant difference between the IC-IOL implantation and SF-PCIOL implantation groups (\( r = 1.16, 95\% CI 0.92–1.47, P = 0.24, \lambda = 27.1\%\); Fig. 2B). There was no significant difference on the publication bias (Begg’s test, \( P = 0.09\); Egger’s test, \( P = 0.24\)).

### Surgical Time

We used the surgical time to estimate the complexity of the procedure. A longer surgical time indicates a more complex surgery, and also means a longer learning course and more resource consumption. Data from four studies were evaluated, and the results showed a statistically significant difference between the two groups (SMD = −2.97, 95% CI −3.44 to 2.50, \( P = 0.00, \lambda = 92.6\%\); Fig. 2C). There was no significant difference on the publication bias (Begg’s test, \( P = 0.73\); Egger’s test, \( P = 0.28\)).

### Complications

We used the incidence of complications to estimate the safety of the 2 groups of IC-IOL implantation and SF-PCIOL implantation, and 5 out of the 7 studies provided available information on complications (\( r = 0.86, 95\% CI 0.61–1.20, P = 0.04, \lambda = 59.8\%\); Fig. 2D). There was no significant difference on the publication bias (Begg’s test, \( P = 0.81\); Egger’s test, \( P = 0.58\)). Then we estimated the incidence of some single common complications to evaluate the safety of the 2 groups. We found no significant difference on the IOL dislocation between both groups (\( r = 0.22, 95\% CI 0.10–0.50, P = 0.31, \lambda = 16.2\%\); Fig. 2E). Moreover, there was no evidence of publication bias (Begg’s test, \( P = 0.45\); Egger’s test, \( P = 0.97\)).
There were also no differences in RD between the 2 groups ($\text{RR} = 0.63$, 95% CI 0.18–2.22, $P = 0.62$, $I^2 = 0.0\%$; Fig. 2F), and no publication bias (Begg’s test, $P = 1.00$; Egger’s test, $P = 0.91$).

Lastly, we estimated the incidence of CME, which showed no difference between the IC-IOL and SF-PCIOL groups ($\text{RR} = 0.64$, 95% CI 0.28–1.48, $P = 0.51$, $I^2 = 0.0\%$; Fig. 2G), without publication bias (Begg’s test, $P = 0.45$; Egger’s test, $P = 0.49$).

**DISCUSSION**

Implantations of IC-IOL and SF-PCIOL are the mainstream operation methods in visual rehabilitation to treat aphakia without sufficient capsular support to hold an IOL in the posterior capsule. Although there are several previous studies and reviews focusing on the surgical procedure and outcomes between IC-IOL and SF-PCIOL implantations,29–31 the conclusions are controversial, and no systematic review has compared IC-IOL and SF-PCIOL implantations in treating aphakia without sufficient capsular support. Since each operation has advantages and specific complications, it is difficult to determine which is mostly suitable for the management of patients without sufficient capsular support to hold an IOL in the posterior capsule. Thus, we conducted a meta-analysis to compare the efficacy, safety, and complexity between IC-IOL and SF-PCIOL implantations in correcting aphakia without adequate capsular support.

In the seven enrolled studies, there was no significant difference in efficacy and safety between IC-IOL and SF-PCIOL groups, but the IC-IOL group had a significant shorter surgical time and learning curve the SF-PCIOL group. Treatments with IC-IOL involved corneal incision and IOL push-in; the IC-IOL could fix on the iris by its clamp, which can be helpful to shorten the operation time and to simplify the procedure. By contrast, SF-PCIOL treatments needed to fix the IOL by suture, which meant a more complicated and time-consuming

**Table 2.** Postoperative CDVA (logMAR) in IC-IOL and SF-PCIOL Groups at the Last Follow-Up Visit

<table>
<thead>
<tr>
<th>Author</th>
<th>IC-IOL, mean ± SD</th>
<th>SF-PCIOL, mean ± SD</th>
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<tr>
<td>Zheng</td>
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<td>Hazar</td>
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<td>Farrahi</td>
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<td>Hara</td>
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<td>Saleh</td>
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**Figure 1.** Flow chart of study selection process.
FIGURE 2. (A) Forest plot of risk estimates of postoperative CDVA (logMAR; 95% CIs) from studies on IC-IOLs and SF-PCIOLs. (B) Forest plot of risk estimates of the number of eyes achieving 20/40 or better postoperatively associated with IC-IOLs and SF-PCIOLs. (C) Forest plot of risk estimates of surgical time associated with IC-IOLs and SF-PCIOLs. (D) Forest plot of risk estimates of complications associated with IC-IOLs and SF-PCIOLs. (E) Forest plot of risk estimates of IOL dislocation associated with IC-IOLs and SF-PCIOLs. (F) Forest plot of risk estimates of RD associated with IC-IOLs and SF-PCIOLs. (G) Forest plot of risk estimates of CME associated with IC-IOLs and SF-PCIOLs.
operation. We speculated that the more complicated and time-consuming operation could lead to a more invasive assault of the eyes, corresponding to more operative complications. Different operation methods could give rise to rarer operative complications. However, we did not confirm the direct relationship between complications and operation time in this study. Therefore, further study is needed to investigate the relationship between the two factors.

With regard to safety, there was no significant difference between the two groups. The iris claw-IOL was fixed on the iris by haptics. It might have a higher rate of various complications that are related to the iris and pupils (e.g., iris atrophy, pigment deposits, pigment dispersion, pupillary distortion, endothelial cell loss, etc.). Decentration of IOL, suture erosion, and macula edema occurred at a higher rate in patients with SF-PCIOL implantations. Therefore we estimate the incidence of some single common complications (IOL dislocation, RD, and CME) to evaluate the safety of the two groups. Our results showed no significant difference between both groups. Four studies\textsuperscript{29,30,40,44} thought that there were no significant differences between the two groups. The study of Zheng et al.\textsuperscript{32} found the following in the SF-PCIOL group: one eye with temporarily elevated IOP at day 1 that was immediately managed by laser peripheral iridotomy; four eyes with persistently elevated IOP; three of which were managed by antiglaucomatous medication; the last was managed by trabeculectomy. Farrahi et al.\textsuperscript{39} mentioned that there were two patients with raised IOP in both IC-IOL and SF-PCIOL groups. Therefore, we estimate the incidence of some single common complications (IOL dislocation, RD, and CME) to evaluate the safety of the two groups. Our results showed no significant difference between both groups. Four studies\textsuperscript{29,30,40,44} thought that there were no significant differences between the two groups. The study of Zheng et al.\textsuperscript{32} found the following in the SF-PCIOL group: one eye with temporarily elevated IOP at day 1 that was immediately managed by laser peripheral iridotomy; four eyes with persistently elevated IOP; three of which were managed by antiglaucomatous medication; the last was managed by trabeculectomy. Farrahi et al.\textsuperscript{39} mentioned that there were two patients with raised IOP in both IC-IOL and SF-PCIOL groups.

Corneal endothelial cells (ECs) approximately decrease 0.5% to 1% annually after the age of 2 years. Thus, the cell density decreases from 6000/mm\textsuperscript{2} at birth to 2000/mm\textsuperscript{2} at age 60 years. The minimum cell density for maintaining a normal function is generally considered to be 300 to 500/mm\textsuperscript{2}. Corneal decompensation, corneal edema, bullous keratopathy, and even loss of vision will happen when the number of ECs is less than the minimum. Typically, having ECs less than 800 is a contraindication of intraocular surgery. The anterior chamber depths are more demanding in IC-IOL implantation for avoiding the direct friction with corneal endothelium. In the seven included studies, there was no available data for calculating pooled SMD to evaluate the difference between both groups. There were three studies\textsuperscript{29,30,38} mentioning that there was no statistically significant difference on postoperative endothelial cell loss between groups ($P > 0.05$). The follow-up time of the three studies was probably approximately 1 year. The endothelial cell loss changes very slowly, so more studies with longer follow-up time are needed to further confirm the findings.

### References


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