Iris-fixated intraocular lens (IOL) is considered a safe and effective option for the correction of aphakia in patients with insufficient capsular support. This systematic review aims to summarize the existing evidence about the Artisan/Verisyse IOLs and to assess the influence of the IOL position on the postoperative outcomes. Three different databases were used for this systematic review and metaanalysis (PubMed, Scopus, and Embase). We searched for case series or clinical trials comparing the prepupillary versus retropupillary Artisan/Verisyse implantation. The statistical analysis was performed with the programming language R (version 3.6.1 2019-07-05). The number of articles included in the meta-analysis was six, with 506 eyes included in total. We found no significant differences in postoperative corrected distance visual acuity (CDVA) (0.309 [0.089-0.528] vs. 0.32 [0.2-0.44]), spherical equivalent (SE) (0.0153 D [-0.362 to 0.393] vs. -0.329 D [-0.62 to -0.038]), and central corneal cell density (CECD) (1669.85 cells [1605.949–2150.937] vs. 1635.99 cells [1413.64–1858.363]) between the prepupillary and the retropupillary implantation, respectively. There were no significant differences in the rates of cystoid macular edema (CME) (7.7% vs. 9.8%), pupil deformation (4.5% vs. 5.4% retropupillary), or IOL luxation (2.3% and 2.2%). We found little influence of the IOL position in the postoperative analyzed outcomes. Thus, the implant position should be based on the surgeon’s technical experience. Double-blind randomized prospective studies would improve the available evidence on the best implant position for the Artisan/Verisyse IOL.

Key words: Aphakia Without Capsular Support, Artisan intraocular lens, influence of Artisan position, intraocular lens, IOL, iris-fixated IOL, surgical correction of aphakia

The surgical approach and the intraocular lens (IOL) implant technique in patients without capsular support could be challenging. Several procedures have been proposed for the correction of aphakia, such as transscleral-sutured Posterior Chamber Intraocular Lens (PC IOLs), sutureless intrascleral-fixed IOLs, angle-supported Anterior Chamber Intraocular Lens (AC IOLs), and iris-fixated IOLs.[1-3] Iris-fixated IOLs are preferred by some surgeons due to their lower surgical times and rates of intraoperative and postoperative complications compared with transscleral-sutured PC IOLs and angle-supported AC IOLs.[4-5]

Artisan aphakia 205 (Ophtec BV, Groningen, The Netherlands) is the most popular model of iris-fixated IOL at the time of publication of this paper. This model is a convex-concave version that increases the distance between the IOL and the corneal endothelium. More recently, in 2005, another iris claw IOL became available, that is, Verisyse (Abbott Medical Optics, Inc.). Both IOLs were originally designed for a prepupillary fixation. However, a retropupillary fixation of the IOL is also possible, easier to implant and is theoretically safer to the corneal endothelium.[5-9]

Nowadays, there is no consensus among the reports supporting the evidence for or against one of these two possible configurations of the IOL. This lack of evidence could be explained by the shortage of randomized controlled trials comparing the prepupillary fixation of the IOL against the retropupillary fixation of the IOL. In addition, there is no systematic review or meta-analysis published in the literature which analyzes this topic.[10] Therefore, the aim of this systematic review and meta-analysis is to summarize the existing evidence about the Artisan/Verisyse IOLs and to assess the influence of the IOL position on the postoperative outcomes.

Methods

Search strategy

This systematic review was performed with guidance from the Cochrane Handbook for Systematic Reviews of Interventions.[10] We formulated our Patient Intervention Comparation Outcome (PICO) question: Does the “Retro-Iris
Fixation of Artisan/Verisyse IOL (I) in “Adult patients with aphakia with insufficient capsular support” (P) lead to different “Postoperative visual acuity, central cell density, intraocular pressure (IOP), refractive error, and rates of postoperative complications” (O) compared to the “Pre-iris fixation of Artisan/Verisyse IOL” (C)?

Three different databases were used to answer this question (PubMED, Scopus, and Embase). Only the articles that were published between 1/1/1999 and the 1/9/2019 were included, and the filter “humans” was applied when available. The search terms were “(iris-claw OR artisan OR iris-clip OR Verisyse) AND (intraocular lens OR cataract surgery)” for PubMed, “‘iris clip lens’:ab, ti OR ‘artisan’:ab, ti OR ‘verisyse’: exp OR ‘Verisyse’” for Embase, and “(‘iris clip lens’ OR artisan OR verisyse OR ‘iris clip’ OR ‘iris-fix’) AND (‘capsular support’)” for Scopus. A snow-ball search strategy was also used in the search of articles.

Inclusion criterion was cohort studies, case series, or clinical trials performed on aphakic patients with insufficient capsular support comparing the prepupillary Artisan or Verisyse lens implantation against the retropupillary implantation. To be included in the review, the follow-up period had to be at least 3 months. Studies performed exclusively on patients with Marfan syndrome, anophthalmia, high myopia, retinal detachment, corneal graft, or pediatric population or published in a language different than English or Spanish were excluded from the systematic review.

Studies included were independently reviewed by two authors. Articles were evaluated with the aid of the ROBINS-I tool. Disagreements between these two authors’ evaluations were discussed between them. If there was not an agreement after exposing their arguments, the article was independently evaluated by a third author in order to make a final decision.

Data extraction
Once duplicate articles were removed, a database was created. This database was filled independently by two authors. In order to be included in the database, means and standard deviations had to be calculated in the original paper for the continuous variables, while either the number of events or the proportions must be reported for the discrete variables.

The variables included in the database were the following: year of publication, study design, mean age, follow-up, pre- and postoperative corrected distance visual acuity (CDVA) measured in Logarithm of the Minimum Angle of Resolution (logMAR), pre- and postoperative spherical equivalent (SE), pre- and postoperative IOP, pre- and postoperative central corneal cell density (CECD), postoperative cystoid macular edema (CME), pupil deformation, and IOL subluxation and decentration. We considered mispositioning of the IOL with both haptics fixated as decentration, and loose fixation of one of the haptics as subluxation.

Figure 1: Schematic presentation of the selection of articles through literature search
Statistical analysis

The statistical analysis was performed with the programming language R (version 3.6.1 2019-07-05) and the packages metaphor (v2.1-0) and meta (v4.9-6). A logarithmic risk ratio was calculated when discrete variables were compared, and standardized mean difference was performed when continuous variables were compared. If the heterogeneity of the studies was significant, a random effect model was chosen. On the contrary, when the heterogeneity was low, a fixed effect model was applied. We used the same R packages for the visual representation of the results with the realization of the respective forest plots.

Results

The flow chart of articles chosen for the review is illustrated in Fig. 1. The number of articles that compared a prepupillary with a retropupillary implantation of Artisan or Verisyse were six, with an aggregated sample size of 506 patients.

Evaluation of the quality of evidence

Five out of the six studies included in the study were retrospective case reports. Only one article was a prospective randomized trial. The characteristics of the studies included in the meta-analysis are described in Table 1. Fig. 2 shows the results of the ROBINS-I test employed for study quality assessment. The summary of the evidence of the recommendation based on the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) system is presented in Table 2.

Baseline characteristics of the patients included in the analysis

The mean age of the patients was 67.24 for the prepupillary group and 69.79 for the retropupillary group. The mean age was not significantly different between both groups ($P = 0.389$). The standardized means and proportions for each implant position are specified in Table 3.

Corrected distance visual acuity

Fig. 3 summarizes the analysis of the postoperative outcomes based on the IOL position. Both fixation positions showed an improvement in the mean best-corrected visual acuity after the surgery [Fig. 4]. The mean postoperative uncorrected distance visual acuity (UCDVA) was $0.309$ (95% confidence interval [CI] 0.089–0.528) for the prepupillary implantation and $0.32$ (95% CI 0.2–0.44) for the retropupillary fixation. No significant differences between the mean prepupillary and retropupillary implantation ($P = 0.559$) were found.

![Figure 2: Summary of the risk of bias of the included studies according to ROBINS-I](image-url)
Table 1: Characteristics of the studies included in the systematic review

| Study                          | Study size | Study type | PICO question                                                                 | Follow-up |
|-------------------------------|------------|------------|--------------------------------------------------------------------------------|-----------|
| Hazar et al[4]                | 90 eyes included: 35 AC-IFIOL, 24 RP-IF IOL; 31 eyes with a three-piece SF-PC IOL | RCS       | To evaluate the results of three different secondary IOL implantation procedures in aphakic eyes without capsular support | AC-IFIOL: 12 ± 7.7 months, RP-IFIOL: 10.1 ± 7.3 months |
| Helvaci et al[14]             | 40 eyes included: 20 AC-IFIOL and 20 RP-IFIOL | Prospective randomized and single blinded | To compare the outcomes of anterior chamber and retropupillary implantation of iris claw Artisan IOL | 6 months |
| Hernández Martínez and Almeida González[15] | 76 eyes included; 29 AC-IFIOL and 47 RP-IFIOL | RCS       | To evaluate the safety, refractive, and visual results of an iris claw IOL for aphakia (Artisan) according to the technique used | 33 ± 21.8 months |
| Mora et al[16]                | 60 eyes included; 28 AC-IFIOL and 32 RP-IFIOL | RCS       | To compare the functional and clinical outcomes of the iris claw IOL placed on the anterior versus posterior surface of the iris | 12 months |
| Toro et al[12]                | 180 eyes included; 87 AC-IFIOL and 93 RP-IFIOL | RCS       | To compare the long-term efficacy and the rate of complications of anterior versus posterior iris claw IOL implantation to correct for the treatment of aphakia without sufficient capsule support | 60 months |
| Touriño Peralba et al[7]      | 95 eyes included; 57 AC-IFIOL and 38 RP-IFIOL | RCS       | To describe the demographic data, evaluate the long-term refractive and anatomical outcomes, and report the incidence of complications of anterior iris (prepupillary) and posterior iris (retropupillary) fixation of the Artisan aphakia iris claw IOL | 12 months (median) IQR=18 |

IOL=Intraocular lens, IQR=Interquartile range, PICO=Population Intervention Comparison Outcomes, RCS=Retrospective case series, RP-IF=Retropupillary-Iris Fixated, AC-IF=Anterior Chamber-Iris Fixated, SF-PC=Scleral Fixated - Posterior Chamber

Table 2: Grade rating of the certainty of each variable included in the meta-analysis

| Outcome                              | No. of participants (studies) | Relative effect (95% CI) | Findings with prepupillary implantation | Findings with retropupillary implantation | Quality and justification for rating |
|--------------------------------------|-------------------------------|--------------------------|----------------------------------------|------------------------------------------|-------------------------------------|
| Postoperative CDVA (logMAR)          | 411 patients (five studies)   | −0.06 (-0.25; 0.14)     | 0.309 (0.098-0.528)                    | 0.32 (0.200-0.440)                       | Low                                 |
|                                       |                               |                         |                                        |                                          | Mostly based on observational studies |
| Postoperative spherical equivalent (D)| 112 patients (two studies)    | −0.26 (-0.25; 0.14)     | −0.329 (−0.620; −0.038)                | 0.015 (−0.362; 0.393)                    | Very low                             |
|                                       |                               |                         |                                        |                                          | Mostly based on observational studies |
|                                       |                               |                         |                                        |                                          | Affected by the type of incision (i.e., scleral tunnel) |
| Postoperative intraocular pressure    | 279 patients (three studies)  | −0.08 (-0.31; 0.16)     | 14.643 (14.413-14.873)                 | 14.939 (14.528-15.672)                   | Low                                 |
|                                       |                               |                         |                                        |                                          | Mostly based on observational studies |
| Postoperative central endothelial cell density | 466 patients (five studies) | 0.10 (-0.09; 0.28)     | 1669.85 (1419.589-1920.110)            | 1635.99 (1413.640-1858.363)             | Low                                 |
|                                       |                               |                         |                                        |                                          | Mostly based on observational studies |
|                                       |                               |                         |                                        |                                          | Only three out of five studies with more than 1 year of follow-up |
| Rate of cystoid macular edema         | 434 patients (four studies)   | 0.40 (-0.24; 1.03)      | 9.8% (2.7%-28.7%)                      | 7.7% (2.8%-19.4%)                       | Low                                 |
|                                       |                               |                         |                                        |                                          | Mostly based on observational studies |
| Rate of pupil deformation             | 374 patients (four studies)   | −0.17 (-1.15; 0.81)     | 4.5% (2.2%-9.0%)                       | 5.4% (2.63%-10.6%)                      | Low                                 |
|                                       |                               |                         |                                        |                                          | Mostly based on observational studies |
| Intraocular lens luxation             | 434 patients (four studies)   | −0.10 (-1.54; 1.33)     | 2.31% (0.9%-6.0%)                      | 2.20% (0.8%-5.7%)                       | Low                                 |
|                                       |                               |                         |                                        |                                          | Mostly based on observational studies |

CDVA=corrected distance visual acuity, CI=confidence interval
Refractive results
The mean postoperative SE was closer to zero in the retropupillary fixation group (0.0153 D [95% CI 0.362 to 0.393]) compared to the prepupillary fixation (~0.329 D [95% CI ~0.62 to ~0.038]) [Fig. 5]. However, this difference was not statistically significant ($P = 0.181$).

Intraocular pressure
The mean postoperative IOP was 14.457 mmHg (95% CI 14.413–14.73) for the prepupillary implantation and 14.940 mmHg (95% CI 14.528–15.672) for the retropupillary implantation. No significant differences between both groups in either the preoperative IOP or the postoperative IOP were found. In addition, there were no significant differences between the pre- and the postoperative IOP in either of the groups.

Endothelial cell density
The mean postoperative CECD was 1669.85 cells (95% CI 1605.94–2150.937) for the prepupillary group and 1635.99 cells (95% CI 1413.64–1858.363) for the retropupillary implantation [Fig. 4]. No significant differences in the CECD between groups ($P = 0.309$) were found. The mean decrease during the follow-up was not significantly different between groups, with the mean decrease being 11.105% for the prepupillary implantation and 12.588% for the retropupillary implantation.

Postoperative complications
Fig. 6 summarizes the analysis of the postoperative complications based on the IOL position. The rate of CME was lower in the retropupillary group (7.70%) compared to the prepupillary group (9.80%), although this difference was not statistically significant ($P = 0.257$). The rate of pupil deformation, IOL subluxation, and decentration was similar in both groups.

Discussion
Surgical correction of aphakia in the absence of capsular support is still controversial. One of the most versatile
Approaches is the implantation of the Artisan aphakia model. This IOL is a rigid Polymethyl Methacrylate (PMMA) iris claw lens available from +2.0 to +30.0 D and in both toric and non-toric configurations. This iris claw IOL allows its fixation at a prepupillary or retropupillary position. To the best of our knowledge, this is the first meta-analysis studying the influence of the Artisan/Verisyse implant position in the postoperative outcomes.

We found several limitations while conducting this systematic review. The inconsistency in the method for reporting continuous variables (i.e., reported differently to mean and standard deviations) made us exclude some potential data from the meta-analysis. Another limitation of the study is that five out of the six articles included are retrospective case series with the inherent limitation of this study design. This was an inevitable concession due to the absence of double-blinded controlled clinical trials and because only one prospective article in this topic was published by the time this article was written.[12,14] To mitigate the influence of these study limitations, the quality of the evidence included in the meta-analysis was taken into account when our group evaluated the certainty of the recommendation [Table 2].

Artisan IOL was originally designed for a prepupillary fixation. The retropupillary fixation was described by Mohr as an adaptation of the prepupillary implantation technique, placing the concavity of the IOL upward.[6] These types of fixations avoid the realization of an iridotomy to prevent pupillary blocks. In addition, surgeons tend to consider the retropupillary implantation easier than the prepupillary fixation. However, this difficulty could be compensated with the help of the VacuFix® (Ophtec BV) for the prepupillary fixation to the iris.

The implant in both positions enhanced the baseline CDVA [Fig. 4], with an expected mean CVA between 0.089

| Table 3: Results of the meta-analysis |
|--------------------------------------|
| **Variable** | Prepupillary implantation | Retropupillary implantation | **P** |
| No. | Mean | 95% CI | No. | Mean | 95% CI |
|---|---|---|---|---|---|
| **Age** | 250 | 67.237 | 63.125 | 71.350 | 251 | 69.787 | 67.205 | 72.369 | 0.389 |
| **Pre-CDVA** | 170 | 0.772 | 0.3469 | 1.1977 | 169 | 0.763 | 0.424 | 1.102 | 0.445 |
| **Post-CDVA** | 198 | 0.309 | 0.089 | 0.528 | 213 | 0.32 | 0.2 | 0.44 | 0.559 |
| **Pre-IOP** | 20 | 4.98 | 4.161 | 5.8 | 20 | 4.87 | 4.103 | 5.637 | 0.936 |
| **Post-IOP** | 48 | -0.329 | -0.62 | -0.038 | 64 | 0.0153 | -0.362 | 0.393 | 0.181 |
| **Pre-CECD** | 235 | 1878.443 | 1605.949 | 2150.937 | 231 | 1871.586 | 1667.606 | 2075.567 | 0.517 |
| **Post-CECD** | 235 | 1669.85 | 1419.589 | 1920.11 | 231 | 1635.99 | 1413.64 | 1858.363 | 0.309 |
| **CME** | 227 | 0.098 | 0.027 | 0.287 | 207 | 0.077 | 0.028 | 0.194 | 0.257 |
| **Pupil deformation** | 199 | 0.045 | 0.022 | 0.09 | 175 | 0.054 | 0.0263 | 0.106 | 0.754 |
| **IOL decentration** | 227 | 0.0395 | 0.016 | 0.09 | 207 | 0.0272 | 0.012 | 0.061 | 0.745 |
| **IOL subluxation** | 227 | 0.0231 | 0.009 | 0.06 | 207 | 0.022 | 0.008 | 0.057 | 0.886 |

CDVA=corrected distance visual acuity, CECD=central endothelial cell density, CI=confidence interval, CME=cystoid macular edema, IOL=Intraocular lens, IOP=intraocular pressure, SE=spherical equivalent. Standardized means and proportions for each implant position.
and 0.52 logMAR, and no significant differences were found in terms of CDVA between the prepupillary and retropupillary implantation. In consequence, we consider that CDVA is less conditioned by the implant position than by the preexisting pathology of the eyes.

We found a closer to zero mean SE in the retropupillary group, which was nonsignificant [Fig. 5]. In 2018, Hernández Martínez and Almeida González also reported a significantly different SE when the IOL position was compared, with the mean SE being closer to zero in the retropupillary group. However, Hernández Martínez and Almeida González reported a higher rate of patients between the range of 1 D of SE with the prepupillary implantation. But no data has been reported on the refraction target when these procedures were carried out.

Several difficulties appear when optimization of the postoperative SE is intended. First, most of these eyes, subsidiaries for an iris claw implant, have previous complicated surgeries or ocular traumas, which make the IOL calculation more difficult. Second, constant optimization may be considered in order to improve refractive results after Artisan implantation. Third, A-constant has to be adjusted depending on the implant position. Therefore, when a retropupillary implantation is chosen and the IOL constant has to be adapted, changing the optical SRK-T A-constant from 115.7 to 116.8, according to the manufacturer specifications.

One of the main disadvantages of the Artisan’s design is its inflexibility. That is, for IOL implantation, a wide incision is needed. This incision could lead to high levels of surgical-induced astigmatism (SIA) and poor postoperative SE. In this study, the differences in SIA and postoperative astigmatism between implants’ positions have not been analyzed due to the absence of articles studying these variables. As reported before, there are no differences between the position of the lens and the resulting SE. Baykara described the possibility of an IOL implant through a scleral tunnel, rather than corneal incisions. Hernández Martínez and Almeida González reported that with a corneal incision, only 3.33% of his patients relayed under ±1 D of SIA, which improved up to 66.67% when Artisan was implanted through scleral tunnel.

One major concern with any lens with iris support is the loss in CECD. The CECD loss seems to be more related to the type of surgical procedure concurrent with the iris-fixated IOL implant, rather than the IOL position [Fig. 7]. Consequently, the major rate of cell loss has taken place during the surgery, which slowed down during the follow-up. We found similar means of postoperative CECD when the results of the articles with >12 months of follow-up were combined, as is shown in Fig. 4.

To the best of our knowledge, the only study that reported significantly higher rates of endothelial cell loss with prepupillary fixation was performed in patients with previous penetrating keratoplasty. Gicquel reported a mean cell loss of 19% in the first year with the prepupillary implantation,
compared to 3.7% with the retropupillary implant. However, if a difference in the rate of CECD loss depending on the IOL position in patients without previous keratoplasty exists, it is unlikely to be of a similar magnitude to that described by Gicquel.[8]

In our study, both implant positions seem to be safe, with a combined rate of 1.9% of corneal decompensation during the follow-up for the articles included. However, we could not compare the rates of corneal decompensation based on the position of the implant because this data was not specified in the original papers.

In our study, the resulting mean CECD loss was 11.11% for the prepupillary implantation and 12.56% for the retropupillary implantation. This result appears to go against the common belief that the retropupillary fixation is safer to the endothelium. Although, as we said before, the main decrease in CECD occurs during the procedure and not in the follow-up, as one would expect if the IOL was in contact with the endothelial cells, we have to contextualize our data. As we pointed out before, our main source of data is retrospective case series. In this type of studies, the surgeon selects the type of procedure based on the characteristics of each patient, and for some surgeons, the concern remains that the prepupillary IOL damages the endothelium. Therefore, it is most likely for patients with preoperative lower CECD or corneal guttae to end with a retropupillary implant. Some authors, for example, Touriño Peralba et al. in 2018, wrote this differentiation in the study protocol, indicating a retropupillary implantation when the CECD was less than 1200 cells or the anterior chamber was less than 3.0 mm.[7]

Another concern with the implantation of iris claw IOLs is the development of postoperative CME. In this study, a nonstatistically significant lower rate of CME in the retropupillary group (7.70%) compared to the prepupillary group (9.80%) was found [Fig. 8]. This rate of CME obtained with iris-fixed IOLs is lower than the 12% rate reported by Sindal in 2016 with scleral-fixed IOLs (both sutured and sutureless fixation) and the 14.3% rate described by Kansal in 2019 with sutureless scleral-fixed IOLs.[17,18]

Conclusion

In conclusion, this systematic review found little influence of the IOL position on the postoperative analyzed outcomes. The choice of the place of Artisan/Verisyse fixation should be based on the surgeon’s technical experience. Double-blind randomized prospective studies would improve the available evidence on the best implant position for the Artisan/Verisyse IOL.

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Conflicts of interest
There are no conflicts of interest.

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