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REVIEWS

Iris-claw (Artisan[®]/Artiflex[®]) phakic intraocular lenses for high myopia and high hyperopia

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Sergio Kwitko^{1,2} and
Andressa Prestes Stolz¹

¹Ophthalmology Department, Hospital
de Clínicas de Porto Alegre and
OftalmoCentro, Porto Alegre,
RS, Brazil

²Av. Nilo Peçanha, 724/401,
Porto Alegre, RS, CEP 90.470-000,
Brazil

[†]Author for correspondence:

Tel.: +55 513 330 7733

Fax: +55 513 330 7733

sergio@oftalmocentro.com.br

Artisan[®]/Artiflex[®] phakic intraocular lenses (pIOLs) demonstrate reversibility, high optical quality with better best spectacle-corrected visual acuity, refractive predictability, and stability compared with keratorefractive surgeries, in addition to the potential gain in visual acuity in myopic patients due to retinal magnification. With proper anatomical conditions, this lens also shows good results in hyperopic patients. Combined with corneal refractive surgery as an additional procedure, this pIOL shows the most predictable optical result. The main complications of iris-fixated anterior chamber pIOLs are chronic subclinical inflammation, corneal endothelial cell loss, cataract formation, secondary glaucoma, iris atrophy and dislocation. Comprehensive preoperative evaluation and long-term postoperative follow-up examinations are needed to monitor for and prevent serious complications. This article is a review of iris-claw pIOLs, and addresses the results and their complications.

KEYWORDS: Artiflex[®] phakic intraocular lenses • Artisan[®] phakic intraocular lenses • high hyperopia • high myopia • phakic iris-claw anterior chamber intraocular lens

The correction of refractive errors at the corneal plane, especially for higher ametropia, gives better visual quality and larger visual field than spectacles. Potentially serious complications of contact lens wearing and the popularization of corneal laser refractive surgery have led an increasing number of patients toward surgical options for the correction of ametropia. Higher refractive errors are, however, outside the boundaries of safety and effectiveness of corneal surgery [1]. With the aim of preventing corneal ectasia, severe glare and worsened best-corrected visual acuity, eyes with insufficient corneal thickness, inappropriate curvature, borderline tomography findings, and/or eyes with high myopia (≥ 8.0 diopters [D]) and high hyperopia (≥ 4.0 D) are best treated with intraocular refractive surgeries [2–4].

Clear lens extraction or refractive lens exchange has been employed for the correction of higher ametropia, but has some significant complications limiting its widespread adoption, such as an increased risk of retinal detachment in myopic eyes [5,6], macular cystoid edema following capsulotomy with neodymium: yttrium aluminium garnet (YAG) laser [7] and loss of accommodation in young patients.

Phakic intraocular lenses (pIOLs), including angle-supported anterior chamber lenses, posterior chamber lenses and iris-fixated lenses, are other less invasive options that are available. The favorable points of this technique are its reversibility (surgical pIOL removal), fast visual recovery and preservation of accommodation [8].

Angle-supported anterior chamber lenses to correct naturally occurring myopia in patients who have a normal lens was proposed by Strampelli in 1954 [9]. Joaquin Barraquer had much experience with these lenses in Spain during the 1950s [10], but abandoned the idea because of adverse results [11]. The main problems with these implants are a high incidence of pupil ovalization secondary to iris retraction, chronic endothelial damage by peripheral touching and damage to the anterior chamber angle [2]. Today, the Baikoff model NuVita MA20[™] (Bausch & Lomb), the Kelman Duet Implant Phakic IOL (Tekia, Inc., CA, USA) and the AcrySof[®] Cachet[®] (Alcon Labs, Inc., TX, USA) are some of the commercially available lenses [8].

Posterior chamber phakic lenses or pre-crystalline intraocular ‘contact lenses’ (Visian Implantable Collamer Lens[™], STAAR[®] Surgical

Company, CA, USA) are associated with potential pupil-block glaucoma, pigment dispersion and a high incidence of cataract, in particular cortical and anterior subcapsular cataracts [12–15].

The iris-fixated lens, on the other hand, is stabilized further from the cameral angle, corneal endothelium and crystalline lens [16], being the most implanted pIOL today. Another advantage is optical: the claw principle guarantees centering of the lens over the pupil [17], and rotational stability, which is especially important for toric lenses [18]. Originally designed in 1978 to correct aphakia, the iris-fixated lens was modified by Worst [19] and Fechner *et al.* [20] into a biconcave structure with a vault in order to make it suitable for implantation in high myopic phakic eyes, known as the Worst–Fechner iris-claw lens, marketed in 1986 [21]. This was later converted into a convex–concave configuration, named the Worst myopia claw lens (1991), and later on as the Artisan® pIOL, approved by the US FDA in 2004. At present, two lenses are marketed: the Artisan Phakic IOL (Ophtec BV, Groningen, The Netherlands) and the Verisyse® phakic IOL (Advanced Medical Optics, CA, USA) [21,22].

Technical information

The Artisan Phakic IOL is made of an UV light-absorbing polymethyl methacrylate (PMMA) single piece, and is 8.5 mm long in overall length (7.5 mm for pediatric implantations or small eyes) [23], with varying optic diameters, depending on power. There are two models for myopia – model 206, a 5.0-mm optic (for IOL powers from -3.0 D to -23.5 D) (FIGURE 1), and model 204, a 6.0-mm optic (for IOL powers from -3.0 D to -15.5 D) (FIGURE 2) [24]. The smaller range of powers of the larger model can be explained by its peripheral proximity to the endothelium. The lens has a slight anterior 0.87 mm vault, allowing enough distance to both anterior lens capsule and the corneal endothelium [24]. The distance from the optic edge to the endothelium ranges from 1.5 to 2 mm depending on the dioptric power, anterior chamber anatomy and diameter of the optic [24]. For the correction of hyperopia, the model 203, with a 5-mm optic, is available in powers ranging from +1.00 to +12.00 D [24,25]. Before 1997, the lens was available in only 1.0 D power increments; since 1997, it has been available in 0.5 D increments for

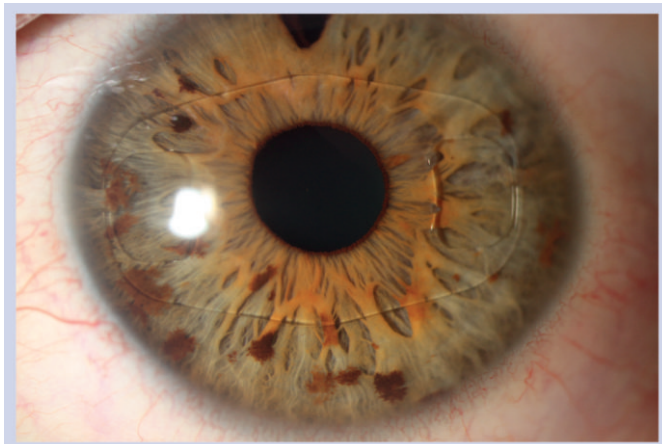


Figure 1. A 5.0-mm optic Artisan® lens.

all models. In Europe, a toric Artisan model is available with parameters similar to the Artisan, but with cylindrical powers up to 7.5 D [8].

The Artiflex® II AC 401 Phakic IOL (Ophtec BV) is a foldable version of the Artisan Phakic IOL made of three pieces: a 6.0-mm similar convex–concave optic zone design, made of hydrophobic polysilicone and two opposed haptics made of PMMA to enable fixation on the midperipheral iris (FIGURE 3). Overall length is 8.5 mm and powers range from -2 to -14.5 D in 0.5 D steps.

The Verisyse phakic IOL is a single-piece, unfoldable lens, manufactured from an UV light-absorbing PMMA material. The lens, distributed in the USA, has exactly the same design as the Artisan and is available in two models, VRSM5US (5.0 mm diameter) and VRSM6US (6.0 mm diameter). The only difference is the dioptric power: Verisyse is available only in 1.0 D increments from -5.0–20 D (model 206), and from 5.0 to 15 D (model 204) [21].

For iris-claw phakic IOL implantation, eyes should have an anterior chamber depth (ACD) measured from the corneal epithelium to the anterior surface of the crystalline lens of 3.2 mm or greater (myopia) [8] and 2.8 mm or greater (hyperopia) [26], scotopic pupil diameter shorter than the lens optic size (5–6 mm), and an endothelial cell density (ECD) of at least the value of the upper 90% confidence interval of the average cell loss as a function of age (usually 2300 cells/mm²) [8].

The preoperative evaluation of a patient for an iris-claw pIOL should be very comprehensive. A complete ophthalmologic examination should be performed, including all the exams required for keratorefractive surgery, as well as specialized testing to detect any pathology that may be a contraindication to this pIOL, such as any angle abnormalities, uveitis, glaucoma or cataract [8].

The van der Heijde formula, which uses the mean corneal curvature, adjusted ultrasound central ACD (ACD – 0.8 mm or 0.9 mm in cases of Artiflex) and spherical equivalent of the patients' cycloplegic correction at a 12-mm vertex, enabled calculation of the pIOL's power [27]:

$$\text{Power} = n / (n/k + P_s - d) - n / (n/k - d)$$

where *n* is the refractive index of the aqueous (1.336), *d* is the distance between the anterior corneal vertex and the principal plane of the IOL in meters (depth of the anterior chamber minus 0.8 mm), *k* is the dioptric power of the cornea, and *P_s* is the equivalent power of the eye's spectacle correction at the corneal plane.

Users can access dioptric powers by the Ophtec site through Ophtec's online Artisan and Artiflex lens calculation program [101].

Surgical procedure

Preoperatively, patients receive prophylactic fourth-generation fluoroquinolone drops for 24 h, and miotic drops to reduce the risk of the lens touch during implantation, and to facilitate haptic enclavation and centration of the pIOL in the optical axis.

Since the development of the surgical technique, by Worst *et al.* [4], several variations have been used. The surgical procedure for the original rigid Artisan model and for the Artiflex foldable lens are similar, instead of the smaller, self-sealing, 3.2-mm clear

corneal incision allowed by the foldability of the Artiflex lens. For the rigid model, a 5.2- or 6.2-mm length corneoscleral tunnel at the 12 o'clock position is needed, depending on the IOL optic zone diameter.

After two stab incisions placed at 10 and 2 o'clock in the direction of the enclavation sites, and under protection by an ophthalmic cohesive viscosurgical device, the pIOL is inserted into the anterior chamber using a specially designed implantation device for Artiflex (Operaid Artiflex® Implantation Spatula; Ophtec) (FIGURE 4). After positioning, the iris tissue is grasped and enclavated into the haptics at 3 and 9 o'clock with the aid of an Operaid Artisan/Artiflex Enclavation Needle (Ophtec) (FIGURE 5). An iridectomy is made surgically or before surgery by a neodymium:YAG laser. The incision is sutured with 10-0 nylon in Artisan cases and for safety in some Artiflex cases.

Author results (unpublished data)

We retrospectively reviewed the results of the correction of high refractive errors in 108 eyes (69 patients) with the Artisan/Artiflex pIOLs, with a mean follow-up period of 24 months (range: 24–96 months). The mean preoperative age was 34.17 ± 8.57 (range: 18–56 years). Mean spherical equivalent was reduced from -12.26 ± 6.74 D (range: -7.75 to -22.50 D) to -1.14 ± 0.88 D in the high myopic group (98 eyes), and from $+7.45 \pm 2.27$ D (range: +7.00 to +11.25 D) to -0.08 ± 2.07 D in the high hyperopic group (ten eyes). The mean preoperative cylindrical power was -1.94 ± 1.45 D and remained stable at the last follow-up visit, -1.34 ± 1.05 D. In total, 14 eyes had further laser-assisted *in situ* keratomileusis (LASIK) or photorefractive keratectomy procedures to correct residual refractive errors, without complications.

Best-corrected spectacle visual acuity improved by one or more Snellen lines in 54% of the eyes, stayed the same as preoperative values in 35%, and decreased by one line in 10% of the eyes. There was one case of loss of more than one line on the Snellen chart.

Mean endothelial cell loss in this patient population was 5.3% (mean preoperative ECD was 2489 ± 384 cells/mm², and 2366 ± 412 cells/mm² at the last follow-up).

Seven eyes (5.6%) needed IOL repositioning: five because of dislocation of the lens (two secondary to a blunt trauma, and three due to progressive iris atrophy), and two eyes due to halos. Seven eyes developed cataract (5.6%) 6 months to 8 years after IOL implantation, all in myopic patients over 40 years old, and one had retinal detachment 1 year after surgery (0.9%); also a high myopic patient. These incidences are comparable to the literature [3,8,21,28,29].

Two eyes developed temporary postoperative intraocular hypertension, one due to a papillary block due to an incomplete YAG laser iridotomy.

No cases of endophthalmitis, corneal decompensation, glaucoma or chronic uveitis occurred.

Long-term clinical results

Results of the main studies on Artisan lens for myopia and hyperopia, with longer than 2 years follow-up, are shown in TABLE 1. These long-term follow-up studies have confirmed effectiveness

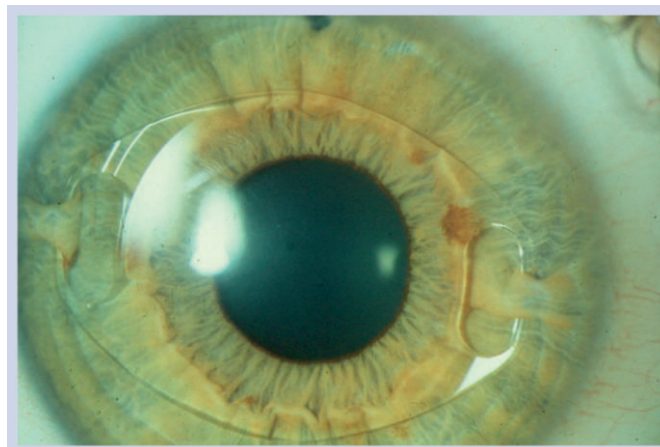


Figure 2. A 6.0-mm optic Artisan® lens.

and stability already shown by short-term and multicenter clinical trials [25,30–32].

In terms of effectiveness, more than 90% of eyes achieve a refraction within 1 D of the intended correction, and stability occurs within the first few years after surgery [28].

Since pIOLs are implanted in healthy and phakic eyes, it is required that the implanted device provides a long-term tolerance by the ocular tissues. In relation to safety, concerns with iris-claw pIOLs are uveitis, secondary intraocular pressure elevation, formation of cataract and endothelial cell loss [8].

Most studies report no clinically relevant chronic inflammation, apart from individual cases only. However, some authors have shown detectable elevated flare levels [33]. Intraocular pressure elevation is observed only immediately after surgery, and has been associated with residual viscosurgical device and postoperative eye drops (steroids) [33]. Secondary cataract formation is another very unusual occurrence after iris-claw pIOL implantation. Because of the earlier onset of cataract in highly myopic eyes, it is difficult to state whether the postoperative occurrence of the opacity is innate or secondary to surgery. This hypothesis is reinforced by the result of a four-times higher incidence of cataract after myopic Artisan/Verisyse pIOL (1.1%) than after hyperopic Artisan/Verisyse, found by a recent meta-analysis [34]. Another

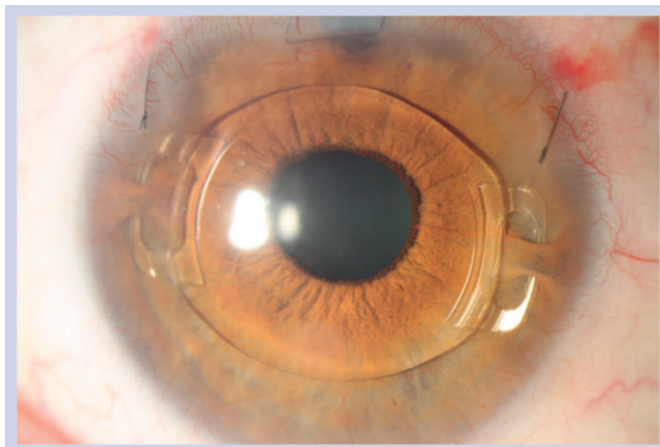


Figure 3. Artiflex® lens.

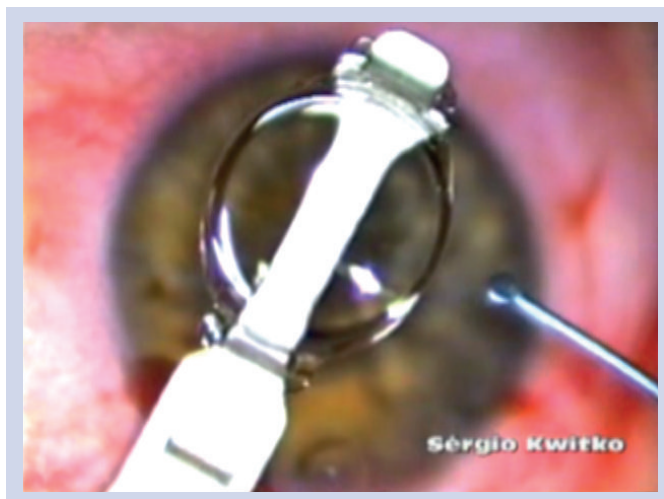


Figure 4. Artiflex® implantation spatula holding the lens.

important aspect is that the old biconcave design of iris-claw lens was related to a higher incidence of cataract (2.2%) than the improved lens in the current market [34].

Although this new design (convex–concave with an anterior vault) was made in order to prevent complications, it shows a prominent edge of the optic that may produce corneal endothelial damage in some eyes [35]. With regard to this topic of particular concern, some studies have found a greater decrease of ECD with the old [36] and even with the new design [37], although the US FDA Ophtec Study [38] demonstrated that implantation of the Artisan iris-claw IOL did not result in a significant loss of ECD at up to 2 years postoperatively. For the first 2 years, authors found endothelial cell losses from zero [30,38] to 8.9% [25,33]. The variability of these values is usually explained by surgical trauma added to differences on endothelial cell counts after contact lens discontinuance.

The history of postoperative corneal endothelial cell loss is not clear. Even natural loss of corneal endothelial cells, approximately 0.6% per year [39], is not well defined for patients with high refractive errors. A theoretical model predicted a mean yearly



Figure 5. Artiflex lens being enclavating in the iris.

endothelial cell loss of 1.0% after Artisan implantation [26]. The European Multicenter study found a cumulative 8.9% change in the absolute mean number of cells at the second year, reducing to an additional 0.7% change at the third year [25]. Another study showed a 3-year cumulative loss of 2.2%, increasing to a later more significant decrease on endothelial cell count from the third to fourth year (an additional 4.3%) and from the sixth to seventh year (an additional 3.5%) [40]. Results of studies with a follow-up period longer than 2 years are shown in TABLE 2.

For the late postoperative period, the proximity of the optic edge to the endothelium was found to be a risk factor for endothelial cell loss after pIOL implantation [26]. This could explain the significant negative correlation between ACD and loss of endothelium [40], and the higher endothelial cell loss after the myopic Artisan compared with the hyperopic Artisan [24], as the height of the Artisan IOL and therefore the potential closeness to the cornea increases with its dioptric power and optic zone diameter. One study used a new software update of the optical coherence tomography (Visante; Carl Zeiss Meditec Inc.) to calculate the edge distance in the preoperative setting using a pIOL simulation program. They described a model to predict how long the pIOL can remain safely in the eye using the preoperative edge distance, and the preoperative ECD count [26].

There are a few particular cases in most studies with inexplicably high endothelial cell losses [41]. This occurrence reinforces the need for a strict follow-up and the explanation of pIOL whenever necessary.

The lower incidence of cataract and endothelial cell loss after hyperopic Artisan [24,34] correlates with findings of a study using ultrasonic biomicroscopy that found that, in hyperopic eyes, adequate space was maintained between the pIOL and the corneal endothelium, angle and crystalline lens [42].

Good safety recommendations are:

- Considering smaller ACD (less than 3.2 mm [37] and even 3.5 mm [40]) a contraindication for the procedure, depending on the preoperative corneal endothelial cells (never less than 2000 cells/mm²), and on the patient's age [26];
- A sufficient ACD for the calculated pIOL is necessary so the distance between the pIOL and the corneal endothelium is not less than 1.5 mm [33];
- Considering eye rubbing an absolute contraindication for this surgery and one of the issues that must be discussed preoperatively with patients [24];
- Patient age is a very important consideration as ACD and ECD tend to reduce with aging [40]. An estimated ACD decrease of 20 μm/year would result in a decreasing edge distance of 0.02 mm/year [26].

The good predictability of refractive outcomes and patient satisfaction with visual acuity results with the Artisan lens [43] made this pIOL a very suitable option for high myopic patients. Several authors have compared the effectiveness and safety of LASIK with those of Artisan/Verisyse pIOLs in moderate and high myopia. Malecaze *et al.* prospectively compared these procedures and

Table 1. Long-term refractive results of the Artisan®/Verisyse® phakic intraocular lens.

Study (year)	Eyes enrolled initially, n (n patients)	Eyes with complete follow-up, n (n patients)	Follow-up (years)	pIOL	SE preoperative	SE postoperative	Postoperative UCVA (i.e., efficacy)	Postoperative BCVA (i.e., safety)	Ref.
Budo <i>et al.</i> (2000)	518 (335)	249	3	Myopic Artisan: 5 mm	-12.95 ± 4.35	-57.1% ± 0.5 D -78.8% ± 1 D	20/20 33.7% ≥20/40 76.8%	20/20 61.5% ≥20/40 93.9%	[25]
Stulting <i>et al.</i> (2008)	662	231	3	Myopic Verisyse: -6 mm (80%) -5 mm (20%)	-12.3 ± 3.2		20/20 34.6% ≥20/40 84%		[21]
Silva <i>et al.</i> (2008)	26 (15)	19 (12)	5	Myopic Artisan: -5 mm (8%) -6 mm (92%)	-11.81 ± 2.93	-0.37 ± 0.69	20/20 73.7% ≥20/40 94.7%		[37]
Benedetti <i>et al.</i> (2007)	49 (30)	49 (30)	5	Myopic Artisan: -6 mm -5 mm	-13.60 ± 7.3	-1.32 ± 1.2			[29]
Guell <i>et al.</i> (2008)	274	88 165	5	Myopic Verisyse: -5 mm -6 mm	-19.8 ± 3.23 -11.27 ± 3.11	-2.64 ± 2.24 -0.98 ± 1.07	≥20/40: -14.8% (5 mm) -42.8% (6 mm) (3 months postoperative)	20/20: -0% (5 mm) -7.4% (6 mm)	[24]
Guell <i>et al.</i> (2008)	41	28	5	Hyperopic Artisan	+4.92 ± 1.7	-0.51 ± 0.85	≥20/40 42.8% ≥20/40 82% (3 months postoperative)	20/20: 17%	[24]
Tahzib <i>et al.</i> (2007)	177 (89)	89 (49)	10	Myopic Artisan: 5 mm	-10.36 ± 4.69	-0.7 ± 1.00		≥20/40 93.3% ≥20/20 52.8%	[28]

BCVA: Best-corrected visual acuity; pIOL: Phakic intraocular lens; SE: Spherical equivalent; UCVA: Uncorrected visual acuity.

reported similar predictabilities for both, but best-corrected visual acuity values and patients' subjective evaluation of quality of vision were better in the Artisan-treated group [44]. Nio *et al.* reported better uncorrected visual acuity values, predictability and contrast sensitivity in the Artisan group [45].

Better than choosing between these two techniques, the most adequate idea is their association. Zaldivar *et al.* introduced the term 'Bioptics' to describe LASIK after a posterior chamber pIOL implantation in patients for whom lens power availability was a problem [46]. Similarly, Guell *et al.* developed the idea of 'adjustable refractive surgery' with the combined implantation of a 6-mm optic phakic iris-claw IOL (Artisan/Verisyse) and a 6.5-mm optical zone LASIK procedure [47,48]. This combination may be the most predictable and safe for moderate and high refractive errors. The pIOL corrects the greatest amount of spherical error, and afterwards, corneal refractive surgery deals with spherical and astigmatic residual errors, with the precision of corneal refractive surgical procedure for low ametropia.

Adjunctive refractive procedures with the application of the excimer laser through either photorefractive keratectomy or LASIK are usually performed 3 months after the pIOL implantation, in order to achieve refractive stability. In cases of LASIK, the flap can be created on the same surgical act of Artisan/Artiflex implantation, or 3 months after.

Expert commentary

Surgical correction of high refractive errors with iris-claw pIOLs is a good option that shows higher predictability, stability and quality of vision compared with corneal refractive surgery. In addition, design improvements on this pIOL, safety measures on surgical procedure, reversibility and the possibility of correction of residual refractive error with corneal surgery have been responsible for the popularization of the Artisan pIOL [3,25].

Table 2. Long-term follow-up of Artisan®/Verisyse® phakic intraocular lenses.

Study (year)	Type of pIOL	Eyes enrolled initially (n)	Eyes with complete follow-up (n)	Follow-up (years)	Mean SE preoperative	ECD loss (%)	Ref.
Stulting <i>et al.</i> (2008)	Verisyse® 6 mm (80%) 5 mm (20%)	662	232	3	-12.3 (4.2)	4.76	[21]
Budo <i>et al.</i> (2000)	Myopic Artisan® 5 mm	518	129	3	-12.95 ± 4.35	9.6	[25]
Doors <i>et al.</i> (2010)	Myopic Artisan 5/6 mm Artiflex® 6 mm	306	79 53 20	3 5 7		4.91 4.34 5.41	[26]
Saxena <i>et al.</i> (2008)	Myopic 5/6 mm Artiflex 6 mm	318	122 51	3 5	-12.25 ± 4.20	2.2 8.3	[40]
Guell <i>et al.</i> (2008)	Myopic Verisyse 5 mm Myopic Verisyse 6 mm	101 173	88 165	5	-19.8 ± 3.23 -11.27 ± 3.11	11.3 10.9	[24]
Benedetti <i>et al.</i> (2007)	Myopic Artisan 6 mm Myopic Artisan 5 mm	49	49	5	-13.60 ± 7.3	9	[29]
Silva <i>et al.</i> (2008)	Myopic Artisan 5 mm (8%)/6 mm (92%)	26	19	5	-11.81 (2.93)	14.05	[37]
Tahzib <i>et al.</i> (2007)	Myopic Artisan 5 mm	177	89	10	-10.36 ± 4.69	8.86	[28]
Guell <i>et al.</i> (2008)	Hyperopic Artisan	41	34	4	+4.92 ± 1.7	6.4 (NS)	[24]

ECD: Endothelial cell density; NS: Nonsignificant; pIOL: Phakic intraocular lens; SE: Spherical equivalent.

The Artisan/Artiflex pIOL based on the iris fixation is stabilized further from the cameral angle, corneal endothelium and crystalline lens [16] compared with angle-supported and posterior chamber pIOLs, reducing the incidence of cataract, glaucoma and endothelial cell loss. Another advantage is optical: the claw principle guarantees centering of the lens over the pupil [17] and rotational stability; especially important for toric lenses [18].

However, a critical step in the process is determining whether a patient is a good candidate for iris fixation. It is imperative, for safety reasons, that a complete preoperative evaluation is performed and all the inclusion criteria must be strictly followed: no anterior chamber abnormalities; endothelial cell count of more than 2000 cells/mm²; pupil diameter smaller than the optical zone; ACP greater than 3.2 mm for myopic and 2.8 mm for hyperopic correction; and peripheral distance from endothelium to IOL optic edge greater than 1.5 mm.

Another important consideration is discussing the procedure, risks and postoperative compliance with the patient.

Five-year view

The ideal intraocular lens has not yet been developed. It would be an accommodative IOL to be implanted through a very small incision, filling out the capsular bag completely, and would last for a long period of time with no need for YAG capsulotomy and with perfect refractive adjustment.

While this perfect lens does not exist, the pIOL has the advantage of preserving crystalline lens accommodation. Of the commercially available pIOLs, the iris-claw pIOL is the one with more qualities than defects. This superiority has been reached after some design modifications, such as the convex–concave design, anterior vault and foldability.

However, we are continuously learning from complications. We believe that, more likely than additional design modification, to prevent undesirable results, preoperative high technology evaluation is necessary, and inclusion criteria are well described and becoming more restrictive. In addition, postoperative regular examinations are needed, and, whenever necessary, explantation is always an alternative.

Key issues

- The Artisan®/Artiflex® new design – convex–concave with an anterior vault – is associated with fewer complications than the older models.
- Phakic iris-claw intraocular lens with adjunctive keratorefractive surgery is the most predictable and safe surgical option for moderate and high refractive errors compared with both procedures alone.
- Performing complete preoperative evaluation and following strict inclusion criteria are necessary for safety reasons.
- Inclusion criteria: no anterior chamber abnormalities; endothelial cell count of more than 2000 cells/mm²; pupil diameter smaller than the optical zone; anterior chamber depth greater than 3.2 mm for myopic and 2.8 mm for hyperopic correction; and peripheral distance from endothelium to intraocular lense optic edge greater than 1.5 mm.
- Postoperative compliance with regular ophthalmologic examination and endothelial cell count (specular microscopy) are needed indefinitely.

Financial & competing interests disclosure

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes

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