Iris-Fixated Intraocular Lenses for Ametropia and Aphakia

Pedro S Simões¹, Tiago B Ferreira²
¹Egas Moniz Hospital, Lisbon, Portugal, ²Hospital da Luz, Lisbon, Portugal

ABSTRACT
Implantation of intraocular lens with Iris-fixation is a safe, efficient and predictable surgical procedure, which empowers the refractive surgeon with singular capabilities. Among their advantages are the reversibility, preservation of accommodation and a broad spectrum of ametropic correction. This lens also appears to be a valid option, with a favorable complication rate, for the treatment of aphakic eyes without capsular support. This article is a review of iris-fixated intraocular lenses and considers their principal indications, complications, and outcomes.

KEY WORDS
Aphakia; Iris-fixated Intraocular Lenses; Phakic Intraocular Lenses; Refractive Errors

Correspondence to:
Dr. Pedro Simões; Egas Moniz Hospital, Lisbon, Portugal; Tel: +351 21 043 1000; E-Mail: pedro.santana.simoes@gmail.com

OVERVIEW
Three types of Phakic intraocular lenses (pIOLs) are commonly used: (I) angle-supported anterior chamber lenses; (II) posterior chamber lenses; and (III) iris-fixated lenses. This review will focus on the latter. Jan Worst developed, in 1978, an iris claw intraocular lens (IOL) for the correction of aphakia following cataract surgery (1). Later, the concept was modified for use in a Phakic eye and the first iris-fixated pIOL was implanted by Fechner and Worst in 1986 (2). Iris-fixated pIOLs have two opposed claw haptics that fixate the lens on the iris by enclavation of midperipheral iris stroma, where the iris is less vascularized and less reactive (3). In 1991, the original biconcave Worst myopia claw lens was changed into the convex–concave shape. This design decreased the potential for complications, improved the optical performance and simplified the implantation technique. In 1992, the first hyperopia lens model was implanted (4). In 1998, the name of the lens changed to Artisan lens (Ophtec B.V., Groningen, the Netherlands), Verisyse in the US (5). The Artisan iris-fixated lens is a one-piece all polymethyl methacrylate (PMMA) IOL. The total length of the lens is 8.5 mm with an optic of 5 or 6 mm in diameter. Since 1999, the Artisan lens is also available for astigmatism correction. In 2003, the foldable iris-fixated Artiflex pIOL (Ophtec B.V.), Veriflex in the US, became available (5). This model was based on the Artisan platform, with a flexible, convex-concave, 6 mm silicone optic, PMMA haptics and overall length of 8.5 mm (6).
accelerating visual recovery (5, 6). Since 2009, the Artiflex lens is also available in Europe for astigmatism correction. Table 1 summarizes iris-fixated pIOLs specifications.

Table 1: Available Iris-fixated pIOLs specifications. Adapted from Alio, J.L. and Perez-Santonja (7).

| Model        | Material        | Power (D)          | Optic diameter (mm) |
|--------------|-----------------|--------------------|---------------------|
| Artisan/Verisyse | PMMA, one-piece | Myopia -1 to -15.5 | 6                   |
|               |                 | Myopia -1 to -23.5 | 5                   |
|               |                 | Hyperopia +1 to +12| 5                   |
|               |                 | Toric +6 to -23, torus +1 to +7 | 5             |
|               |                 | Aphakic +2 to +30  | 5.4                 |
| Artiflex / Veri-flex | Polysiloxane optic; PMMA haptics | Myopia -2 to -14.5 | 6                   |
|               |                 | Toric -1 to -13.5, torus -1 to -5 | 6             |

REFRACTIVE ERROR

Ametropias are the most common eye problem in the US. Among individuals over age 40, 30.5 million have significant myopia and 12 million visually suffer from high hyperopia. Other common refractive errors include astigmatism and presbyopia (8, 9). Refractive surgery is nowadays a valid alternative to treating a broad range of refractive errors and, consequently, the number of people seeking this care is likely to increase (8, 10).

Various surgical modalities and techniques exist to treat a broad range of refractive errors. Laser corneal refractive surgery is effective, safe and has been the favored option for refractive surgery over the last decade (11). However, restrictions imposed by corneal thickness, curvature or pupil size make it inadequate to treat some ametropic eyes, particularly those with high refractive errors (12, 13).

Refractive lens exchange with implantation of an appropriate posterior chamber IOL can correct the ametropia. Though, lensectomy results in a complete loss of accommodation for pre-presbyopic patients and carries some retinal risks, especially, in patients with high myopia (14, 15). Iris-fixated pIOLs increase the capabilities of refractive surgery as they have the potential to correct any ametropia, including hyperopia and astigmatism. Their power does not depend on tissue healing, and their effect is reversible. Furthermore, the crystalline lens remains intact, and accommodation is preserved (15, 16). Some authors have proposed an alternative methodology, combining corneal and intraocular procedures to improve results in high ametropia (17). This approach called bioptics, consists in IOL implantation followed by laser corneal refractive surgery and offers a different surgical option to correct important refractive errors (18). Iris-fixated pIOLs might take part in bioptics as well. Phakic IOLs have also been proposed as a surgical option to correct astigmatism and spherical ametropia in contact lens intolerant keratoconus patients (19). As a combined treatment, iris-fixated pIOLs have a significant role in the management of residual spherocylindrical refractive errors, after other keratoconus treatment modalities have been used, namely, corneal collagen cross-linking (20) or intracorneal ring segments (ICRS) (21).

ARTISAN / VERISYSE

Follow-up of the Artisan pIOL report that correction of moderate to high myopia is a stable, predictable and safe method, when inclusion criteria for surgery are applied (22). Different studies stated that stabilization of the postoperative refraction occurs in the early years after implantation, the great majority of the eyes achieve a refraction within 1.0 D of the intended correction and more than 60% of the patients gained two or more Snellen lines of corrected distance visual acuity (CDVA). Complications are infrequent and rarely cause loss of corrected visual acuity (14,23-25).

High hyperopia is a challenge in refractive surgery. Although the predictability of the refractive results appears to be lower than those in the correction of myopia and astigmatism (as with other surgical procedures for hyperopia), Artisan or Artisan toric pIOLs can correct moderate to high hyperopia, combined or not with astigmatism, with good refractive results. Still, its use is restricted by the anterior chamber depth (ACD), of paramount importance for moderate and high hyperopia, which is typically accompanied by a shallow anterior chamber (26,27). The FDA clinical trial set the inferior ACD limit of 3.2 mm, although 3.0 mm is the value recommended by the manufacturer (14). Table 2 summarizes the additional inclusion criteria in the study.
**IRIS-FIXATED INTRAOCULAR LENSES**

Table 2. Inclusion Criteria – US FDA Artisan / Verisyse Clinical Trial. Adapted From Stulting, R. D., et al. (14)

|                  | Criteria                                                                 |
|------------------|--------------------------------------------------------------------------|
| Age              | 21 – 50                                                                  |
| Axial myopia     | 4.5 D – 22.0 D (Stable manifest refraction)                               |
| Astigmatism      | ≤ 2.0 D (Spectacle plane)                                                |
| ACD              | ≥ 3.2 mm                                                                |
| Pupil size       | ≥ 4.5 mm (Ambient light)                                                |
| Endothelial cell count | ≥ 2000 cells/mm²                                                             |

Phakic intraocular lenses are implanted in a relatively young population, and the possibility of progressive endothelial cell loss over a lifetime is of concern (14). Nevertheless, there is strong evidence in the literature, that the current Artisan Phakic IOL design is long-term stable, and the implanted lens does not continue to stress the endothelium (14, 23). Complications are uncommon and appear to be related to the learning curve, occurring when surgeons are relatively inexperienced (14). Glare levels, accessed using a validated questionnaire, are low. Moreover, overall satisfaction after Artisan pIOL implantation for myopia is excellent (28).

Refractive surgery is controversial in the pediatric population. However, it can be useful for cases of amblyopia with poor compliance or when conventional treatments are unsuccessful, such as high anisometropia and reduced compliance owed to social circumstances or neurobehavioral disorders (29, 30). Though more robust studies are needed, pIOL implantation appears to be an effective option in severe cases of anisometropia associated to amblyopia in children, in whom conventional treatment methods are not adequate and laser refractive surgery is not suitable (30) (Figure 1).

**ARTIFLEX / VERIFLEX**

Modern refractive surgery’s standard of minimally invasive procedures through minor, sutureless wounds, lead into the development of foldable lenses.

Small incisions grant faster visual recovery with less induced astigmatism (6). As stated before, the Artiflex is a foldable version of the Artisan pIOL, with a similar design (Figure 2). Outcomes are mostly comparable with those of previous Artisan studies (31). Though a higher occurrence of pigment precipitates when compared to the Artisan lens has been reported, in most cases they appear to be transient and without clinical significance (6,31). Artiflex pIOL appears to be a useful improvement of the Artisan product family with excellent predictability, efficacy, and safety, when specifications of the manufacturer are taken into account regarding patient selection and postoperative care (6,32). As with the Artisan lens, the author’s experience endorse the importance of the morphometric study of the anterior chamber (AC) during the follow-up period (33).

**APHAKIA**

Following cataract surgery, best result is achieved with the implantation of an IOL in the capsular bag. However, several conditions can lead to aphakia in eyes with insufficient or absent capsule support. Among others, these include crystalline lens subluxation, IOL dislocation, capsular loss during cataract extraction for congenital or juvenile cataract, complicated phacoemulsification for senile cataract and trauma (34,35). The resulting aphakia can be corrected with aphakic spectacles, contact lenses, and implantation of aphakic IOLs (35,36).
Results with spectacles are often poor because of prismatic effects, image magnification, aberrations of images, a limited vision field, and appearance concerns (37). Contact lenses provide better visual results than spectacles; yet, they are associated with a higher risk for microbial keratitis and corneal erosion (38).

Options to surgically correct aphakia include implantation of a transsclerally sutured posterior chamber (PC) IOL (39), angle-supported AC IOL (40), or an iris-fixated IOL (41). Angle-supported AC IOLs are rarely used because of the high incidence of secondary glaucoma, pupil distortion, endothelial cell loss, and IOL instability (42).

Transsclerally sutured PC IOLs preserve the anterior chamber anatomy and cause less endothelial damage than angle-supported AC IOLs. However, they present a high incidence of intraoperative and postoperative complications. In addition, the transscleral fixation of a PC IOL is a technically challenging procedure, requiring a long surgical time and having a steep learning curve (42,43).

Iris-fixated IOLs (view Table 1 for specifications) are easy to place, yield favorable visual outcomes and have a lower incidence of intraoperative and postoperative complications when compared with the previous IOL types (14,43,44). Distinct studies report safe implantation of these IOLs even in the pediatric population (45) (Figure 3).

Primary concern with Artisan aphakic iris-fixated IOL implantation is corneal endothelial cell loss (33). This is of great significance in children, considering their long life expectancy (44). Although more prospective studies of corneal endothelium outcomes, particularly in the young population, are needed, the corneal endothelial cell loss seems to be the result of mechanical injury during surgery (34). Furthermore, mean corneal endothelial cell density (ECD) was comparable to the mean normal ECD in the same age group reported in the literature (45). Another concern is the potential damage to the iris (34). However, the Artisan IOL design provides enough clearance between the IOL and the iris, preventing the IOL from interfering with the normal physiology of the iris, as long as the IOL is properly implanted (46). Other infrequent intraoperative and postoperative complications reported with these IOLs include IOL dislocation, pupillary block glaucoma (ensuring a patent iridotomy is present is of paramount importance in any iris-fixated IOL), retinal detachment, pupil ovalization, hyphema, and cystoid macular edema (23,47).

Implantation of an Artisan aphakic iris-fixated IOL is supported by different studies, which report promising
results and excellent safety, efficacy, predictability and stability for the correction of aphakia in eyes with insufficient capsular support (43,47,48).

CONCLUSION

Modern iris-fixated intraocular lenses are the result of continuing technological evolution over the last 30 years. Their implantation appears a safe, predictable and stable surgical procedure, which offers a broad range of refractive errors correction and reversibility. Aphakia can be corrected with a favorable complication rate. Although the concern has been raised about corneal endothelial loss and a close follow-up is advisable, no reliable evidence puts in danger iris-fixated IOL implantation, when specifications of the manufacturer are taken into account. Sequential use of pIOLs after additional refractive procedures may result in a better visual outcome in selected cases.

DISCLOSURE

Conflicts of Interest: None declared.

REFERENCES

1. Worst J Giris claw lens J Am Intraocul Implant Soc. 1980 Apr;6(2):166-7. PMID: 6997251
2. Fechner PU, van der Heijde GL, Worst JG.. The correction of myopia by lens implantation into phakic eyes. Am J Ophthalmol. 1989 Jun 15;107(6):659-63. PMID: 2729412
3. Ophtec BV 2014; Refractive and Cataract Surgery; The Iris, Artisan/Artiflex. Available at: http://www.ophtec.com/professional/en/refractive-surgery.pdf. Accessed August 29, 2014.
4. Saxena, R. (2009). The Artisan lens: effects on vision quality, the corneal endothelium and vision-related quality of life. Thesis. Rotterdam, Erasmus University
5. Paarlborg JC, Doors M, Webers CA, Berendschot TT, van den Berg TJ, Nuijts RM. The effect of iris-fixated foldable phakic intraocular lenses on retinal straylight. Am J Ophthalmol. 2011 Dec;152(6):969-975.e2. doi: 10.1016/j.ajo.2011.05.024. Epub 2011 Aug 25. PMID: 21871599
6- Dick HB1, Budo C, Malecaze F, Guell JL, Marinho AA, Nuijts RM, Luyten GP, Menezo JL, Kohnen T. Foldable Artiflex phakic intraocular lens for the correction of myopia: two-year follow-up results of a prospective European multicenter study. Ophthalmology. 2009 Apr;116(4):671-7. doi: 10.1016/j.ophtha.2008.12.059. PMID: 19344820
7. Alio, J.L. and Perez-Santonja, J.J. Chapters 1st. in: Jaypee Brothers Medical Publishers. Refractive Surgery with Phakic IOLs. Fundamental and clinical practice (2nd edition). Biopub Inc, New Delhi, India; 2012: 7-9
8. Friedman DS, Congdon N, Kempen J, Tielsch JM. Vision problems in the US: prevalence of adult vision impairment and age-related eye disease in America. Prevent Blindness America 2008 Update of the Fourth edition. Available at: http://www.preventblindness.net/site/DocServer/VPUS_2008_update.pdf. Accessed August 29, 2014.
9. Wolfram C, Höhn R, Kottler U, Wild P, Blettнер M, Bühren J, Pfeiffer N, Misrahi A. Prevalence of refractive errors in the European adult population: the Gutenberg Health Study (GHS). Br J Ophthalmol. 2014 Jul;98(7):857-61. PMID: 24515986
10. McCarty CA, Livingston PM, Taylor HR. Prevalence of myopia in adults: implications for refractive surgeons. J Refract Surg. 1997 May-Jun;13(3):229-34. PMID: 9183754
11. Alió JL, Ortiz D, Mutfuoglu O, Garcia MJ. Ten years after photorefractive keratectomy (PRK) and laser in situ keratomileusis (LASIK) for moderate to high myopia (control-matched study). Br J Ophthalmol. 2009 Oct;93(10):1313-8. doi: 10.1136/bjo.2007.131748. PMID: 18292203
12. Alio, J.L. and Perez-Santonja, J.J. Chapters 2nd. in: Jaypee Brothers Medical Publishers. Refractive Surgery with Phakic IOLs. Fundamental and clinical practice (2nd edition). Biopub Inc, New Delhi, India; 2012: 12-17
13. Schallhorn SC1, Farjo AA, Huang D, Boxer Wachler BS, Trattler WB, Tanzer DJ, Majmudar PA, Sugar A; American Academy of Ophthalmology. Wavefront-guided LASIK for the correction of primary myopia and astigmatism a report by the American Academy of Ophthalmology. Ophthalmology. 2008 Jul;115(7):1249-61. doi: 10.1016/j.ophtha.2008.04.010. PMID: 18598819
14. Stulting RD1, John ME, Maloney RK, Assil KK, Arrowsmith PN, Thompson VM; U.S. Verisyse Study Group. Three-year results of Artisan/Verisyse phakic intraocular lens implantation. Results of the United States Food And Drug Administration clinical trial Ophthalmology. 2008 Mar;115(3):464-472.e1. PMID: 18031820
15. Pop M, Payette Y. Refractive lens exchange versus iris-claw Artisan phakic intraocular lens for hyperopia J Refract Surg. 2004 Jan-Feb;20(1):20-4. PMID: 14763466
16. Alio, J.L. and Perez-Santonja, J.J. Chapters 3rd. in: Jaypee Brothers Medical Publishers. Refractive Surgery with Phakic IOLs. Fundamental and clinical practice (2nd edition). Biopub Inc, New Delhi, India; 2012: 22-23
17. Zaldivar R, Davidorf JM, Oscherow S, Ricur G, Piezzi V. Combined posterior chamber phakic intraocular lens and laser in situ keratomileusis: biopsics for extreme myopia. J Refract Surg. 1999 May-Jun;15(3):299-308. PMID: 10367571
18. Muñoz G, Alió JL, Montés-Micó R, Albarrán-Diego C, Belda J. Artisan iris-claw phakic intraocular lens followed by laser in situ keratomileusis for high hyperopia. J Cataract Refract Surg. 2005 Feb;31(2):308-17. PMID: 15767151
19. Budo C, Bartels MC, van Rij G. Implantation of Artisan toric phakic intraocular lenses for the correction of astigmatism and spherical errors in patients with keratoconus. J Refract Surg. 2005 May-Jun;21(3):218-22. PMID: 15977878
46. Kohnen T, Cichocki M, Koss MJ. Position of rigid and foldable iris-fixated myopic phakic intraocular lenses evaluated by Scheimpflug photography. J Cataract Refract Surg. 2008 Jan;34(1):114-20. doi: 10.1016/j.jcrs.2007.08.037. PMID: 18165090

47. Güell JL, Verdaguer P, Elies D, Gris O, Manero F, Mateu-Figueras G, Morral M. Secondary iris-claw anterior chamber lens implantation in patients with aphakia without capsular support. Br J Ophthalmol. 2014 May;98(5):658-63. doi: 10.1136/bjophthalmol-2013-304035. PMID: 24489374

48. Rao R1, Sasidharan A. Iris claw intraocular lens: a viable option in monocular surgical aphakia. Indian J Ophthalmol. 2013 Feb;61(2):74-5. doi: 10.4103/0301-4738.107198. PMID: 23412525