Journal of
Blindness and Vision Impairment

ScienceAssist International

Review Article | Open Access

A Review on Development of FIOL in the Myopia and High Myopia

Rubén L. Rodríguez-Expósito, Jacob Lorenzo-Morales*

Ophthalmology Service, Hospital Universitario Nuestra Señora de la Candelaria, Canarias, Tenerife, 38010 Islas Canarias, Spain.

***Correspondence:** Jacob Lorenzo-Morales, Ophthalmology Service, Hospital Universitario Nuestra Señora de la Candelaria, Canarias, Tenerife, 38010 Islas Canarias, Spain. Email: jpineroa@ull.edu.es

Received: April 30, 2021; Accepted: May 24, 2021; Published: May 31, 2021

Abstract

The article provides a review of the literature on the history and application of phakic intraocular lenses for correction of high-degree myopia. Typical postoperative complications and peculiarities of the effect on the attention tissues counting on the situation are described for every model of the lens. The analysis of safety and expectations of refractive effect are made. The available leads to the literature allow to gauge the high efficiency of phakic lens implantation within the correction of ametropias of varied degrees, so this method of implantation has been attracting the eye of ophthalmic surgeons for an extended time.

INTRODUCTION

At present, in reference to the event of technology in industry and therefore the increase employed within the field of intellectual work, high demands are placed on the standard of vision in many professions. the foremost common explanation for worsening acuity among the working population is refractive errors. With this pathology, high-degree myopia comes call at the primary place, which doesn't lend itself well to any sort of correction (glasses, contact lenses, refractive laser surgery) [1-3].

This problem remains relevant thanks to the very fact that visual loads appear, ranging from school age and increase with the start of professional activity. consistent with the newest data, by 2020 there'll be about 300 million people with a high degree of myopia within the world, and by 2050 their number will exceed 900 million [4]. To date, the simplest thanks to correct high myopia, which makes it possible to extend acuity and reduce the degree of refractive amblyopia, is that the implantation of phakic intraocular lenses (FIOL).

In this case, this method is suitable in contrast to the laser correction method, especially with large myopia and a skinny thickness of the cornea, where excimer laser interventions could also be unsuccessful or maybe dangerous [5,6]. In Russia, the utilization of FIOL for the correction of ametropias of varied degrees is reflected within the works of Fedorov SN, Zueva VK, Tumanyan ER, Ivashina A.I and other ophthalmic surgeons of the country [7,8].

This procedure has several advantages: predictability, accurate and stable refractive effect, increased spatial contrast sensitivity, safety of accommodation, a brief rehabilitation period, simple implantation, reversibility of intervention if necessary [9-11]. In nearsighted patients, FIOLs give better results than laser keratoablation or extraocular correction methods, since the lens inside the attention creates a bigger image on the retina and increases the utmost corrected acuity by 1-2 lines.

Refractive lensectomy results in a high risk of detachment of the retina, which again speaks in favor of FIOL. The disadvantages of implantation include the necessity for cavitary intervention, early and late postoperative complications thanks to the presence of FIOL within the eye. However, consistent with most researchers, effectiveness and safety depend upon careful adherence to the technology, the right calculations of the FIOL in reference to the interior structures of the attention, also because the selection of patients surely parameters. the utilization of phakic IOLs is clearly justified in patients with initial myopia above -9.0 D (up to 25.0 D), hyperopia quite + 6.0 D (up to 16.0 D) and astigmatism up to 6.0 D. during this case, the depth of the anterior chamber when using anterior chamber models should be a minimum of 3.0 mm, the posterior chamber lenses should be a minimum of 2.8 mm and therefore the density of the

endothelial cells of the cornea should be a minimum of 2000 - 2500 cells/mm.

Refractive surgeons distinguish three sorts of FIOL counting on the situation of the lens within the anterior segment of the eye: anterior chamber with fixation within the region of the anterior chamber angle, anterior chamber with fixation to the iris, posterior chamber with fixation to the ciliary groove or without fixation points. Turning to the history of the creation of the FIOL, one among the primary who developed and applied this method in practice was Dr. Strampelli in 1953, who was the primary to implant the anterior chamber lens inside the attention (Figure 1). FIOL was made from acrylic (PMMA) and was produced during a monolithic design. After 2 years, Dr. Dannheim proposed his model of an anterior chamber phakic lens. Its difference from the Strampelli model was that the haptic elements were made from supramid fiber and were a closed structure, and since 1959 he began to use the particular correction in his clinic J. Barraquer, where quite 230 FIOL implantations were administered, his own modifications that differed from the Dannheim model by the presence of open haptic elements. In Russia, the tactic of phakic correction was first tested by Professor S.N. Fedorov in 1969, the anterior chamber FIOL were made from PMMA and had a haptic a part of nylon 120 microns thick.

All surgeons noted the likelihood of correcting myopia of just about any degree, but the long-term results of the utilization of anterior chamber models of FIOL clothed to be related to a high risk of complications, which include the event of corneal endothelial EDF in 70% of patients, iridocyclitis - 40%, hyphema - 35%, increased IOP with transition to secondary glaucoma - 25%. the event of complications is often explained by the pressure of the supporting elements of the FIOL on the fragile structures of the angle of the anterior chamber. The above listed complications led to the abandonment of the utilization of those FIOL models in ophthalmic practice, despite

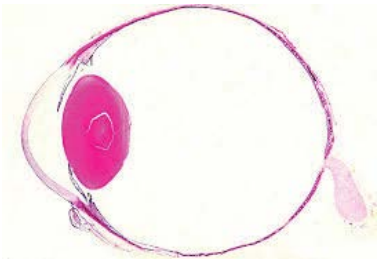

Figure 1: Fixation in the Field of Angulus Iridocornealis.

the high functional leads to the primary days after implantation. thanks to the development of technologies, materials and methods of fixation, the utilization of anterior chamber lenses has resumed, but only now with other places of fixation. M.L. In 1984, Dvali proposed two lens models, one among which was an extrapupillary lens with haptic elements fixed to the basal a part of the iris, the other was angular, fixed within the corner of the anterior chamber, but the assembly of those models was stopped thanks to the frequent development of cataract, EED of the cornea and high blood pressure.

In 1985, G. Baikoff, employing a model of an aphakic IOL as a basis, Kelman multiflex developed a replacement model of anterior chamber phakic lens, called "ZB" [20]. FIOL "ZB" was a monoblock, rigid structure made from PMMA to scale back the pressure on the structures of the angle of the anterior chamber, the FIOL was fixed within the corner of the anterior chamber at only 4 points. Next came the FIOL "ZB5M" and "ZB5MF", the latter features a special coating with fluorine plasma for greater biocompatibility.

Changes touched the corner the lean of the haptic elements - it had been reduced to 200, the haptic elements became thinner, the thickness of the optics was reduced to 250 microns, the diameter of the optics was reduced to 4 mm. These changes allowed the optics to be moved far away from the interior corneal epithelium by a further 0.6 mm. Subsequently, the US company Chiron Vision, now a part of Bausch & Lomb, produced the ZB5MF version under the name NuVita MA 20, during this model the diameter of the optical part was again increased to 4.5 mm, the biconcave shape of the optical part changed to concave convex. But despite all the efforts of the author, this FIOL was discontinued thanks to the shortage of progress in terms of security of this FIOL.

Further, variety of authors proposed various modifications of rigid anterior chamber phakic lenses - "ZSAL-4", "PHAKIC 6", "ACRIOL" et al. The authors made a design change within the sort of a trihedral fringe of the optics, in some cases they increased the diameter of the optics to five.8 mm, covered the optical a part of the FIOL with heparin for better biocompatibility with eye tissues. But the most problems weren't solved - there have been pronounced glare and a halo, there was no rotational stability of the FIOL, pronounced loss of cells of the interior epithelium of the cornea, ovulation of the pupil was often observed, eye hydrodynamics were disturbed (possibly thanks to the constant exposure of the lens support elements and relative pupil blockade

to the trabecula), clouding within the lens (due to poor circulation of the intraocular fluid and, as a result, insufficient nutrition of the lens). consistent with various authors, the event of ovalization is related to chronic ischemic syndrome, which is related to compression of the iris vessels by the contact area of the haptic element of the lens. additionally, it must be borne in mind that each one FIOLs were made up of PMMA, as a result, their implantation required surgical access with a length of 6-7 mm, and in fact its subsequent suture sealing, which led to a quite pronounced postoperative astigmatism and reduced the subjective assessment by patients of the result. Therefore, the eye of scientists turned to the event of anterior chamber phakic lenses with the likelihood of folding and implantation through self-sealing surgical access.

The first such phakic lens was developed by J. Baikoff with the joint participation of the French company IOLTECH and therefore the American CIBA VISION within the late 1990s. The lens was named - GBR/Vivarte. a particular feature of this model is that the use of selective polymerization technology, thanks to which the optics and therefore the ends of the support elements were made from elastic hydrophilic acrylic and therefore the haptic from PMMA, which made it possible to implant the lens through an operative access of 3.2 mm.

The original model of the anterior chamber FIOL, called "Duet Kelman" with three support points within the corner of the anterior chamber, was proposed by Dr. Kelman. FIOL may be a collapsible design, consisting of two parts, where the haptic part is formed of PMMA and therefore the optical part, with a diameter of 5.5-6 mm., made from silicone or hydrophilic acrylic with an anti-reflective coating on the sting. Interestingly, the structure is introduced separately into the anterior chamber and assembled after implantation. a serious advantage of this FIOL are often considered a removable optical unit, which allows for quick and atraumatic replacement just in case of a mistake in calculating the lens power or the presence of any complications.

The following models, which became quite widespread in Europe, were the elastic anterior chamber lenses "I-CARE" and "I-Care Evolution" manufactured in 2003 by Corneal. But in March 2007, anterior chamber models - GBR (IOLtech) and I-care (Corneal) were banned for further use thanks to a catastrophic decrease within the density of endothelial cells within 3 years after implantation.

The last plan to create a secure anterior chamber phakic lens was made by the American company ALCON, introducing the anterior chamber CASHET FIOL within the ophthalmic market at the top of 2008. Unlike other anterior chamber FIOLs, CASHET was made from hydrophobic acrylic with shock absorbing haptic elements and touched the angle of the anterior chamber at 4 points. Unfortunately, the model failed thanks to a progressive decrease within the density of corneal endothelial cells within the distant postoperative period, as in previous models, therefore it had been discontinued and isn't currently used.

According to Dr. Burkhard Dick: "Recently, we've seen an enough FIOL models with fixation within the corner of the anterior chamber, and none of them lasted quite three years and didn't receive FDA (Food and Drug Administration) approval. This method of fixation inevitably results in complications".

To date, the FDA (Food and Drug Administration), the sole anterior chamber iris holder with Artisan/Verisyse (Ophtec, Holland)/ (AMO, USA), developed by the Dutch ophthalmologist J. Worst., has been recognized and approved by the FDA in 1986. The FIOL with the first name "Lobster claw lens" may be a rigid monolithic structure made entirely of PMMA, with slots - claws within the supporting part, the iris tissue is clamped in these slots, thanks to which the lens is suspended within the pupil plane (Figure 2). FIOL with mount for the iris allows you to correct any refractive error, also as astigmatism.

The specified lens was originally wont to correct aphakia if there was no membrane of its own, but over time it had been also suitable for implantation within the phakic eye. Since this lens was made from hard material and required a suture after itself sealing the incision after an outsized surgical approach, the authors began to believe creating flexible lenses, so Artiflex/Veriflex (Ophtec/ AMO) was released. For these models, the optics are made from silicone, and therefore the haptic is formed of

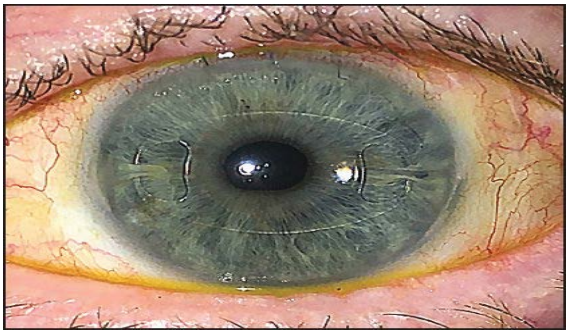

Figure 1: Artisan Iris Claw Lens.

PMMA, which allows them to be implanted through a 3.2 mm wide incision, without subsequent suture sealing.

This iris-fixed lens has the longest history of implantation and provides good refractive results, alongside safety and effectiveness in most cases. Recently, these lenses have received FDA approval. However, in some publications, cases of loss of corneal endothelial cells within the late operational period, ovalization of the pupil, secondary glaucoma, dispersion of iris pigment, atrophy of iris tissue at the sites of in clavation, displacement and dislocation of FIOLs, aseptic uveitis, effects of night glare, and also a rise in protein concentration were described within the moisture of the anterior chamber, detachment of the retina. Therefore, to avoid these complications, many authors mention the necessity for a radical preoperative examination, strict selection criteria for patients and a high level of surgical technique.

In favor of the benefits of a lens with a fixation for the iris, as compared with other FIOLs, it should be noted that there's no problem of selecting the lens diameter suitable for the attention. The lens shifts slightly with changes within the diameter of the pupil thanks to stable fixation, is found at a long way both from the lens and from the rear surface of the cornea, therefore the likelihood of developing cataracts or loss of corneal endothelial cells is extremely small.

In the future, despite the overall use of anterior chamber lenses, Professor Zuev V.K. in 1964 I decided to abandon the thought of putting in the lens within the anterior chamber and place the corrective lens within the posterior chamber of the attention. within the course of this decision, the world's first rear-chamber flexible silicone Teflon-coated lens was created. In 1978, the authors obtained a patent for the first design of the posterior chamber lens of the "fungus" type, which was maintained within the correct position by the sting of the pupil. The optical a part of the lens is inserted into the pupil fringe of the iris, and therefore the haptic part is found within the posterior chamber. thanks to the very fact that the lens is centered by the pupil, this automatically prevents its displacement. In bright light, the pupil doesn't taper but 3 mm in diameter, hence the matter of glare, and when the pupil expands, the standard of vision decreases thanks to light, the halo effect and therefore the lens moving far away from the optical axis. Later, the RSK-1 model was created, which is totally located within the rear chamber and has become the prototype of the lens, manufactured by STAAR.

In 1986, on the idea of MNTK MG, the Fedorov-Zuev model of the RSK-3 type was created, made from silicone and coated with a Teflon coating. The lens went through the trail of modernization and commenced to be made up of collagen, since silicone was toxic and a violation of the Teflon coating developed a progressive decrease within the density of endothelial cells [18]. A hole appeared within the optical part to revive the natural path of outflow of intraocular fluid and stop the effect of suction of the lens to the anterior surface of the lens.

If the primary two models ("RSK-3" and "RSK-1") had only two support elements, then the third model is "RSK -1 (3)" or consistent with the authors the Balashevich-Radchenko lens comes with three fulcrum. additionally to the present, there are several holes at the interface between the optical a part of the lens and therefore the haptic, designed to more easily remove viscoelastic after implantation of a FIOL, which easily migrates to the anterior chamber of the attention, where it are often safely aspirated.

According to the literature, the most complications for these domestic lenses are: anterior subcapsular cataract, especially characteristic of iridocrystal phakic lenses (manifested in damage to the apical surface and structure of the basement membrane, vacuole dystrophy and edema of the anterior capsule) IOL decentration, iridocyclitis, pressure rise (the authors consider, that there's a correlation between the rise in IOP and therefore the irritation of the ciliary processes by the haptic of FIOL).

The purchase by the American-Swiss company STAAR Surgical in 1993 of the manufacturing technology and material of the FIOL, also as patents, confirmed the success and innovativeness of the event of the rear-chamber phakic lenses of the Soviet scientist V. K. Zuev.

The company "STAAR Surgical" under the name "ICL" - Implantable Contact (Collamer) Lens, produced from 1993-1994. model "IC 2020" - prototype "RSK-1", then from 1994-1998 - "IC 2020 - M" and "IC V2, V3", and since 1998. the fourth generation ICL V4 innovation model is produced. In 2011, the Vision ICL model appeared. FIOL passed clinical trials, proved its safety and received the FDA certificate. The evolution of those lenses went by the trail of accelerating the posterior curvature of the optical part (to reduce the likelihood of contact with the anterior surface of the lens), some changes within the shape of the haptic and therefore the presence of a central aqua port (eliminates the necessity for preoperative laser iridotomy or intraoperative iridectomy).

According to lenses of the ICL model, the general cataract development rate was 6%, while in patients older than

45 years, cataracts were observed in 40% of cases. within the literature, during the study, a replacement mechanism was revealed for the formation of anterior subcapsular cataract after force jet washing of viscoelastic through the lens aqua port, but this complication is often avoided by applying bimanual surgical technique.

The Ciba Vision company produces back chamber FIOL PRL (phakic refractive lens) - an elastic monoblock lens made from hydrophobic silicone with an index of refraction of 1.46 and a thickness of 100 microns, designed to correct myopia and hyperopia. The FIOL data differ from ICL lenses during a smaller overall diameter, therefore they are doing not have support on the groove of the membrane but are freely held by the force of capillary attraction. After PRL implantation, the anterior subcapsular cataract is made less frequently, presumably this is often thanks to the so-called "free fixation" phenomenon, there's no support within the ciliary sulcus. Recently, Carl Zeiss Meditec has also been offering PRL lenses.

Nowadays, the domestic rear-chamber lens FIOL-3 has been created within the walls of the MNTK "MG". The lens is formed of a hydrophilic material "contamac CI26" with a water content of 26% and an index of refraction of 1.46. Also, thanks to the presence of relaxing holes within the haptic part, the lens easily adapts to the dimensions of the ciliary groove, and therefore the aqua port within the center of the optical part doesn't block the circulation of chamber moisture. With a follow-up period of up to five years, not one case was revealed with the event of complications.

CONCLUSION

Thus, the results available within the literature make it possible to gauge the high efficiency of implantation of phakic intro ocular lenses within the correction of ametropia of varied degrees. Nevertheless, for half a century, this correction method has met in its path, both ups and downs. Failed implantation attempts, insufficiently inert selection of lens material and postoperative complications prompted researchers to further develop new technologies and improve implants. This problem remains open and relevant therefore, many scientists still work thereon.

REFERENCES

1. Liu X, Fan F, Wang X, Lu Y, Zheng T, Zhou P, et al. Long-Term Observation of Triplex Surgery for Cataract after Phakic 6H Implantation for Super High Myopia. J Opthal. 2016.
2. Bourne RRA, Ali SM, Huq DM, Johnson GJ. Prevalence and causes of blindness and visual impairment in Bangladeshi adults: results of the National Blindness and Low Vision Survey of Bangladesh. Br J Ophthalmol. 2003;87(7): 820-828.
3. Huang D, Schallhorn SC, Sugar A, Farjo AA, Majmudar PA, Trattler WB, et al. Phakic intraocular lens implantation for the correction of myopia: a report by the American Academy of Ophthalmology. Ophthalmology. 2009;116(11):2244-2258.
4. Fricke TR, Wilson DA, Wong TY, Jong M, Naidoo KS, Sankaridurg, et al. Global prevalence of myopia and high myopia and temporal trends from 2000 through 2050. Ophthalmology. 2016;123(5):1036-1042.
5. https://ejmcm.com/article_5967_6c28f3c3f3cf7927f9b-f06ab77ade374.pdf
6. http://lentech.com.co/archivos/estudios/165.pdf
7. Farooqui JH, Acharya M, Kekan M. Current trends in surgical management of myopia. Community Eye Health. 2019;32(105):S5-S6
8. https://eyewiki.aao.org/High_Myopia_and_Cataract_Surgery.
9. Pineda R, Chauhan T. Phakic Intraocular Lenses and their Special Indications. J Ophthalmic Vis Res. 2016;11(4):422-428.
10. https://patient.info/doctor/surgical-correction-of-refractive-errors.htm
11. https://www.doughertylaservision.com/what-surgical-alternatives-are-there-besides-lasik-eye-surgery/