The History of the FIOL Development in the Treatment of High Myopia

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Abstract

The article provides a review of the literature on the history and practical application of phakic intraocular lenses for correction of high-degree myopia. Typical postoperative complications and peculiarities of the effect on the eye tissues depending on the location are described for each model of the lens. The analysis of safety and expectations of refractive effect are made. The available results in the literature allow to evaluate the high efficiency of phakic intraocular lens implantation in the correction of ametropies of various degrees, so this method of implantation has been attracting the attention of ophthalmic surgeons for a long time.

Keywords: Phakic Intraocular Lens; High Myopia; Optical Correction of Refractive Ametropia

Literature Review

At present, in connection with the development of computer technology in industry and the increase in employment in the field of intellectual work, high demands are placed on the quality of vision in many professions. The most common cause of worsening visual acuity among the working population is refractive errors. With this pathology, high-degree myopia comes out in the first place, which does not lend itself well to any type of correction (glasses, contact lenses, refractive laser surgery) [1,15,17]. This problem remains relevant due to the fact that visual loads appear, starting from school age and increase with the beginning of professional activity. According to the latest data, by 2020 there will be about 300 million people with a high degree of myopia in the world, and by 2050 their number will exceed 900 million [27]. To date, the best way to correct high myopia, which makes it possible to increase visual acuity and reduce the degree of refractive amblyopia, is the implantation of phakic intraocular lenses (FIOL).

In this case, this method is acceptable in contrast to the laser correction method, especially with large myopia and a thin thickness of the cornea, where excimer laser interventions may be unsuccessful or even dangerous [14,18]. In Russia, the use of FIOL for the correction of ametropias of various degrees is reflected in 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 short rehabilitation period, ease of implantation, reversibility of intervention if necessary [2,3,5,9,16,37]. In nearsighted patients, FIOLs give better results than laser keratoablation or extraocular correction methods, since the lens inside the eye creates a larger image on the retina and increases the maximum corrected visual acuity by 1 - 2 lines [3,22,29]. Refractive lensectomy leads to a high risk of retinal detachment, which again speaks in favor of FIOL [23,29]. The disadvantages of implantation include the need for cavitary intervention, early and late postoperative complications due to the presence of FIOL in the eye [12].

However, according to most researchers, effectiveness and safety depend on careful adherence to the technology, the correct calculations of the FIOl in relation to the internal structures of the eye, as well as the selection of patients for certain parameters. The use of phakic IOLs is clearly justified in patients with initial myopia above -9.0 D (up to 25.0 D), hyperopia more than + 6.0 D (up to 16.0 D) and astigmatism up to 6.0 D [28,37]. In this case, the depth of the anterior chamber when using anterior chamber models should be at least 3.0 mm, the posterior chamber lenses should be at least 2.8 mm and the density of the endothelial cells of the cornea should be at least 2000 - 2500 cells/mm [22].

Refractive surgeons distinguish three types of FIOl depending on the location of the lens in the anterior segment of the eye: anterior chamber with fixation in 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 of the first who developed and applied this method in practice was Dr. Strampelli in 1953, who was the first to implant the anterior chamber lens inside the eye (Figure 1). FIOl was made of polymethyl methacrylate (PMMA) and was produced in 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 of supramid fiber and were a closed structure, and since 1959 he began to use the actual correction in his clinic J. Barraquer, where more than 230 FIOl implantations were carried out, his own modifications that differed from the Dannheim model by the presence of open haptic elements. In Russia, the method of phakic correction was first tested by Professor S.N. Fedorov in 1969, the anterior chamber FIOl were made of PMMA and had a haptic part of nylon 120 microns thick [3]. All surgeons noted the possibility of correcting myopia of almost any degree, but the long-term results of the use of anterior chamber models of FIOl turned out to be associated with a high risk of complications, which include the development of corneal endothelial EDF in 70% of patients, iridocyclitis - 40%, hyphema - 35%, increased IOP with transition to secondary glaucoma - 25%. The development of complications can be explained by the pressure of the supporting elements of the FIOl on the delicate structures of the angle of the anterior chamber. The above listed complications led to the abandonment of the use of these FIOl models in ophthalmic practice, despite the high functional results in the first days after implantation. Due to the improvement of technologies, materials and methods of fixation, the use of anterior chamber lenses has resumed, but only now with other places of fixation. M.L. In 1984, Dvali proposed two lens models, one of which was an extrapupillary lens with haptic elements fixed to the basal part of the iris, the second one was angular, fixed in the corner of the anterior chamber, but the production of these models was stopped due to the frequent development of cataract, EED of the cornea and secondary hypertension [6].

![Figure 1: Fio1 with fixation in the field of angulus iridocornealis - model Strampelli, 1953 year.](image1.jpg)
In 1985, G. Baikoff, using a model of an aphakic IOL as a basis, Kelman multiflex developed a new model of anterior chamber phakic intraocular lens, called “ZB” [30]. FIOL “ZB” was a monoblock, rigid structure made of PMMA (Figure 2a). In order to reduce the pressure on the structures of the angle of the anterior chamber, the FIOL was fixed in the corner of the anterior chamber at only 4 points. Next came the FIOL “ZB5M” (Figure 2b) and “ZB5MF”, the latter has a special coating with fluorine plasma for greater biocompatibility. Changes touched the corner the tilt of the haptic elements - it was 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 away from the internal corneal epithelium by an additional 0.6 mm.

Figure 2: Fiol with fixation in the angulus iridocornealis: a) ZB b) ZB5M, Baikoff, 1985.

Subsequently, the US company Chiron Vision, now part of Bausch & Lomb, produced the ZB5MF version under the name NuVita MA 20, in 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 due to the lack of progress in terms of security of this FIOL [35].

Further, a number of authors proposed various modifications of rigid anterior chamber phakic lenses - “ZSAL-4”, “PHAKIC 6”, “ACRIOL” and others. The authors made a design change in the form of a trihedral edge of the optics, in some cases they increased the diameter of the optics to 5.8 mm, covered the optical part of the FIOL with heparin for better biocompatibility with eye tissues. But the main problems were not solved - there were pronounced glare and a halo, there was no rotational stability of the FIOL, pronounced loss of cells of the internal epithelium of the cornea, ovulation of the pupil was often observed, eye hydrodynamics were disturbed (possibly due to the constant exposure of the lens support elements and relative pupil blockade to the trabecula), clouding in the lens (due to poor circulation of the intraocular fluid and, as a result, insufficient nutrition of the lens). According to various authors, the development of ovalization is associated with chronic ischemic syndrome, which is associated with compression of the iris vessels by the contact area of the haptic element of the lens [36]. In addition, it must be borne in mind that all FIOLs were made from PMMA, as a result, their implantation required surgical access with a length of 6 - 7 mm, and of course its subsequent suture sealing, which led to a quite pronounced postoperative astigmatism and reduced the subjective assessment by patients of the result. Therefore, the attention of scientists turned to the development of anterior chamber phakic lenses with the possibility 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 the American CIBA VISION in the late 1990s. The lens was named - GBR/Vivarte (Figure 3). A distinctive feature of this model is the use of selective...
polymerization technology, due to which the optics and the ends of the support elements were made of elastic hydrophilic acrylic and the haptic from PMMA, which made it possible to implant the lens through an operative access of 3.2 mm [3].

The original model of the anterior chamber FIOL, called “Duet Kelman” with three support points in the corner of the anterior chamber, was proposed by Dr. Kelman (Figure 4). FIOL is a collapsible design, consisting of two parts, where the haptic part is made of PMMA and the optical part, with a diameter of 5.5 - 6 mm., made of silicone or hydrophilic acrylic with an anti-reflective coating on the edge. Interestingly, the structure is introduced separately into the anterior chamber and assembled after implantation. A major advantage of this FIOL can be considered a removable optical unit, which allows for quick and atraumatic replacement in case of an error in calculating the lens power or the presence of any complications [3].

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 [20]. But in March 2007, anterior chamber models - GBR (IOLtech) and I-care (Corneal) were banned for further use due to a catastrophic decrease in the density of endothelial cells within 3 years after implantation [22].
The last attempt to create a safe anterior chamber phakic intraocular lens was made by the American company ALCON, introducing the anterior chamber CASHET FIOL in the ophthalmic market at the end of 2008. Unlike other anterior chamber FIOLs, CASHET was made of hydrophobic acrylic with shock absorbing haptic elements and touched the angle of the anterior chamber at 4 points. Unfortunately, the model failed due to a progressive decrease in the density of corneal endothelial cells in the distant postoperative period, as in previous models, therefore it was discontinued and is not currently used.

According to Dr. Burkhard Dick: “Recently, we have seen a sufficient number of FIOL models with fixation in the corner of the anterior chamber; and none of them lasted more than three years and did not receive FDA (Food and Drug Administration) approval. My opinion is that this method of fixation inevitably leads to complications” [21].

To date, the FDA (Food and Drug Administration), the only 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 original name “Lobster claw lens” is a rigid monolithic structure made entirely of PMMA, with slots - claws in the supporting part, the iris tissue is clamped in these slots, due to which the lens is suspended in the pupil plane (Figure 5) [34]. FIOL with mount for the iris allows you to correct any refractive error, as well as astigmatism.

![Figure 5: Fiol "Lobster claw lens".](image)

The specified lens was originally used to correct aphakia if there was no lens capsule of its own, but over time it was also suitable for implantation in the phakic eye. Since this lens was made of hard material and required a suture after itself sealing the incision after a large surgical approach, the authors began to think about creating flexible lenses, so Artiflex/Veriflex (Ophtec/AMO) was released. For these models, the optics are made of silicone, and the haptic is made of PMMA, which allows them to be implanted through a 3.2 mm wide incision, without subsequent suture sealing.

Colleagues from Pakistan in their work describe a case where they used an Artiflex lens for a patient with keratoconus after Cross-linking to correct refraction. The specified lens was implanted due to the impossibility of applying contact correction. In the remote postoperative period, no complications were noticed, which indicates the success of this operation [26].

This iris-fixed lens has the longest history of implantation and gives good refractive results, together with safety and effectiveness in most cases. Recently, these lenses have received FDA approval [21]. However, in some publications, cases of loss of corneal endothelial
cells in 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 an increase in protein concentration were described in the moisture of the anterior chamber, retinal detachment [24]. Therefore, to avoid these complications, many authors talk about the need for a thorough preoperative examination, strict selection criteria for patients and a high level of surgical technique [22,33].

In favor of the advantages of a lens with a fixation for the iris, in comparison with other FIOLs, it should be noted that there is no problem of choosing the lens diameter suitable for the eye. The lens shifts slightly with changes in the diameter of the pupil due to stable fixation, is located at some distance both from the lens and from the back surface of the cornea, so the likelihood of developing cataracts or loss of corneal endothelial cells is extremely small [3,26].

In the future, despite the general use of anterior chamber lenses, Professor Zuev V.K. in 1964 I decided to abandon the idea of installing the lens in the anterior chamber, and place the corrective lens in the posterior chamber of the eye. In 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 original design of the posterior chamber lens of the “fungus” type, which was maintained in the correct position by the edge of the pupil [7]. The optical part of the lens is inserted into the pupil edge of the iris, and the haptic part is located in the posterior chamber. Due to the fact that the lens is centered by the pupil, this automatically prevents its displacement. In bright light, the pupil does not taper less than 3 mm in diameter, hence the problem of glare, and when the pupil expands, the quality of vision decreases due to light, the halo effect and the lens moving away from the optical axis. Later, the RSK-1 model was created, which is completely located in the rear chamber and has become the prototype of the lens, manufactured by STAAR.

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

If the first two models (“RSK-3” and “RSK-1”) had only two support elements, then the third model is “RSK -1 (3)” or according to the authors the Balashevich-Radchenko lens comes with three fulcrum. In addition to this, there are several holes at the interface between the optical part of the lens and the haptic, designed to more easily remove viscoelastic after implantation of a FIOL, which easily migrates to the anterior chamber of the eye, where it can be safely aspirated.

According to the literature, the main complications for these domestic lenses are anterior subcapsular cataract, especially characteristic of iridocystal 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, intraocular pressure rise (the authors consider, that there is a correlation between the increase in IOP and the irritation of the ciliary processes by the haptic of FIOL) [10,11,18].

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

The company “STAAR Surgical” under the brand 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 [25]. In 2011, the Visian ICL model appeared. FIOL passed clinical trials, proved its safety and received the FDA certificate. The evolution of these lenses went along the path of increasing the posterior curvature of the optical part (to reduce the

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likelihood of contact with the anterior surface of the lens), some changes in the shape of the haptic and the presence of a central aquaport (eliminates the need for preoperative laser iridotomy or intraoperative iridectomy) [4].

Japanese colleagues argue that monovision using implantation of FIOL data provided good binocular vision at near and long distances, without the development of cataracts, suggesting its feasibility as a new surgical presbyopic approach for early presbyopia (for the dominant eye, the lens was calculated on emmetropia, but for not dominating a small myopia) (monovision) [31].

Among the most common complications are pigment dispersion syndrome, anterior subcapsular cataract, and a decrease in the density of endothelial cells [12,19,32].

According to prof. B. Cochener after implanting the lenses of the ICL model, the overall cataract development rate was 6%, while in patients older than 45 years, cataracts were observed in 40% of cases [22]. In the literature, during the study, a new mechanism was revealed for the formation of anterior subcapsular cataract after force jet washing of viscoelastic through the lens aquaport, but this complication can be avoided by applying bimanual surgical technique [38].

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

Nowadays, the domestic rear-chamber lens FIOL-3 (Figure 6) [13,14] has been created in the walls of the MNTK “MG”. The lens is made of a hydrophilic material "contamac CI26" with a water content of 26% and a refractive index of 1.46. Also, due to the presence of relaxing holes in the haptic part, the lens easily adapts to the size of the ciliary groove, and the aquaport in the center of the optical part does not block the circulation of chamber moisture. With a follow-up period of up to 5 years, not a single case was revealed with the development of complications.

**Figure 6:** The posterior chamber FIOL of the model “FIOL-3”.
Conclusion

Thus, the results available in the literature make it possible to evaluate the high efficiency of implantation of phakic intracocular lenses in the correction of ametropia of various 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 continue to work on it.

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