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The correction of high myopia by posterior chamber lens implantation into phakic eyes

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Objective The aim of the study was to find out the refractive and visual results of posterior chamber lens implantation into phakic eyes for correction of high myopia and the reliability of the method.

Method The Russian designed, negative silicone intraocular contact lenses (ICLs) were implanted into 54 eyes of 30 patients having high myopia by the same surgeon (OFY). Under general anaesthesia in all eyes a negative ICLs were implanted on the crystalline lens through a 6 mm corneal incision at the steepest axis and dilated pupil.

Results A decrease in refractive error was achieved in all eyes. Twenty-four of the eyes (44.4 %) were within ±1.00 diopter (D), and all eyes were within ±2.00 D of the attempted correction. The mean best-corrected visual acuity (BCVA) was 4.25/10 preoperatively and 7.80/10 postoperatively ($p<.001$). No serious complication was seen except for ICL damage by the lens holder in 2 eyes (3.7 %) peroperatively and a transient intraocular pressure (IOP) increase in 9 eyes (16.6 %) in the postoperative period.

Conclusion The clinical and functional follow-up of the ICL implantation indicates that this method of high degree myopia correction is a good alternative when photorefractive keratectomy, LASIK and radial keratotomy are unavailable or unsuitable. A long term follow-up of the results of the negative ICL implantation has not been made yet. Thus the clinical and functional results of this technique indicate the need for further improvement of this method for myopic correction.

Key words Intraocular contact lens, High myopia.

Introduction

Nowadays high degree myopia is still one of the most common refraction pathologies. In the second half of the 20th century, intraocular lens (IOL) implantation surgery has been widely performed for correction of aphakia. After this development some surgeons considered correcting high degree myopia by placing IOLs into the phakic eyes. Implanting an anterior chamber IOL in a phakic eye to correct high degree myopia was developed by Strambelli and Barraquer in the 1950s. This method was recently reviewed by Fechner et al who used the iris-fixated lens and by Baikoff and Perez et al who used the angle-supported lens derived from the Kelman multiflex lens (1-4).

In the 1980s the Russian school introduced the idea of implanting negative IOLs in the posterior chamber, just anterior to the surface of the crystalline lens.[5.] Fyodorov used ICLs of 'the mushroom type'; the haptical portion was positioned between the iris and the lens in the posterior chamber and the optical portion was situated at the pupil's area. This ICL was made of silicone with a 500-600 nm thick teflon coating (6).

The technique of implanting a posterior chamber IOL in a phakic eye to correct high myopia is probably one of the most efficacious and predictable surgical procedures currently available for correcting high myopia. However, the surgeons involved in the problem have not yet come to a common opinion on the negative ICL construction, its position in the eye and its material. Additionally, its long term risks to the iris, lens and corneal endothelium are not well known in detail yet (5,7).

Recently a new silicone lens produced by the Mikof company in Russia is reported to have been successfuly implanted (8,9). The aim of this study was to make clinical and functional follow-ups of negative ICL implantation in high-grade myopia without animal experiments, based on the previous studies.

Material and Method

The Russian-designed negative silicone ICLs were implanted into 54 eyes of 30 patients having high myopia by the same surgeon (OFY). The mean spherical equivalent cycloplegic refraction (SECR) of the patients was 16.31 ± 3.08 D (min. -10.50, max. -21.00 D). The mean age of the patients was 28.22 ± 6.09. There were high grade unilateral myopia in 6 patients (11.1 %) and bilateral myopia 24 patients (88.9 %).

Patient selection criteria included stable myopia greater than -10.00 D, low visual acuity with spectacles and contact lenses or failure in wearing of them, anisometropia due to high unilateral myopia, normal anterior segment with an anterior chamber depth greater than 3.2 mm, and impossibility or unavailability of performing the radial keratotomy, photorefractive keratectomy, LASIK or other corneal refractive surgery and finally an age over 20. Functional defectiveness of the fellow eye, more than 12 mm 'white to white' corneal diameter, cataract, glaucoma, anterior uveitis, some other anterior segment pathologies, serious retinal pathologies and

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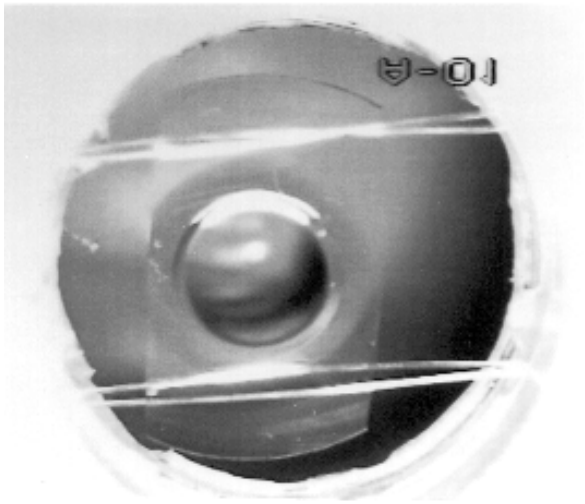
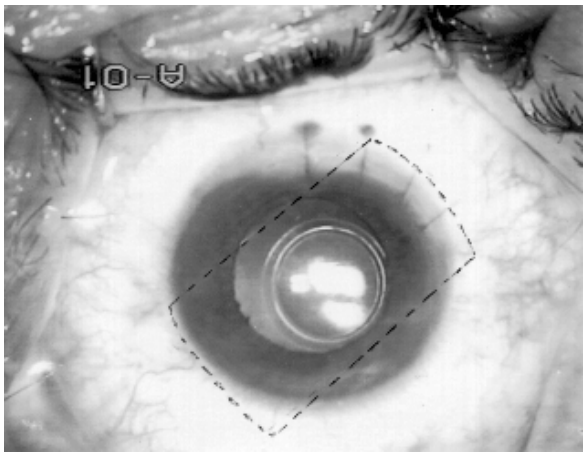
general health problems were among the contraindications for the negative ICL implantation.

All the lenses manufactured by the the Mikof company in Russia came in sterile packed plastic holders. The label on each packet carried the name of the lens, together with dimensions and the diopter of the ICL. These plate-shaped lenses were 11.50-12.50 mm in overall diameter and 4.5-5.0 mm in optical width and of silicone structure (Picture 1, 2).



Picture 1. The ICL in the pocket.



Picture 2. The view of the ICL postoperatively.

Basic examination included visual acuity, manifest and cycloplegic refractions, slitlamp examination, Goldmann applanation tonometry, Goldmann three mirror gonioscopy, binocular vision examination, axial length and anterior chamber depth measurements with ultrasound and indirect binocular ophthalmoscopy. The refractive error of each eye was determined using a computerized refractometer and streak retinoscopy with and without cycloplegia.

The power of the ICL to be implanted was based on the patient's refractive error, the desired correction and the experience of the surgeon.

All operations were performed under general anaesthesia. The pupil was dilated using topical phenylephrine four times, every 15 minutes, one hour before surgery. A 6mm corneal incision at the steepest axis was made. The anterior chamber was filled with 1% sodium hyaluronate (Healon). Peripheral iridectomy was performed in all eyes. Then the silicone ICL was implanted underneath the iris using untoothed forceps; it came to rest just in front of the crystalline lens. Care was taken not to damage the ICL nor the crystalline lens. Then the pupil was constricted with acetylcholin. The corneal wound was suture interrupted with 10/0 nylon. Subconjunctival gentamicin sulphate and steroids were injected, and the eyes were patched.

The postoperative treatment included a topical antibiotic, a mild mydriatic (phenylephrine for one week), a topical steroid (for 1 month) and when required antiglaucomatous therapy.

The mean follow up time was 14.2 ± 3.0 months (min.10, max.19 months). The Wilcoxon Signed-Ranks test in the NCSS computer program was used for statistical analyses.

Results

A significant decrease in refractive error was obtained in all eyes. Twenty four of the eyes (44.4 %) were within ±1.00 D, and all eyes were within ±2.00 D of the attempted correction. The mean SECR was -1.40±0.51 D in the postoperative period.

BCVA after implantation of the ICL was better than before implantation in 49 of the 54 eyes (90.7 %), but remained the same in the other 5 eyes, as 10/10.

The mean BCVA was 4.25/10 preoperatively and 7.80/10 postoperatively. The difference between preoperative and postoperative BCVA values was statistically significant ($p<.001$). The mean BCVA increase was 3.50/10 (Table I). When ICL was implanted unilaterally in 6 eyes, the binocular vision was obtained in 4 patients (66.6 %).

In the perioperative period, a minimal rupture was seen on the edge of the ICL haptic in one case and a damage of the ICL optic in another case due to the strong pressure on the lens by the lens holder. These damaged ICLs were not implanted and replaced by new ones.

Anterior chamber depth (ACD) decreased in all subjects ranging from 0.11 mm to 0.30 mm. The mean ACD was 3.32±0.12 mm postoperatively,

while it was 3.48±0.17 mm, preoperatively. The difference was not statistically significant (p >.05).

Table I. Pre and postoperative data.

Number	Preop. SECR	Post op. SECR	Preop. BCVA	Postop. BCVA	BCVA increase
54	-16.3 D	-1.4 D	4.25/10	7.80/10	3.50/10

In the early postoperative period, IOP increased transiently, not exceeding 26mm Hg, in 9 eyes (16.6 %) and required treatment with beta-blockers for 3-4 weeks. There was marked decentration resulting in ICL removal in one case (1.8 %). In addition, (without disturbing the vision) slight ICL decentration was seen in 3 eyes (5.5 %). In one case, iris prolapsus was seen due to suture insufficiency. No other serious complication such as corneal edema, iritis, severe iris pigment dispersion, change in the anterior chamber angle was seen regardless the type of cataract formation. Subjectively, the patients described an improved quality of vision but no glare.

Discussion

Patients with high myopia who can not use spectacles and contact lenses because of psychological, aesthetic and/or medical problems need to have their problems solved with surgical procedures. Radial keratotomy and photorefractive keratectomy with excimer laser are ineffective in the treatment of high myopia. Epikeratophakia and corneal inlays are difficult tecniques with serious complications. Additionally, although LASIK is an effective treatment for high degree myopia, it was unavailable for us because of expensive technical equipment. Clear lensectomy, although eliminating high degree myopia, leads to loss of accommodation in young patients and an undesirable disability with the risk of retinal detachment (3,8,9).

Posterior chamber negative implants in phakic eyes do not have the risk of clear lens extraction, and they are easily applicable and cost effective. We avoided using the anterior chamber angle-fixed IOLs because of their potential risks for the angle structures and corneal endothelium (2,4).

The silicone negative ICL of the Russian design is implanted behind the iris, just in front of the surface of the crystalline lens. There is a slit space between the ICL optic and the anterior capsule of the crystalline lens without any contact. Unfortunately, because of insufficient technical equipment we could not take a photograph. On the other hand, this lens type does not cause serious iris pigment dispersion and bear no risk for corneal endothelium. It causes fewer complications than other negative IOLs such as the iris fixated lens, angle-supported lens and anterior chamber lens. When indicated, lens removal would not be technically difficult. Additionally, these lenses do not disturb the observation of ocular fundus, therefore we hold the belief that during possible retinal detachment surgery and intravitreal procedures no problem will be created (4,7-9).

Fechner et al reported marked iritis in 2 eyes and ICL exchanges in 4 eyes because of decentration of the lens optic due to shortness of IOLs (10). In our patients we did not see severe iritis, but we observed one ICL decentration that required ICL removal. This ICL had a smaller overall diameter than the ‘white to white’ iris because of faulty measurement.

In the early postoperative period, the IOP increased transiently in 9 eyes. It was probably steroid induced, and when steroid was stopped the IOP decreased to the preoperative level. Fyodorov et al. assumed that the ICL should naturally change the conditions of intraocular fluid circulation and tonography, but there was no data in their study about this matter (6).

In our study, the anterior chamber's depth did not change significantly after the operation. Our results were similar to those Fyodorov et al, but Ertürk et al reported significant decreases down to 0.6 mm.[6,9] They supposed that this decrease in ACD measurements arose as a result of ultrasound waves reflected from the protruding surface of the ICL optic.

Fyodorov reported good visual results in all of the 450 eyes followed up for 5-6 years.[6] Yılmaz et al, Ertürk et al, Fechner et al and Neumann presented their result with the same ICLs and reported good optical results at the 11th Congress of the ESCRS in Insbruck (8-11). In our study, the significant increase of BCVA, independent of myopia degree and visual acuity, was obtained. We attributed this to magnification of the retinal image provided by the double lenses, which is called 'telescopic sight'.

Fyodorov supposed that the increased choroidal blood supply and metabolism in retinal photoreceptors stimulates the retinal vision and the visual acuity in patients with the ICL. The author showed these findings with electrophysiological tests (6).

It is known that binocular vision is an important problem in patients who have different visual acuities for both eyes. In our study, binocular vision was obtained in 66.6 % of the eyes when the negative ICL was implanted unilateraly. Fyodorov achived binocular vision in 75 % of the cases (6).

Our opinion about ICL implantation into high myopic patients is comparable to that other authors. Although long term study has not been reported,

Fyodorov's 5-6 years follow up results give hope for the future of the negative ICL. If LASIK is unavailable for different reasons, negative ICL may be recommended for easily performed without serious complications and as a cost-effective method for correction of high degree myopia.

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