

Long Term Results of Phakic 6 Refractive Implantation for Myopia Correction

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SUMMARY

Objective: To evaluate the safety and the long term results of anterior chamber phakic lens, Phakic 6 Refractive, for myopia correction.

Methods: In this retrospective study we reviewed the charts of 35 myopic patients (62 eyes) who had implantation of anterior chamber phakic lenses (Phakic 6 Refractive, Ophthalmic Innovations International, California, USA) for correction of myopia. The mean age of patients was 26 years (18 to 45 years). The mean spherical refraction was -9.9 (-4 to -18 D). The best corrected distant visual acuity (BCDVA) was 0.92 (1.2 to 0.3) before surgery. The mean follow-up was 8 years (4 to 10). The mean endothelial cell count was 2481 cells/mm² and the mean pachymetry was 540 μ m before surgery. In those patients who needed a second surgical intervention (explantation or lens reposition) the last follow-up visit is the visit before the lens explantation or reposition. The same surgeon (P. R.) performed all surgeries and used the same technique in each surgery.

Results: On the final follow up visit the BCDVA was in the mean 1.02 (1.5 to 0.5). The spherical refraction was in the mean - 0.53 D (-3.0 to +1.0). We noticed a 16% decrease in the mean number of corneal endothelial cells, and no change in the pachymetry values. We had to explant the lenses in 7 eyes (12 %) because of the decreased endothelial cells count. 2 eyes (3.0 %, 1 patient) had to receive treatment for glaucoma, 4 eyes (6.5 %) had to have the artificial lens repositioned, 1 patient had to have photocoagulation therapy for a retinal tear. 93 % of the study eyes had stable refraction during the study period. There was a 10 % increase in the average BCDVA, and there as a 95 % improvement of the original refractive error.

Conclusions: In selected cases, the implantation of Phakic 6 Refractive anterior chamber lens is a viable option despite it is currently largely abandoned.

Key words: ptosis surgery, fronto-tarsal sling, biocompatible PVC

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INTRODUCTION

Implantation of an anterior chamber lens (AC IOL) was first performed in the 1950s [5] as one of the possible solutions following extra- and intracapsular extraction of a cataract, but due to the large number of complications the application of this technique was discontinued. It was not until 1980 that Baikoff [4] introduced second generation anterior chamber lenses, which had more favourable results. Since this time there has been a constant development and new and more sophisticated types of anterior chamber lenses are appearing on world markets. Today the most common indication for implantation of an AC IOL is a complicated cataract surgery, in which a rupture of the posterior chamber

occurs, and it is also used for correction of high refractive errors.

Despite the fact that there has been a substantial development of corneal refractive surgery, and these procedures now are highly safe and have excellent results, they are not appropriate for all patients. They cannot be used on patients with high refractive errors or a thin cornea. In these cases, implantation of a phakic intraocular lens remains the only option for successfully helping these patients.

In our population we included patients who had had a Phakic 6 Refractive lens implanted for correction of myopia. This type of lens was produced in California, USA, in the years 2000–2003. The Phakic 6 Refractive is an “angle-supported” lens – the haptics are embedded in the chamber angle.

The Phakic 6 Refractive is an anterior chamber phakic lens specially developed for the correction of high myopia, which cannot be removed by a corneal refractive procedure. However, with this type of AC IOL there was a rapid diminution of endothelial cells [1], and as a result these lenses were withdrawn from the market after some time. Our study is interesting in that we have a postoperative observation period of 8 years on average, which is unusual for this type of lenses.

METHODOLOGY

Our study is retrospective, we included 35 patients (62 eyes), who were operated on at our workplace for correction of high myopia in the period from 2000 to 2003. An anterior chamber phakic lens of the type Phakic 6

Refractive from the company Ophthalmic Innovations International Inc. (today named Aaren Scientific Inc.) was implanted into all the eyes. This lens has an optical part arching 1 mm forward. The diameter of the optical part is 6 mm for lenses from -10 sfd to -25 sfd and 5.5 mm beyond -25 sfd. The diameter of the entire lens with the haptics is 11.5 mm to 14.0 mm, graded at intervals of 0.5 mm. The average age of the patients in our population was 26 years (18 to 45 years). We included only patients who did not have any ocular surgical procedure in their anamnesis. The average refraction before surgery was -9.9 sfd (-4 to -18 sfd). Preoperatively the best corrected visual acuity (BCVA) was on average 0.96 (0.3 to 1.2). We examined BCVA on Snellen's optotypes. The postoperative observation period was on average 8 years (4 to 10 years). The average values of the number of endothelial cells was 2481 cells/mm² before surgery, pachymetry 540 µm, "white to white" distance was on average 12.12 mm (11.0 to 13.0 mm) and the average depth of the anterior chamber (endothelium – anterior chamber of lens) was 3.58 mm (3.10 to 4.05 mm).

The last follow-up examination on the patients in whom a further surgical intervention was necessary (explantation, repositioning) was conducted always before the surgical procedure. All patients in the group were operated on by a single surgeon (P.R.) and the same operating technique was always used. The number of endothelial cells was examined by a Noncon ROBO PACHY Specular Microscope (Konan, Japan).

RESULTS

In the last follow-up visit, BCVA was on average 1.02 (0.5 to 1.5). Spherical refraction was on average -0.53 sfd (from -3.0 sfd to + 1.0 sfd). We recorded a reduction in the number of endothelial

cells by 16 %, pachymetry remained postoperatively unchanged. In 7 eyes (12%) it was necessary to explant these lenses due to the pronounced diminution in the number of endothelial cells. The average time from the surgical procedure to explantation was 6 years (4-7 years), in 2 eyes (3 %, 1 patient) there was an incidence of glaucoma and pharmacotherapy was required. In 4 eyes (6.5 %) repositioning of the AC IOL was performed and in 1 patient (1 eye) laser photocoagulation was required for a retinal tear. The majority of patients (93 %) had stable refraction throughout the entire observation period. BCVA improved by 10% and there was an improvement of the original refractive error by 95 %.

DISCUSSION

Implantations of a phakic lens in patients with a high refractive error have several advantages in comparison with corneal refractive procedures. Refractive procedures on the cornea do not enable us to correct high myopia for a number of reasons: excessively thin cornea, disproportion between size of pupil and area necessary for ablation during refractive procedure, quality of vision and changes in the peripheral corneal asphericity [2]. Another big disadvantage of corneal procedures is the irreversibility of the changes caused by the keratotome and laser. Following implantation of a phakic lens we are able to explant the lens in the case of more serious complications, and practically bring the eye back to its preoperative condition [3]. As described earlier in the literature, the main reason why Phakic 6 Refractive lenses are not available on the market was the rapid diminution of endothelial cells [2], which also corresponds to our results. The most common complications in our patients were also diminution of endothelial cells, due to which 12 % of eyes underwent explantation of the

lens. In the literature it is described that Phakic 6 Refractive lenses have an excessively curved and relatively wide optic part, due to which the edge of the optic part of the lens encroaches upon the central peripheral of the corneal endothelium, thus accelerating the diminution of the number of endothelial cells [4]. Despite the fact that the production of Phakic 6 Refractive lenses has now been discontinued, our results are relatively satisfactory, since we observed an improvement of the average value of BCVA by 10 %, which means that in 42 % of eyes corrected visual acuity was better after the surgery than before. This improvement in BCVA was recorded primarily in patients with high myopia (on average -12.0 sfd). This was caused by the fact that in the case of higher dioptric corrections, various types of aberrations occur in the lenses of glasses, which do not enable perfect correction of the patient. We regard this improvement of BCVA as a great advantage in comparison with other types of procedures. In the observed patients we did not observe a higher incidence of glaucoma diseases or retinal tears; the incidence was the same as in the comparable population of myopic patients. With regard to the fact that new and more sophisticated types of phakic lenses are constantly being developed, it is difficult to compare Phakic 6 Refractive lenses with other types.

CONCLUSION

Despite the fact that the production of Phakic 6 Refractive lenses has now been discontinued, our results are satisfactory. Through the long-term observation of these lenses we demonstrated that the implantations of newer and more sophisticated types of anterior chamber phakic lenses have a significant place in modern refractive ophthalmosurgery for the correction of high myopia.

LITERATURE

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