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Artisan phakic intraocular lens for correcting high myopia

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Abstract

Objectives: To evaluate the safety indexes and efficacy of Artisan phakic intraocular lens (IOL) for the correction of high myopia. *Methods*: Retrospective interventional case series reports. Thirty-one eyes (22 patients) with myopia from −5.25 to −19.00 diopters underwent implantation of an Artisan phakic IOL. Follow-up examinations were performed at 1 day, 1 week, 1 month, and 3 months. The following parameters were recorded: manifest refraction, slit-lamp examination, applanation tonometry, uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), complications or adverse reactions. The primary variable was the refractive outcome at 3 months. Secondary variables were change in BSCVA, and efficacy and safety indexes. *Results*: At 3 months, mean spherical equivalent was −0.50 ± 0.36 diopters (range, −1.25 – plano). In 29 eyes (93.5%) UCVA was 6/12 or better; the other three eyes had UCVA of 6/15. The difference between preoperative and 1 week postoperative BSCVA was not statistically significant ($p=0.25$). Comparison of BSCVA at 1 week and at 1 month was statistically significant ($p=0.05$); this difference was even more significant at 3 months ($p=0.01$). The BSCVA remained the same or improved for all the eyes. BSCVA for 20 eyes (64.5%) had improved one or more lines in visual acuity. Mean endothelial cell loss at 3 months was 3.96%. *Conclusion*: The Artisan lens is a safe, predictable, and efficacious method to correct high myopia. Postoperative gain in BSCVA was achieved for the majority of eyes. Future study to assess safety indexes and risk of complications is required with long-term follow-up.

Introduction

For many years spectacles and contact lenses have been the only options for correcting myopia, but they often result in inferior optical images (aberrations and miniaturization), unwanted cosmetic appearance, and significant inconvenience. In the last years several keratorefractive procedures, such as epikeratoplasty, excimer laser photorefractive keratectomy, and more recently laser *in situ* keratomileusis, (LASIK) have been all used to correct high myopia [1, 2]. Far better results have been achieved by using LASIK, but more complications have been reported in high myopic eyes after using LASIK, in which a small optic zone diameter and/or deep ablation are necessary. Complications, such as unpredictability, regression, iatrogenic keratectasia, flap-related complications, severe night glare, and loss of spectacle-corrected visual acuity, have also been reported recently [3–6].

Intraocular procedures, such as clear lens extraction (CLE) with intraocular lens (IOL) implantation, and phakic IOLs, have been also used to correct high myopia. CLE with IOL implantation has been criticized because of a theoretical increased incidence of postoperative retinal detachment and accommodation loss in young subjects [7]. There are three types of phakic IOLs: angle-supported anterior chamber lenses, posterior chamber lenses, and iris-fixated lenses. Angle-supported anterior chamber lenses, posterior chamber lenses have potential disadvantages. The angle-supported anterior chamber lens, such as the Baikoff or Nuvita lens, can cause chronic

compromise of the anterior-chamber angle, leading to glaucoma; pupil ovalization [8]. The posterior-chamber implantable contact lens, such as the Staar lens, can induce cataracts, because of contact with the crystalline lens; pigment dispersion, glaucoma [9].

The third category of phakic IOLs, iris-fixated lenses, are the subject of this study. The only such lens that is commercially available is the Artisan lens (Ophtec BV, Groningen, Netherlands). It was designed by Jan Worst in 1986, and was formerly known as the Worst–Fechner Claw lens. This lens has two pincer-like haptics through which a small knuckle or iris is drawn so they secure the lens and the optic lies immediately anterior to the plane of the iris (Figure 1). In recent years, several reports assessing Artisan IOLs for correcting high myopia have been published, suggesting that it is a safe, stable, efficacious, and predictable method to correct high myopia [10–12]. The present study attempts to evaluate the safety and efficiency of the Artisan phakic IOL for the correction of high myopia.

Patients and methods

Patients

This retrospective study included 31 consecutive myopic eyes (22 patients) operated by the Department of Ophthalmology ("Sheva Enaim"), Soroka University Medical Center, Beer-Sheva and "Enaim" Ophthalmological Center, Jerusalem, by two surgeons between January 2002 and December 2002. Each patient was informed of the procedure orally and written and signed a detailed informed consent form.

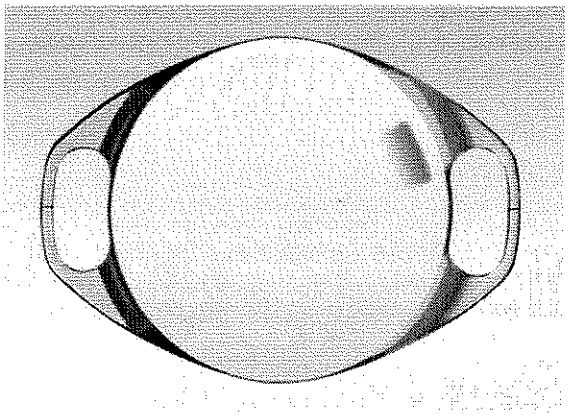

Figure 1. Schematic diagram of the Artisan lens (Courtesy of Ophtec BV, Groningen, Netherlands).

Artisan lens

The Artisan IOL used in this study is made of one-piece clinical quality ultraviolet absorbing polymethylmethacrylate. The lens is designed so that the two haptics lie in the plane of the iris, and the optic vaults 0.69 mm anterior to the iris. The design is intended to prevent chafing of the papillary margin during pupillary movement. We used the model 204, with an optical zone of 6 mm, which has the potential to reduce night-time glare, but increases the risk of induced astigmatism because it is inserted through a slightly larger incision (Figure 2). In eyes with Spherical Equivalent (SE) more than −15 diopters (D) (5 cases), a 5 mm optical zone lens (model 206) was used. The lens power needed for emmetropia was calculated by the manufacturer before surgery by inserting SE refraction, keratometry, and anterior chamber depth into the Van der Heijde formula [13]. The lenses used in this study were available in power increments of 1 D. The surgeon choses a lens power close to the power needed for emmetropia.

Surgical procedure

The surgical technique was as previously described [14–16]. In short, the technique consisted of a corneoscleral incision of 6 mm at 12 O'clock. The anterior chamber was filled with a viscoelastic substance (Healon GV®) before inserting the Artisan lens. It was rotated 90° so that the axis of the lens lies perpendicular to the direction of insertion. The surgeon then grasped the optic of the lens with a special holding forceps. A small knuckle of iris was drawn through the pincer of each haptic with a disposable enclavation needle. Subsequently, a peripheral iridectomy or iridotomy was performed. All viscoelastic material was removed carefully with balanced salt solution, after which the incision was closed with nylon 10/0 interrupted sutures. Gentamycin 20 mg with

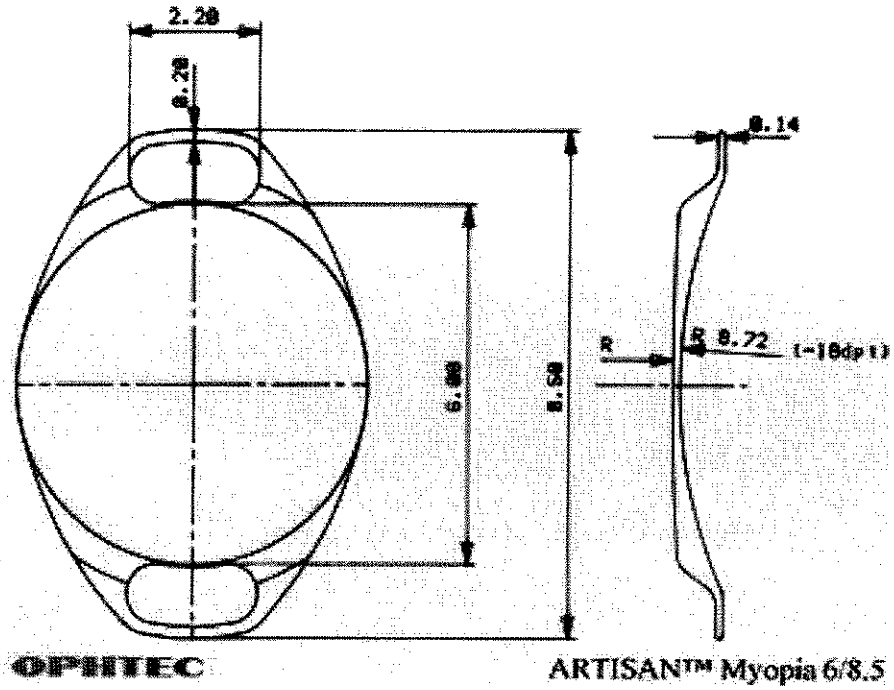

Figure 2. Diagram of the Artisan lens model 204, with an optical zone of 6 mm (Courtesy of Ophtec BV, Groningen, Netherlands) with relevant dimensions.

betamethasone 3 mg was injected subconjunctivally immediately after surgery. Postoperatively, dexamethasone and chloramphenicol drops qid were used during the first 3 weeks, and tapered during 4 more weeks.

Clinical examination

The preoperative examination included manifest refraction, corneal pachymetry, a complete eye examination including slit-lamp microscopy, intraocular pressure measurement, and funduscopy, uncorrected visual acuity (UCVA), and best spectacle-corrected distance visual acuity (BSCVA). The visual acuity was expressed in decimal form and then was converted into Snellen notation. Follow-up examinations were done at 1 day, 1 week, 1 month, and 3 months. At each postoperative examination, the following parameters were recorded: manifest refraction, slit-lamp examination, intraocular pressure measurement, UCVA, and BSCVA. The refraction was expressed as spherical equivalent. Any complications or adverse reactions were also recorded.

Outcome measures and statistical analysis

The primary outcome variable was the refractive outcome at 3 months. Secondary outcome variables were efficacy index (ratio postoperative UCVA to preoperative BSCVA) at 1 week, 1 month, and 3 months; safety index (ratio postoperative BSCVA to preoperative BSCVA) at 1 week, 1 month, and 3 months; change in BSCVA, and safety (percentage of eyes loosing one or more Snellen lines of BSCVA).

Statistical analysis of the results was performed using Student t-test. A p-value of 0.5 was considered statistically significant.

Results

Patient population

Thirty-one eyes of 22 patients were included in this study. There were 6 male and 16 female patients, ranging from 19 to 41 years (25.7 ± 5.9 years). The preoperative measurements were as follows: anterior chamber depth, 3.44 ± 0.26 mm (range, 3.02–4.28 mm); keratometric reading of

44.36 ± 2.09 D (range, 41.38–47.5 D); corneal pachymetry of 476.94 ± 33.41 microns (range, 403–530 microns).

Refractive outcome

Preoperative SE was −11.25 ± 3.33 D (range, −23.5 to −5.25 D). Ten eyes (32%) had SE less than −10 D, 16 eyes (52%) had SE between −10 and −15 D, and 5 eyes (16%) had SE between −15 and −23.5 D.

At 1 month mean SE was −0.62 ±0.41 D (range, −1.50 to 0.25 D). SE was between plano and −0.5 D in 14 eyes (45.2%), in 28 eyes (90.4%) SE was within ±1.00 D of emmetropia, and in all eyes SE was within ± 2.00 D of emmetropia.

At 3 months, mean SE was −0.50 ± 0.36 D (range, −1.25 – plano). SE was between plano and −0.5 D in 21 eyes (67.8%), in 29 eyes (96.8%) SE was within ±1.00 D of emmetropia, and in all eyes SE was within ±2.00 D of emmetropia.

Preoperative refractive cylinder power was −1.42 ± 0.99 D (range, −3.75–0 D). At 3 months, mean refractive cylinder was −0.78 ± 0.58 D (range, −3.00–0 D). The difference between preoperative and postoperative cylinder at 3 months was statistically significant (p = 0.0015).

Visual outcome

Preoperatively UCVA was worse than 0.05 (Snellen equivalent of 6/120). UCVA was 0.42 ± 0.21 at 1 week, 0.62 ± 0.23 at 1 month, and 0.69 ± 0.17 at 3 months. In 29 eyes (93.5%), UCVA was 6/12 or better; the other three eyes had UCVA of 6/15.

There was a statistical significant difference between preoperative UCVA and UCVA at 1 week, UCVA at 1 week and UCVA at 1month ($p < 0.00001$ in both cases). Difference between UCVA at 1 month and UCVA at 3 months was not statistically significant (p = 0.06), so the maximal UCVA was obtained as soon as during the first month. The efficacy index ratio was 0.54 ± 0.29 at 1 week, 0.82 ± 0.34 at 1 month, and 0.95 ± 0.36 at 3 months.

Safety

Mean preoperative BSCVA was 0.80 ± 0.18. At 1 week BSCVA was 0.76 ± 0.22, and 0.84 ± 0.19 at 1 month. The safety of the Artisan lens was evident within the first three months, with a BSCVA of 0.95 ± 0.10.

The difference between BSCVA preoperatively and BSCVA at 1 week was not statistically significant (p = 0.25). However, comparisons between BSCVA at 1 week and BSCVA at 1 month and between BSCVA at 1 week and BSCVA at 3 months were statistically significant (p = 0.05, p = 0.01, respectively).

The BSCVA remained the same or improved in all the eyes. Twenty eyes (64.5%) improved one or more lines of visual acuity. The safety index ratio was 1.02 ± 0.39 at 1 week, 1.16 ± 0.48 at 1 month, and 1.29 ± 0.39 at 3 months.

In Figure 3 the preoperative and postoperative BSCVA are presented and in Figure 4, the change in Snellen lines of BSCVA.

Predictability – spherical equivalent

The deviation of the achieved SE correction from the calculated SE correction was calculated. After 3 months, in 28 eyes (90.4%) SE was within ±1.00 D of emmetropia, and in all eyes SE was within ±2.00 D of emmetropia.

Postoperative complications

No corneal edema, iris atrophy, IOL decentration, hyphema, high IOP, iris prolapse, IOL corneal touch, retinal detachment, cataract, or other

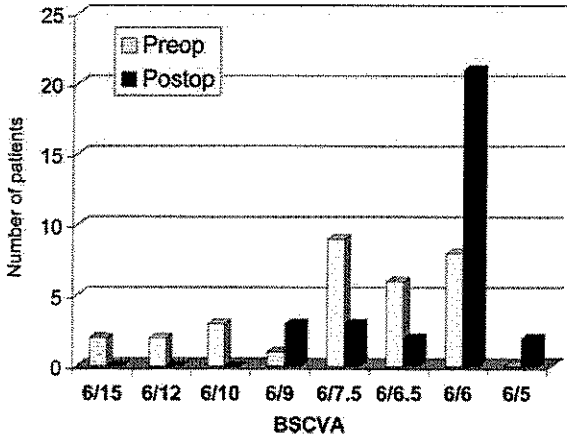

Figure 3. Preoperative versus postoperative BSCVA at 3 months.

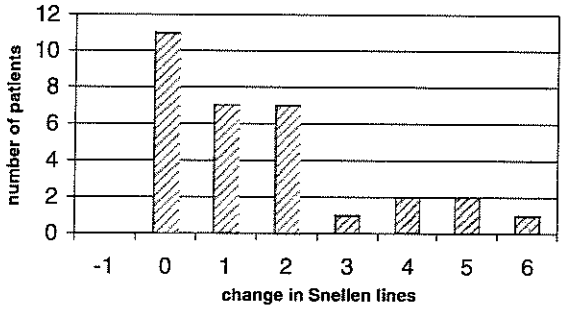

Figure 4. Change in lines of BSCVA after implantation of Artisan lens.

complications were observed postoperatively. No secondary surgical intervention was needed.

Corneal endothelium

Endothelial cell density was measured before surgery and at 3 months after the operation. In 21 eyes with 3-month endothelial cell counts, the preoperative endothelial cell count averaged 2925 ± 377 cells/mm^2. At 3 months after the operation, mean cell density in these eyes was 2809 ± 414 cells/mm^2, with a mean loss of 3.96%.

Discussion

Postoperative UCVA and BSCVA results of this study demonstrate the safety, efficacy, and predictability of the Artisan phakic IOL to correct high myopia. Three months after surgery, spherical equivalent was −0.50 ± 0.36 D. Statistical significant differences in UCVA and BSCVA were observed as soon as 1 month after surgery. No significant postoperative complications were observed. These results are similar to the reported in the literature [10–12].

Spectacle-corrected visual acuity is expected to improve after surgical correction to high myopia because of elimination of the spectacle correction creates a relative magnification, making the letters on the chosen eye chart easier to see [17]. In this study BSCVA was the same or improved in all the eyes, and an improvement of one or more lines of visual acuity was observed in 19 eyes (64.5%). This finding is significant in contrast to LASIK, where 3–5% of highly myopic eyes typically lose two or more lines of BSCVA [18, 19]. The good preservation of BSCVA with the Artisan lens is also related to the high optical quality of IOL and the undisturbed corneal optics, whereas with the use of LASIK procedure, corneal optics are changed [17]. In light of the adverse effects of LASIK, there is reasonable cause to recommend Artisan lens over LASIK for the correction of high myopia. But Artisan lens implantation is an intraocular procedure, and serious postoperative complications can occur. In this study there were no significant complications. The most frequently reported postoperative complications [10–12] have been irregular pupil (0.4–1.2%), transient corneal edema (0.8–1.4%), transient intraocular pressure elevation (1.4%) and decentered Artisan lens (in up to 2%) and are surgeon depended/bad indication or complicated surgery.

Another potential complication with phakic IOL is cataract development and vacuoles. In fact, they are due to the use of dispersive viscoelastics which causes increased intracellular vacuolization of lens epithelial cells [20]. Maloney et al. [11] described two cases of asymptomatic lens vacuoles on crystalline lens after 6 months. The authors suggested that the vacuoles may have been caused during surgery, and could be related to surgeon inexperience. In reports with longer follow-up periods (up to 3 years) no cataract formation was reported. Only sporadic cases of age-related nuclear cataract with no opacification of the anterior capsule have been described by Landesz et al. [12] (one case in 67 eyes) and Budo et al. [10] (six cases in 518 eyes). Longer follow-up would be needed to assess the impact of Artisan IOL implantation in cataract formation.

The impact of the Artisan lens on the corneal endothelium has been evaluated in several studies. Menezo et al. [21] found a mean cell loss of 3.9% at 6 months which increased to 13.4% at 4 years. They suggested that endothelial damage might have occurred during the surgical procedure. Similar results were found in other studies [10, 12]. In the present study we found a mean endothelial cell loss of 3.96% after surgery.

Recently, prospective trials have been compared Artisan lens implantation with LASIK for the correction of high myopia [22, 23]. Although both procedures were found to be similarly effective, stable, predictable and safe, best-corrected visual acuity and subjective evaluation of quality of vision were better for Artisan. In cases of thin

corneas (under 480 microns) and high refractive errors, LASIK is contraindicated.

Also recently, a toric phakic IOL for the correction of myopia or hyperopia with astigmatism has been introduced by the manufacturer [24], with promising results after 6 months. In our series, in all the 10 cases with preoperative cylinder greater than −2.00 D, the final cylinder was less than −0.75 D. But for astigmatism errors greater than −3.00 D, the possibility of toric phakic IOL implantation has to be considered.

This study suggests that Artisan phakic IOLs implantation is more effaceable and can be the better choice for a patient with moderate or high myopia. Larger sample size, followed by a longer follow-up period, is needed to verify and assess the impact of the Artisan lens on the corneal endothelium, the crystalline lens, and the iris and possible complications.

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