Comparison of Iris Claw Phakic Lenses Implant Versus Corneal Laser Techniques in High Myopia. Five Years Follow-up

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Article

Keywords: phakic lenses, myopia, PRK, Femto-LASIK

Posted Date: June 22nd, 2022

DOI: https://doi.org/10.21203/rs.3.rs-1711305/v1

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Abstract

Background

To evaluate the efficacy and safety of Femto-LASIK, PRK, and Artiflex/Artisan phakic lens implantation in the surgical correction of myopia at three months, one, two, and five years of follow-up.

Methods

A retrospective study was proposed in patients who underwent Femto-LASIK technique (287 eyes of 171 patients), PRK (245 eyes of 191 patients), and phakic lens implantation (147 patient eyes) between 2010-2011 with a preoperative spherical equivalent greater than -6 diopters. The effectiveness and safety indexes were calculated during follow-up, comparing Femto-LASIK, PRK, and Artiflex/Artisan phakic lens implantation. In addition, a multivariate linear regression model was estimated.

Results

There were statistically significant differences in effectiveness and safety until five years when comparing Artiflex/Artisan versus PRK and Femto-LASIK (p<0.01). A linear regression model has established whose dependent variable was the UCVA at five years and independent variables were spherical equivalent preop, phakic lens implantation, and PRK. The model explained 30.32% of the patients' visual acuity variability at five years.

Conclusions

Artiflex/Artisan type phakic lens implantation is an effective, safe, and predictable technique at three months, 1, 2, and 5 years with stable refractive results throughout the follow-up periods compared with PRK surgery and Femto-Lasik. The model presented shows phakic lens surgery increases the UCVA result at five years and surgery with PRK decreases this final result.

Introduction

According to the World Health Organization (WHO), myopia, in general, is defined as a refractive error with a spherical equivalent (SE) equal to or less than −0.50 diopters in each eye. The definition of high myopia is considered when the SE is equal to or less than −6.00 diopters in each eye [1–3]. This threshold was also defined by the American Academy of Ophthalmology [4].

The concept of high myopia should not be confused with pathological myopia. Although the excessive elongation of the eye and the presence of a posterior staphyloma could be promoted factors in the development of degenerative changes associated with the latter [5], refractive error or axial length are not criteria "per se" of pathological myopia [6, 7]. Pathological myopia can also be defined as an entity in which chorioretinal atrophy is equal to or more severe than diffuse atrophy [7, 8]. In Western Europe, according to some authors, the percentage of myopic people in 2020 will be around 30–35% [9]. Along
with an increase in high myopia [9], which leads to an increase in cataracts [10], glaucoma, retinal detachment [11], or pathological myopia [7].

The treatment of refractive errors, especially myopia, has been one of the fastest-growing fields of ophthalmology in recent decades. Nowadays, it has avoided ablations of large areas that increase the risk of postoperative corneal ectasia and the presence of optical aberrations that limit the patient's final visual outcome. On the other hand, the criteria for treating significant refractive errors not suitable for treatment with excimer or femtosecond laser have also changed over time. Therefore, the extraction of the transparent lens is widely used to correct myopia in a wide age range. However, limiting this technique before 55 years old is necessary due to the increased risk of retinal detachment. Faced with these limitations, when other less invasive treatments are not feasible or inconvenient, the implantation of a phakic lens to correct refractive errors appears to be an option.

Among the phakic lenses, angular-supported phakic lenses have practically disappeared from the market due to the frequent association with a decrease in the endothelial cell population in the medium and long term [12, 13]. Nowadays, the lenses used by refractive surgeons are the Implantable Posterior Camera Lens (ICL) or the iridian fixation phakic lens as Artiflex and Artisan. Artiflex is a foldable lens that fixes the position of the iris and the anterior chamber through an incision of 3.2 mm and has only a single size in its diameter, unlike other phakic lenses. Artisan is the equivalent unfoldable model for more than −14 dioptres of myopia. The anatomical requirements for implanting both lenses are similar [14–21].

This work aims to compare the efficacy and safety of Femto-LASIK, PRK, and Artiflex/Artisan phakic lens implantation in the surgical correction of myopia at three months, one, 2, and 5 years of evolution and to propose a linear predictive model of visual acuity without correction at five years of refractive procedures and to evaluate its validity.

**Materials And Methods**

**Study Design and Patient Selection**

It is a retrospective observational analysis whose source of information is the medical records of patients treated at the “Instituto Médico de la Vision” (Almería). The study included 245 eyes of 191 high myopic patients treated with the PRK technique, 287 eyes of 171 patients treated with the Femto-LASIK technique, and 147 phakic lenses of 95 patients implanted between 2010-2011. Patients were reviewed at the center at three months, one year, two years, and five years after the surgical procedure. All patients were high myopes (spherical equivalent greater than -6 diopters). For the phakic lens implantation technique, 147 patient eyes were analyzed, all operated on by the same surgeon. The lens implanted in all cases was the folding phakic Worst model with iridian fixation. The anterior chamber location (Artiflex, Ophtec, Groningen, The Netherlands) was used to correct myopia from -6 to -14 diopters. The authors declare no commercial interest.
The criteria for choosing PRK or Femto-LASIK were topographic stability, preoperative pachymetry, and calculated ablation depth. In addition, phakic lens surgery was proposed in all cases of laser surgery contraindications.

**Inclusion Criteria**

All patients in the study met the following inclusion criteria: do not wear contact lenses two weeks before surgery, stable refraction at least two years before surgery, and age over 21; in the case of corneal surgery: corneal topographic stability and sufficient pachymetry according to the refractive defect to be corrected. In addition, in the case of phakic lenses, the anterior chamber depth is greater than or equal to 3.4 mm as measured from epithelium, endothelial cell counts greater than or equal to 2500 cells /mm², mesopic pupil diameter less than or equal to 6.5 mm, and astigmatism less than or equal to 2.00 D.

**Exclusion Criteria**

The general exclusion criteria were: patients under 21 years of age, active pathology of the eye, cataract, glaucoma (in case of phakic lenses), chronic recurrent uveitis, previous eye surgery, macular or retinal pathology, systemic autoimmune disease, diabetes mellitus, and pregnancy.

In addition, corneal laser surgery was excluded: cases with evidence of ectasia or suspicion of keratoconus evidenced by corneal topography estimated postoperative corneal thickness was less than 350 microns, ocular disease, or active systemic disease affecting corneal healing. The study does not include retreatment cases for any refractive surgery

**Patient Information**

The principles of the Declaration of Helsinki of the World Medical Association were followed. In addition, all patients signed an Informed Consent form in advance of surgery more than 24 hours before surgery and were provided with a copy.

**Preoperative Exploration**

The preoperative examination included: Determination of uncorrected visual acuity (UCVA) and best-corrected visual acuity (BCVA) (Topcon ACP8) Snellen type of letters and using the decimal scale, from 0.05 to 1 in mesopic conditions. Contact lens wearers were asked to stop wearing contact lenses two weeks before the examination. Refractive measurement using auto refractometer-keratometer (Nidek ARK-700, Japan). Biomicroscopy: Slit-lamp examination (HaagStrait BQ 900, Switzerland) was performed to rule out the presence of pathology in the anterior ocular pole that contraindicated surgery. Tonometry: Intraocular pressure was measured by non-contact tonometry (Reichert Inc. Buffalo, NY. USA). Pachymetry: By ultrasonic pachymetry (DGH 500. DGH Technology Inc. Exton. PA. USA). Biometrics: The axial logarithm of the eyeball was determined by ultrasonic biometry (DGH 500. DGH Technology Inc.
Exton, PA, USA). Funduscropy was performed with posterior pole lens (Superfield NC, Volk Inc., OH, USA) and indirect ophthalmoscopy with +20 D lens (Volk Inc., OH, USA) 64. Corneal topography: corneal topography examination was carried out using a projection corneal topography using a Placido disc, obtaining an elevation map, and an aberrometry study of the anterior face of the cornea (CSO, Florence, Italy). Endothelial cell count: A specular endothelial cell microscope (SP-2000, Topcon, Japan) was used to obtain a photographic image of the endothelium using the corneal reflection. The calculation of cells is performed automatically with polygonization of 20 cells marked manually on the image taken. Pupillometry: pupillary diameter was determined under mesopic conditions (Pupilograph, Florence, Italy).

**Excimer Laser**

**Surgical Techniques**

Three days prior to surgery, the patient was prescribed cleaning of the eyelids with Cilclar wipes (Alcon), treatment with diclofenac sodium drops 0.1% (Voltaren, Novartis AG, Switzerland), and Ofloxacin eye drops 3 mg/ml (Exocin, Allergan Inc, Irvine, CA). Then, the surgery was performed using topical anesthetic drops, oxybuprocaine 0.4%, and tetracaine. All surgeries were performed by the same surgeon using the same techniques and the same protocol [23].

The excimer laser used in all cases was the OSIRIS Laser (OSIRIS, SCWIND, Germany). Laser calibration was performed at the beginning of each surgery.

In the case of PRK, the de-epithelialization was performed with the laser according to the described technique [23]. Diluted mitomycin C 0.02% was used during PRK surgery for at least 20 seconds. Postoperative treatment was tobramycin eye drops (Tobrex, Alcon Laboratories, Ft Worth, TX) three times daily and 0.25% fluorometholone (FML Forte, Allergan Inc, Irvine, CA) prescribed four times daily for one month. The haze or regression was treated with topical corticosteroids when necessary.

In the case of Femto-LASIK, a superior hinged flap of 8.5 to 9 mm in diameter and thickness was made with the femtosecond laser (Intralase, Abbot) depending on the patient. The depth of the keratectomy ranges from 90 to 400 microns [24]. Lamellar dissection is achieved by minimal impacts, around 3 microns in diameter. The impacts are applied following a grid pattern. Subsequently, the flap must be lifted with a blunt spatula, starting in an area close to the hinge. Postoperative treatment was tobramycin and dexamethasone (Tobradex, Alcon Laboratories, Ft Worth, TX) four times a day for one week.

The lens implantation procedure was the same for all cases and was performed according to the following steps: One week before surgery, an upper iridotomy was performed with a YAG laser (Nidek, Tokyo, Japan) to prevent a possible blockage in the circulation of the aqueous humor. Intraoperative miosis was maintained by perfusion of acetylcholine in the anterior chamber (Acetylcholine 10 mg/ml Cusí, Lab. Alcon). Two 1.5 mm lumbar incisions are made at III h and IX h. The anterior chamber was
maintained by injecting Artivisc viscoelastic 0.55 ml (Lab. Ophtec, Groningen). A 3.2 mm limbal incision is made at XII h, through which the lens is inserted into the anterior chamber using the insertion spatula provided. The lens is oriented on the iris in the chosen position and locked into the iris tissue underlying the haptics, using the specific holding and locking forceps [25-26]. 0.1 ml of cefuroxime 1% is introduced into the anterior chamber to prevent endophthalmitis. Postoperative treatment was tobramycin and dexamethasone (Tobradex, Alcon Laboratories, Ft Worth, TX) four times a day for the first week and a weekly descending pattern for up to 4 weeks.

**Statistical Analysis**

SPSS version 27 (IBM SPSS Inc, Chicago, USA) and R statistical software (version 3.5.1) were used in the statistical analysis. The data were expressed with the mean and standard deviation (SD) for quantitative variables or frequencies and percentages for qualitative variables. The Kolmogorov-Smirnoff test was used to check the normality of the quantitative variables. P values of less than 0.05 in this test indicated that the variables did not follow a normal distribution in some time intervals, so it was necessary to apply non-parametric tests (Mann-Whitney U). The period variable was analyzed two by two in the bivariate analysis with the Wilcoxon test. Differences were considered statistically significant in all cases for an alpha error of less than 0.05 (p < 005). The effectiveness index is defined as the ratio of postoperative UCVA to preoperative BCVA for each period. The safety index is determined as the ratio of postoperative BCVA to preoperative BCVA for each patient in each follow-up period.

A multivariate linear regression model was calculated. The dependent variable was the UCVA at five years. All the requirements of the multivariate linear regression model were reviewed: the linear relationship between the dependent variable and the independent quantitative variables (graph of aggregate variables), the absence of collinearity between variables (IVF < 2.5), homoscedasticity (homogeneity of the variance of the model calculated by Breusch-Pagan test), normality of the residuals of the model verified by the Shapiro-Wilk test.

**Results**

The distribution of the total number of 679 eyes by surgical technique was: Artiflex (128 eyes, 18.9%), Artisan (19 eyes, 2.8%), Femto-LASIK (287 eyes, 42.3%), and PRK (245 eyes, 36.1%).

Table 1 and 2 evaluate and compare the effectiveness indexes according to techniques. Safety indexes were evaluated according to techniques in Table 3 and 4.

A linear regression model whose dependent variable is the UCVA at five years is established. After analyzing the statistical significance between the preoperative and the dependent variables, a linear model was calculated. The surgical technique was classified into three categories: phakic lens, PRK, and FS-LASIK. The model is calculated by the forward-backward method of variable inclusion and exclusion. Table 5 evaluates the statistical significance of the linear regression model coefficients.
The model explains 30.32% of the variability of the patients' visual acuity at five years and has been obtained as a result that surgery with aphakic lens increases the UCVA result (0.43 more) at five years, and surgery with PRK (-0.08) decreases this final result.

The algorithm would be expressed as follows:

UCVA 5 years = 0.96 + 0.04(Sph Equiv preop) + 0.43(Phakic lens) - 0.08(PRK)

The linearity conditions were fulfilled:

- Histogram of the residuals with quasi-normal distribution
- Kolmogorov-Smirnoff Normality Test of the residuals not significant (p=0.05).
- Breach-Pagan test of heteroscedasticity is not significant (p=0.1177).
- Variance inflation factors < 2: Spherical Equivalent preop IVF=1.14 and IVF Techniques=1.06.

There were no severe complications in any refractive surgery with laser and phakic lenses. After Artiflex phakic lens surgery, the corneal endothelial cells remain stable during the follow-up period, although there is a moderate decrease in the patient's preoperative status. The endothelial cell count decreased significantly in the Artisan implant, although it remained above 2000 cells per mm². (Figure 1)

**Discussion**

The study has determined that the mean safety index of all techniques at five years was more significant than 1 (Table 2). However, the effectiveness index at five years of the surgical techniques (Table 1) was 0.82 and 0.86 for PRK and FS-LASIK corneal ablation techniques, respectively, and higher for phakic lenses. In addition, there is a statistically significant difference between the 5-year effectiveness of PRK and Femto-LASIK with Artiflex lens implantation, with the effectiveness of the lens being superior (Table 3).

Gershoni et al. [27] reported that the clinical outcomes of Femto-LASIK were slightly better than those of PRK. Another study compared the results of Femto-LASIK and PRK to correct high myopia and found that Femto-LASIK showed that UCVA was better than PRK [28]. Hashemi et al. [29], in a 6-month follow-up, found efficacy rates of 0.99 ± 0.07 and 0.93 ± 0.22 (p = 0.192) in Femto-LASIK and PRK, respectively, and safety rates of 1.01 ± 0.05 and 1.01 ± 0.14 (p = 0.949), respectively. Hersh et al. [30], in a prospective randomized multicentre study with a 6-month follow-up, concluded that although the improvement in uncorrected visual acuity is faster in LASIK than in PRK, the long-term efficacy and safety results are generally similar between the two procedures in the correction of moderate-high myopia. Sorkin et al. [31] demonstrated that high myopia PRK with mitomycin-C application in eyes at risk of developing high ectasia is a safe and effective alternative to LASIK. In a systematic review and meta-analysis, Wen et al.
showed no statistically significant differences in visual outcomes in terms of efficacy and safety between Femto-LASIK and PRK. Femto-LASIK performed better in predictability than PRK.

The mean safety has been above 1 in all follow-up periods in all phakic lenses. The evolution of efficacy has been above one throughout the follow-up period, reaching a maximum of 1.16 at two years and decreasing slightly to 1.10. Comparatively, studies have published efficacies one year after surgery with an index of 1.13. The studies referring to Artisan refer to efficacy indices at one year between 0.79 and 1 [33, 34]. Cakir et al. [35], in a review of 5-year results, concluded that Artisan IOL implantation is an effective and safe procedure for the surgical treatment of high myopia. A similar conclusion is drawn in Monteiro et al. [36] and Charters et al. [37], referring that phakic intraocular lenses are extremely useful in high myopia and an excellent addition to refractive armamentarium in clinical practice. Hashemi et al. [38], in their comparison study between PRK-MMC and phakic lens implantation, show that phakic IOL implantation was better than PRK-MMC in correcting high myopia in terms of visual quality. However, the two methods had no difference in visual acuity. According to the Miraftab et al. [39] 3-year results, phakic lens implantation is better than PRK-MMC for treating patients with myopia > 8.0D. A systematic review by Wu et al. [40] compared both types of iris-anchored phakic lenses, rigid and foldable, provided updated evidence. They found that the foldable lens group was superior in efficacy and safety in treating high myopia to the rigid lens group. Yuan et al. [41], after a 5-year follow-up, showed that lens implantation fixed to the anterior iris was effective, predictable, and reversible in correcting high myopia in phakic eyes.

Other authors, such as Martinez et al. [42], conclude that the phakic lenses are the first choice in the correction of high ametropia and in cases where the ocular surface or cornea is not suitable for keratorefractive techniques, and the excellent results of safety and efficacy that are obtained are confirmed. After three years of follow-up, Morral et al. [43] show that the Artisan iridian fixation phakic IOL is an effective and safe procedure for correcting moderate-severe refractive errors.

The main limitation of this work is the sample size, and as in most prospective studies, many patients are lost to follow-up at five years for unknown reasons and do not allow the possibility of complications to be identified.

In conclusion, PRK surgery, Femto-Lasik and Artiflex/Artisan type phakic lens implantation is an effective, safe, and predictable technique at three months, 1, 2, and 5 years, with stable refractive results throughout the follow-up periods. Phakic lenses produce a magnifying effect in myopic patients who improve their UCVA and BCVA superior to their preoperative conditions. Concerning phakic lens implantation, corneal endothelial cells remain stable during the follow-up period, although there is a moderate decrease in the patient's preoperative status. The predictive model calculated that surgery with a phakic lens increases the UCVA result at five years, and surgery with PRK slightly this final result.

Declarations

Funding
The authors declare that no funds, grants, or other support were received during the preparation of this manuscript.

**Competing Interests**

The authors have no relevant financial or non-financial interests to disclose.

**Author Contributions**

All authors contributed to the study's conception and design. HAA, APR, and GCL performed material preparation, data collection, and analysis. HAA wrote the first draft of the manuscript and all authors commented on previous versions. All authors read and approved the final manuscript.

**Ethics approval**

This study was performed in line with the principles of the Declaration of Helsinki. Therefore, the Ethics Committee of the University of Almería Code was approved: EFM 179/2022. However, this is an observational study. Therefore, the Department of Nursing, Physiotherapy, and Medicine of Almeria University Research Ethics Committee has confirmed that no ethical approval is required.

**Consent to participate**

Informed consent was obtained from all individual participants included in the study.

**Consent to publish**

The authors affirm that human research participants provided informed consent for the publication of the anonymized data.

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Tables

Tables 1-5 are available in the Supplementary Files section.

Figures
Figure 1

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- TABLE1EYE.xlsx
- TABLE2EYE.xlsx
- TABLE3EYE.xlsx
- TABLE4EYE.xlsx
- TABLE5.xlsx