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# Bioptics by angle-supported phakic lenses and photorefractive keratectomy

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PURPOSE. *To assess efficacy and safety of the combination of angle-supported phakic intraocular lenses (IOLs) and photorefractive keratectomy (PRK) for the correction of myopia and astigmatism.*

METHODS. *Prospective, non-randomized single-surgeon study on 48 patients (76 eyes) undergoing angle-supported phakic IOL implantation with surgical peripheral iridectomy, followed 2 to 3 months later by PRK to correct residual refractive error. Twenty-three patients (33 eyes) achieved good uncorrected visual acuity with IOL implantation alone and did not undergo PRK. Thus, the study was completed by 25 patients (43 eyes) with preoperative mean defocus equivalent (DEQ) of 15.73 D (SD 4.67 D) and mean astigmatism of –2.87 D (SD 1.39 D).*

RESULTS. *Eight months after PRK, mean spherical equivalent was –0.08. Mean DEQ was 0.47 D (SD 0.37); 42/43 eyes (98%) were within ±1 D of DEQ, and 33/43 eyes (77%) within ±0.5 D. Mean uncorrected visual acuity was 0.7 (SD 1.9). Safety index was 1.25; efficacy index 1.11. Best-corrected visual acuity improvement (0.16) was statistically significant (95% CI: 1.1 to 2). Halos were moderate in 6/25 patients (24%); severe in 1/25 patients (4%). Endothelial cell density decreased by –6.6%. Pain after PRK was severe in 3/25 patients (12%) and moderate in 13/25 patients (52%). Complications were recurrent iridocyclitis in one eye, transient ocular hypertension in two eyes, and incomplete iridectomy in one eye.*

CONCLUSIONS. *Angle-supported phakic IOLs followed by adjustment by PRK offer good efficacy, predictability, and safety to manage large refractive myopic errors. (Eur J Ophthalmol 2005; 15: 1-7)*

KEY WORDS. *Bioptics, Myopia, Phakic intraocular lens, Photorefractive keratectomy*

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## INTRODUCTION

Phakic intraocular lenses (IOL) represent an emerging technique to correct refractive errors when corneal procedures are contraindicated; however, residual refractive errors after their implantation may require secondary enhancing procedures. The term bioptics refers to the combination of two refractive techniques (IOL implantation followed by a corneal procedure) to correct primarily large refractive errors with astigmatism, or to fine-tune the results of IOL surgery (1). Proposed bioptics methods include posterior chamber phakic IOL plus laser *in situ* keratomileusis (LASIK) (1, 2), posterior chamber phakic IOL plus photorefractive keratectomy (PRK) (2), phacoemulsification plus LASIK (3-5), iris-fixated phakic IOL plus LASIK (6), and angle-supported phakic IOL plus LASIK (7).

Angle-supported phakic IOLs are implanted by the simplest technique, and PRK is the preferred excimer laser procedure in Italy and performed by 47% of refractive surgeons in the United States (8); however, their association for bioptics has not been assessed.

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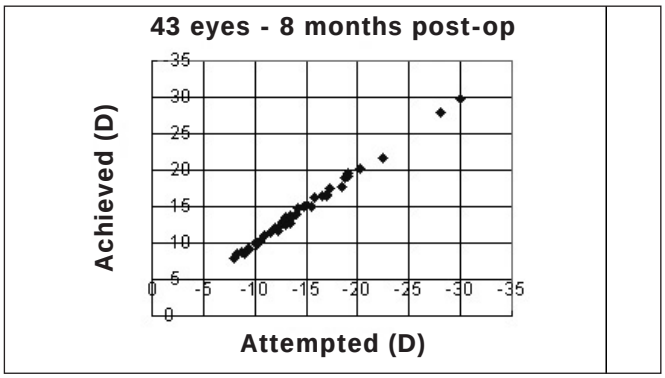


**Fig. 1 -** *Scattergram of attempted vs achieved correction (spherical equivalent) 8 months after bioptics by angle-supported phakic intraocular lens and photorefractive keratectomy in 43 eyes.*

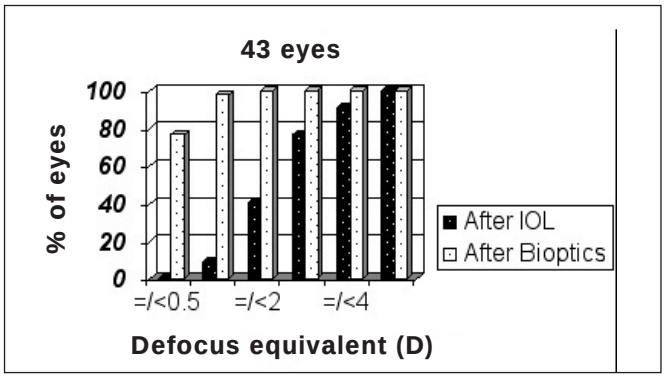


**Fig. 2 -** *Defocus equivalent after angle-supported phakic intraocular lens implantation (black columns) and after completed bioptics by photorefractive keratectomy (white columns) in 43 eyes.*

We evaluated refractive results and safety of the combination of angle-supported phakic IOLs and PRK for the correction of myopia and astigmatism.

## PATIENTS AND METHODS

### *Study design*

This is a prospective, non-randomized single-surgeon study on 48 patients (76 eyes) undergoing angle-supported phakic IOL implantation followed by PRK in the period between September 2001 and October 2002. The internal Ethical Board Committee approved the study. All patients provided informed consent.

For myopia associated with astigmatism, correction of the spherical component was aimed by phakic IOL implantation, and astigmatism corrected by subsequent PRK. For myopia greater than –26 diopters (D), a –24 D phakic IOL (maximum available power) was implanted, and residual error correction was carried out later by PRK. PRK was offered at no extra cost, and performed bilaterally 2 to 3 months after IOL implantation. If the patient was satisfied with phakic IOL implantation alone, PRK was omitted.

Inclusion criteria were age between 25 and 50 years, motivation to reduce spectacle dependence, myopic refraction, subjective contact lens intolerance, impossibility to obtain full correction by a single corneal technique (PRK or LASIK), 18 months refractive stability, endothelial cell density superior to 2450 cells/mm$^3$, a scotopic pupil diameter inferior to 6.1 mm, anterior chamber depth (excluding corneal thickness) superior to 2.9 mm, corneal thickness superior to 450 microns, and horizontal corneal diameter ("white-to-white") between 11.4 mm and 12.6 mm.

Preoperative exclusion criteria were professional driving, diabetes, collagen disorders, amblyopia, glaucoma or ocular hypertension, ocular inflammatory diseases, corneal disease (including keratoconus, epithelial and stromal abnormalities, history of recurrent erosions), crystalline lens disorders, retinal or optic nerve disease, previous corneal surgery, and best-corrected visual acuity (BCVA) inferior to 0.3. Preoperative evaluation comprised autorefractometry, manifest and cycloplegic refraction, BCVA, undilated and dilated slitlamp and fundus examination, tonometry, pupillometry and white-to-white measurement by the computed videokeratographer Keratograph (Oculus, Germany), computed videokeratography, corneal specular microscopy, ultrasound biometry, and ultrasound central pachymetry. Corneal endothelium was evaluated by non-contact Robo-P specular microscope (Konan, Japan), in terms of cell density (cells/mm$^3$), and percentage of hexagonal cells (evaluating polymorphism; normal: >60%). One hundred cells per mm$^3$ were measured; the angle of study was 46°.

Minimal required follow-up was 8 months after PRK.

Initially, 48 patients (76 eyes) were enrolled. Twenty-three patients (33 eyes) were excluded after IOL implantation because they were satisfied with this procedure alone. Finally, bioptics was completed by 25 patients (43 eyes).

The mean age of the 25 patients who completed the

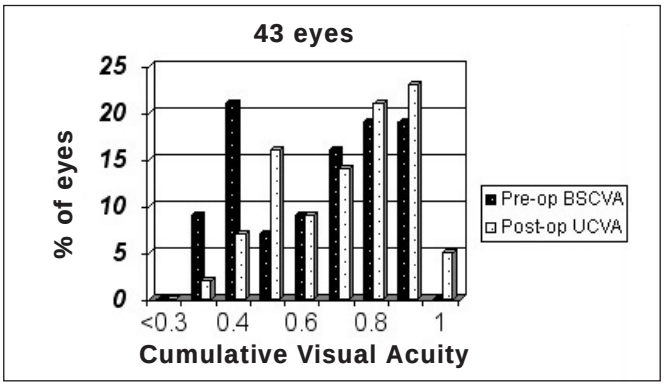


**Fig. 3 -** *Efficacy of bioptics by angle-supported phakic intraocular lens and photorefractive keratectomy in 43 eyes. Black columns: preoperative best-corrected visual acuity. White columns: postoperative uncorrected visual acuity.*

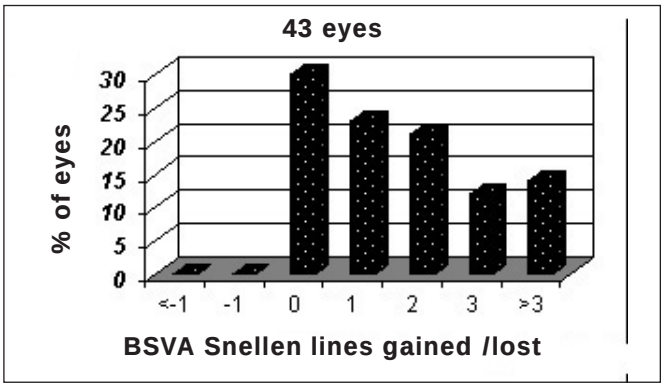


**Fig. 4 -** *Changes in best-corrected visual acuity after bioptics by angle-supported phakic intraocular lens and photorefractive keratectomy in 43 eyes.*

study was 34.8 years ((standard deviation (SD) 7.6; range 25 to 50)). Ten were men (40%). Mean BCVA was 0.63 (SD 0.21). Mean spherical equivalent (SE) was –14.3 D (SD 4.77; range –8.25 to –30 D).

Statistical analysis was performed by StatView (Abacus Concepts, Berkeley, CA), and p values <0.05 were considered statistically significant; 95% confidence intervals were calculated by CIA Software (BMJ, Bristol, England).

Predictability was measured as attempted vs achieved SE, and as percentage of eyes within 0.5 D and 1 D of defocus equivalent (DEQ) (9). Surgically induced astigmatism was evaluated after IOL implantation by vector analysis (10).

Safety was evaluated by assessing the percentage of eyes losing lines of BCVA and by safety index (postoperative BCVA/preoperative BCVA) (9).

Efficacy was evaluated by assessing postoperative uncorrected VA (UCVA) and by efficacy index (postoperative UCVA/preoperative BCVA) (9).

## *Phakic IOL implantation*

The ZSAL-4 (Morcher GmbH, Germany), a planoconcave, poly(methyl methacrylate) single-piece lens, manufactured in three overall diameters of 12.5, 13, and 13.5 mm in powers from –6 to –24 D, with a total optical zone of 5.5 mm and an effective optical zone of 5 mm, was used in the study (11). The IOL power was obtained by the van der Hejde formula (12), but no more than 2 D of astigmatism were entered in the calculation of SEQ, in order to obtain a postoperative myopic cylinder (e.g., with a refraction of –10 D sphere –4 D cylinder, a –11 D SEQ was considered, instead of –12 D), because a myopic astigmatism is more efficiently corrected by PRK. The overall IOL diameter was calculated by adding 1 mm to the horizontal corneal diameter.

Surgery was performed on an outpatient basis, with peribulbar anesthesia. Our technique was previously described (13). Briefly, a peripheral iridectomy was performed, and the IOL inserted through a sclero-corneal 5.5x3 mm tunnel (along the steepest meridian in the superior 180°). Follow-up visits were made at 6 hours; 1, 2, 7, 14, and 21 days; and 2 months. They comprised UCVA and BCVA, autorefractometry, slitlamp evaluation, funduscopy, iridectomy patency assessment, and tonometry. Corneal specular microscopy was performed at 1, 2, 6, and 12 months after IOL implantation.

When presumed steroid-induced ocular hypertension was observed in the first eye, dexamethasone eyedrops were only used for 2 days if the fellow eye was operated on, and then diclofenac eyedrops started on the third day.

## *Photorefractive keratectomy*

Ciprofloxacin 0.3% eyedrops were administered 60 and 30 minutes before operation. Topical anesthesia consisted of one drop of 0.4% oxibuprocaine 10 and 5 minutes prior to surgery. After manual corneal de-epithelialization for a diameter of 9 mm, PRK was performed with the Bausch & Lomb 217c excimer laser,

in Planoscan mode. Chilled BSS was then poured onto the stromal bed. A Soflens 66 F/M, +0.5 D soft contact lens (Bausch & Lomb) was applied to the eye, and ciprofloxacin eyedrops and diclofenac unpreserved eyedrops were instilled. Postoperatively, topical ciprofloxacin was instilled 5 times a day for the first week, topical diclofenac 4 times a day for 2 days, and unpreserved hyaluronic acid eyedrops (Hyalistil) as artificial tears four to six times a day. Follow-up visits after PRK were at days 1, 3, 5, and 7, and then monthly.

The contact lens was removed when epithelialization was complete (usually day 4 to 7), and 0.1% fluorometholone eyedrops (Flarex) were started 3 times a day for the first month, then tapered if the refraction was within 0.5 D, stopped if overcorrection was found at 1 month.

Haze was graded as follows: grade 0 = totally clear at the slitlamp; grade 0.5 = trace, barely visible at the slitlamp with indirect, broad, tangential illumination; grade 1 = minimal haze, seen with difficulty with direct and diffuse illumination (14). More severe haze grades were not observed.

One week after PRK, patients were asked to grade their pain on a four-point scale: none, mild, moderate, severe (15).

Mean follow-up after PRK was 9.4 months (SD 1.04; range 8 to 11). No patient was lost at follow-up. No secondary procedures such as IOL exchange or explantation, or repeat excimer laser were needed.

## RESULTS

### *Refractive outcome*

Mean astigmatism induced by IOL surgery (before PRK) was 1.26 D (SD 1.01 D; range 0 to 4.2 D; 95% CI: 0.94 to 1.57). Eight months after PRK, mean BCVA was 0.79 (SD 0.18); mean UCVA was 0.7 (SD 1.9).

As for predictability (Figs. 1 and 2; Tab. I), after IOL implantation, 17/43 eyes (40%) were within ±2 D of DEQ, 4/43 eyes (9%) within ±1 D of DEQ, and no eye (0%) within ±0.5 D of DEQ. Eight months after PRK, 42/43 eyes (98%) were within ±1 D of DEQ, and 33/43 eyes (77%) within ±0.5 D of DEQ. Mean SE was –0.08.

Concerning safety and efficacy (Figs. 3 and 4), safety index was 1.25; efficacy index 1.11. BCVA improvement (0.16) was statistically significant ($p<0.05$ with Wilcoxon test for paired data; 95% CI for the mean difference between paired samples: 1.1 to 2 decimals).

Stability was assessed by comparing mean DEQ

**TABLE I -** REFRACTIVE CHANGES AFTER EACH PROCEDURE IN BIOPTICS BY ANGLE-SUPPORTED PHAKIC INTRAOCULAR LENS (IOL) IMPLANTATION AND PHOTOREFRACTIVE KERATECTOMY (PRK) IN 43 EYES

| Time | DEQ (SD; range) | Absol. sphere (SD; range) | Astigmatism (SD; range) |
|---|---|---|---|
| Preoperative | 15.73 (4.7; 9.5 to 30) | 12.8 (5; 6.5 to 30) | –2.9 (1.4; 0 to –6) |
| 2 mo after IOL implant | 2.54 (1.1; 1 to 5)* | 0.49 (0.8; 0 to 4.5)* | –2.4 (1.2; 0 to –5) |
| 8 mo after PRK | 0.47 (0.5; 0.4 to 1.5)† | 0.12 (0.2; 0 to 1)† | –0.46 (0.7; 0 to –2)* |

*p<0.01 With Wilcoxon test for paired data
†p<0.05 With Wilcoxon test for paired data
DEQ = Mean defocus equivalent in diopters; SD = Standard deviation; Absol. sphere = Absolute spherical error in diopters; Astigmatism = Mean astigmatism in diopters

**TABLE II -** CORNEAL ENDOTHELIAL CHANGES AFTER EACH PROCEDURE IN BIOPTICS BY ANGLE-SUPPORTED PHAKIC INTRAOCULAR LENS (IOL) IMPLANTATION AND PHOTOREFRACTIVE KERATECTOMY (PRK) IN 43 EYES

| Time | Cells/mm$^3$ (SD) | Variation in cell density, % | Hexagonal cells, % |
|---|---|---|---|
| Preoperative | 2912 (321) | 73 | |
| 2 mo after IOL implant | 2749 (405)* | –5.6 | 62 |
| 8 mo after PRK | 2718 (355) | –1 | 65 |

* p<0.05 With Student test
Cells/mm$^3$ = Mean endothelial cell density; SD = Standard deviation

at 3 months and at 8 months after PRK in a paired fashion; the variation (0.62 D versus 0.47 D, respectively) is not significant with Wilcoxon test for paired data.

### *Complications*

Intraocular pressure (IOP) rise associated with topical steroids was found in 2 patients (2 eyes) 5 and 7 days after IOL surgery. Steroids were discontinued and the IOP returned to normal values in approximately a week. The fellow eye was treated with steroids 2 days only, and did not develop intraocular hypertension. The first patient's father was subsequently found to have undiagnosed open angle glaucoma.

Initial pupillary block was discovered at 6 hours in 1 patient, caused by incomplete iridectomy, and solved by one spot of Neodymium:yttrium, aluminum, and garnet (Nd:YAG) laser on the persisting pigment layer.

IOL rotation was observed in one patient 1 month after implantation. The IOL had moved 45° but remained centered and stable in the new position until the last follow-up.

Recurrent iridocyclitis presented in the right eye of a 50-year-old man, 3 months after bilateral IOL implantation, 1 month after PRK, and 2 months after knee surgery. Posterior synechiae developed for 120°, the IOL and iridectomy remained free, with no IOL precipitates. The iridocyclitis responded well to atropine 1% and dexamethasone 0.1% eyedrops, but recurred three times. Final visual acuity was not affected.

Minimal pigment deposits on the IOL surface were present in both eyes of one patient, with no other inflammatory signs.

Moderate pupil ovalization along the major overall IOL diameter developed in 6/43 eyes (14%) of 5 patients. The difference between the two pupillary diameters was less than 1.5 mm.

Nocturnal halos after IOL implantation and before PRK were observed by 7/25 patients (28%) (4 with monocular implant, 3 with bilateral implant). In 3 patients (2 bilateral) the halos disturbed night driving, while in the remaining 4 they were described as moderate. In 6 patients, the mesopic pupil was 6 mm, in the seventh patient, 5.5 mm. No ovalization was associated with halos.

After PRK enhancement, halos were considerably reduced in 4/7 patients. The final result was that in 6/25 patients (24%) moderate halos did not disturb night activity, whereas in 1/25 patients (4%) with monocular implant night driving was possible but not comfortable. The latter patient however did not consider IOL explantation.

Pain after PRK was reported as severe in 3/25 patients (12%), moderate in 13/25 patients (52%), and mild to none in 9/25 (36%).

Corneal haze was in all cases equal or inferior to 1.

Predictability (attempted vs achieved DEQ) is described in Figure 1. The improvement of DEQ after enhancement by PRK is evidenced in Figure 2. Efficacy (BCVA/UCVA) achieved by bioptics is described in Figure 3, and changes in BCVA (safety) in Figure 4. Refractive changes after each single procedure are reported in Table I, and endothelial changes after each procedure in Table II.

## DISCUSSION

The association of angle-supported phakic IOLs and PRK resulted in our series as effective as other bioptics techniques (1, 2, 6, 7). In particular, a good predictability was achieved, with 98% of eyes within 1 D of emmetropia, and with an acceptable complication rate. After IOL implantation, residual errors in our series were mainly due to myopic astigmatism (mean DEQ 2.54 D, and mean astigmatism –2.4 D), which was effectively corrected by subsequent PRK. The effect of surgical incision on astigmatism was variable (SD 1.01 D). Severe to moderate pain after PRK was experienced in 64% of patients.

Single procedures to correct high myopia with astigmatism include phakic IOLs plus limbal relaxing incisions (16) and toric phakic IOLs (17). The former technique has a variable effect, while the latter requires a foldable IOL, precise power calculation, and a rotational stability. However, combined techniques have the advantage of fine-tuning refractive results.

The rationale for combining angle-supported phakic IOL with PRK is reduced costs and short learning curve. The drawbacks of this technique are those peculiar to angle-supported phakic IOL (namely, endothelial long-term safety, pupil ovalization, and halos) and PRK (i.e., pain, haze, and regression).

Halos caused by angle-supported phakic IOLs are not superior to those observed with other models (18).

In our series, halos were well tolerated by most patients, especially after PRK enhancement, thus showing that they also depend on residual refractive error. IOL rotation and pupil ovalization are opposite effects of incorrect IOL sizing, and significant ovalization is reported in 5.9% to 17.4% of angle-supported phakic IOLs (9, 19-22). Endothelial safety after combined angle-supported phakic IOL and PRK has not been evaluated before. In our series, it was comparable to simple angle-supported phakic IOL implantation (20-22).

The case of recurrent iridocyclitis in our series might have been triggered by PRK, which is known to increase aqueous flare level (23, 24). However, subclinical inflammation is a common finding after the implantation of angle-supported phakic IOLs (25), and a 1% incidence of chronic iridocyclitis has been reported after this surgery (26).

LASIK is the preferred enhancement technique for bioptics, because of refractive stability and reduced pain (1-7), and the theoretical risk of endothelial damage by anterior chamber IOLs during suction in LASIK has been ruled out (7). However, although associated with more pain, PRK is performed without suction, and haze and regression are uncommon after treatments for low myopia and myopic astigmatism.

In conclusion, angle-supported phakic IOLs followed by adjustment by PRK offers good efficacy, predictability, and safety to manage large refractive myopic errors, achieving 98% of eyes within 1 D of emmetropia, and with few complications. The choice of PRK instead of LASIK as enhancing technique can be justified in some professional environments, in which PRK is the preferred excimer laser technique because of simplicity and reduced costs.

Long-term endothelial safety of anterior chamber IOLs, halos, and pain after PRK are the main issues to be assessed. Halos are improved by PRK enhancement, while pain can benefit from advancements in surface ablation techniques.

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