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Retrospective Outcomes and Patient Satisfaction with Previous Refractive Surgery and Multifocal Intraocular Lens Implantation

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Abstract

Aim: To report pre, post-surgical visual outcomes and satisfaction after cataract or clear lens surgery, with multifocal intraocular lens implantation, in patients with previous refractive surgery.

Methods: Retrospective study of postoperative outcomes and satisfaction in patients with previous refractive surgery and Multifocal Intraocular Lens (MF-IOL) implantation. Preoperative variables: time LASIK performed, visual acuity, Uncorrected (UCVA) and best corrected (BCVA), Spherical Equivalent (SE), Addition (Add), SimK and pachymetry, pupillometry. Postoperative data: UCVA, BCVA, SE, and Add. Results grouped as: general, cataracts *vs.* clear lens (CL), segmented *vs.* trifocal MF-IOL, and myopes *vs.* hyperopes. Patients completed a satisfaction and difficulty questionnaire (Q). Data was analyzed using paired student-t test, with Bonferroni adjustment. Linear regression analysis between normally distributed preoperative variables and survey data were reported.

Results: Mean results recorded for 30 eyes, mean age 52.3 ± 6.2 years; pre-LASIK SE -2.8 ± 3.8D, segmented MF-IOL in 22 eyes and 8 eyes with trifocal IOL. Pre/postoperative results: SE: -0.02 ± 2.5/-0.1 ± 0.25D, far UCVA: 0.34 ± 0.2/0.90 ± 0.1, near UCVA: 0.43 ± 0.4/1.0 ± 0.02, Add: 1.4 ± 1.2/0.2 ± 0.6D, far BCVA: 0.90 ± 0.2/0.95 ± 0.1, and near BCVA: 0.99 ± 0.04/1.0 ± 0.0. Mean Q satisfaction points (0-10): far VA: 7.5 ± 2, near VA: 8.1 ± 2.3, intermediate VA 8.1 ± 1.7. Mean questionnaire difficulty points (0-4) results were: far VA 1.3 ± 1.5, near VA 1.5 ± 1.5, halos 1.5 ± 1.6, and 94% would repeat their choice. Near vision and night driving difficulties scored higher for myopes with greater preoperative SE (R^2=0.5; p=0.05 and R^2=0.7; p=0.02, respectively).

Conclusion: Multifocal intraocular lens implantation, in patients with previous refractive surgery, significantly improved mean near and far UCVA, and addition. Satisfaction was high and post LASIK SE correlated significantly with near vision and night driving difficulty in myopic patients.

Keywords: Cataract; LASIK; Multifocal intraocular lens; Presbyopia

Introduction

Patients with previous refractive surgery, either laser in situ keratomileusis (LASIK) or photorefractive keratectomy (PRK) usually seek to remain spectacle-free after cataract or presbyopia surgery. Studies have reported satisfactory refractive results after implantation of premium intraocular lens (IOL) in eyes with previous myopic or hyperopic LASIK [1-6].

Although reports are limited, cases could be challenging due to postoperative refractive surprises, with posterior lens exchange or laser surgery enhancement, and little is known regarding patient pre-surgical characteristics or postoperative satisfaction, spectacle independence, or the effect of LASIK induced corneal aberration [1,6,7].

Newer diffractive trifocal and sectorial refractive multifocal intraocular lenses (MF-IOL) have shown to provide effective visual function restoration and high patient satisfaction [8-17].

Trifocal diffractive IOLs, like FineVision IOL (25% hydrophilic acrylic and 6.15 mm optic diameter, PhysIOL, Liége, Belgium) combine two diffraction gratings, one with +1.75D and the other with +3.5D for near vision, which truly offers trifocality during myosis [13,16]. The segmented refractive MF-IOL (Lentis Mplus ,Oculentis GmbH, Berlin, Germany) is a one-piece zonal intraocular lens with plate haptics having large aspheric distance-vision zone and a sector-shaped zone with 3.0D of near addition (Add), embedded on the posterior surface [12].

Recently, Yoshino et al. reported good visual results in LASIK patients with diffractive IOL, however, a review highlighted the lack of information regarding LASIK patients' characteristics, side effects, and satisfaction after MF-IOL implantation [1,15].

We present a retrospective report on pre and post-surgical outcomes and patient satisfaction, after clear lens (CL) or cataract surgery with trifocal or segmented IOL implantation, in patients with previous refractive surgery.

Subjects and Methods

This was a retrospective, observational, longitudinal study of patients with previous refractive surgery who underwent multifocal intraocular lens (MF-IOL) implantation, after cataract or clear lens (CL) surgery, with at least 12 months follow-up. We complied with the 1995 Declaration of Helsinki principles and all patients read and

signed a written informed consent form before undergoing any surgical procedure. Medical charts were reviewed, pre and post-operative data (last visit) was recorded for analysis, and patients were later asked to fill out a satisfaction and difficulty questionnaire (Q), the cataract TyPE Spec questionnaire translated to Spanish and modified to include: General far and near vision satisfaction (0-10 points each) and difficulties (0-4 points each) for far, near, intermediate visions, halos, specific activities, and whether or not they would repeat the procedure. Patients personally filled out the questionnaire (Q), on the medical center or online [18]. Preoperative data included: time LASIK had been performed, far and near (30 cm) uncorrected visual acuity (UCVA), best corrected (BCVA; decimal scale), spherical equivalent (SE), addition (Add), topography data (SimK, corneal astigmatism, and corneal thinnest pachymetry; ORBSCAN DP-3002 model, v. 3-14; Technolas Perfect Vision, GmBH), pupillometry (Colvard, Oasis medical, Glendora, California, USA), RMS in μm (Zywave II Aberrometer v 5.2, Bausch & Lomb), and MF-IOL implanted (segmented or trifocal). Postoperative data records for far/near UCVA, BCVA, SE, and ADD followed up for at least one year. Biometry was performed by one technician, using the IOLMASTER 500 (Carl Zeiss Meditec AG, Jena, Germany), and MF-IOL power calculated with the Haigis-L formula [7].

Data was introduced on a Microsoft 2013 Excel sheet (Microsoft Corporation). Results were recorded as mean and standard deviation (SD), student t-test (with Bonferroni adjustment) used for data results comparison [19]. Bonferroni adjustment set a stricter threshold to define significance (multiplying the p-values for each of the pair-wise comparisons by the number of comparisons) and thus reducing type I error. Bonferroni correction for $p \leq 0.05$ was set at $p \leq 0.002$ for general and CL variables (N=30 and N=24 eyes, respectively), $p \leq 0.01$ for myopic and hyperopic group variables, and $p \leq 0.003$ for questionnaire variables (N=15).

Pre and post-operative results were recorded for all eyes, eyes with cataracts, and clear lens (CL) eyes. Patients were also grouped into those implanted with trifocal *vs.* segmented IOL, and with either hyperopic or myopic LASIK, for comparative purposes (based on pre LASIK refractive error).

The Shapiro-Wilkes normality tests run for preoperative nominal variables. Linear regression analysis for normally distributed dependent variables matched to survey data scores.

Results

Data was collected for 17 patients (9 men and 8 women; 30 eyes), with mean age of 51.5 ± 6.3 years, pre-LASIK refraction yielded 16 hyperopic eyes, 14 myopic eyes, one CL patient had preop mixed refractive error (RE pre -4.3D SE, post 0.0D SE; LE pre 0.8D SE, post -0.6D SE, 12.2 ± 3.5 years mean time LASIK performed, and mean pre-LASIK SE was -2.8 ± 3.7D. LASIK had been performed in 29 eyes, PRK in one, and re-treatment with flap re-lift and laser in 7 eyes. Mean values included: pupil diameter of 5.7 ± 0.9 mm, pachymetry 510 ± 54.5 μ, SimK 42 ± 2.8D, topography astigmatism 1.1 ± 1.1D, RMS 1.9 ± 1.7 μm (12 eyes), and MF-IOL mean power +21 ± 3.5D. General mean pre-LASIK SE was -3.6 ± 3.7D, 1.8 ± 0.6D for hyperopes, and -5.5 ± 2.2D for myopes. Twenty-two eyes underwent implantation of refractive segmented IOL (17 eyes with +3.0 Add-Oculentis MPLUS LS 313; 5 eyes +1.50 Add COMFORT LS 313) while eight eyes were implanted with the trifocal diffractive IOL (FineVision PhysIOL®). We implanted segmented IOL (+1.50 Add) in three patients (55-y-old bilateral cataract, 46-y-old monocular cataract, and 45-y-old bilateral CL. Six eyes underwent cataract surgery (two patients bilateral and 2 monocular surgery) while 24 eyes had CL surgery (12 patients had bilateral simultaneous surgery; 5 were myopes and 7 hyperopes). Four patients underwent monocular surgery and, of these, one with cataracts and the other with amblyopia, and two CL surgery.

Mean preoperative data for patients who underwent clear lens surgery included: age 51 ± 7 years, pupil 5.1 ± 0.9 mm, pre-LASIK SE -1.4 ± 4D, years LASIK performed 12 ± 4.4 years; pachymetry 533 ± 41 μ and far BCVA 0.9 ± 0.1 ($p \leq 0.05$), 42 ± 2.8D, far UCVA 0.4 ± 0.2, near UCVA 0.3 ± 0.3, near BCVA 1.0. ± 0.0, and Add 1.3 ± 1.1D.

Preoperative data comparison for the myopic and hyperopic group, respectively, resulted in age 48.5 ± 4.3; 54.2 ± 8.4 years, pupil 5.1 ± 0.7; 4.9 ± 1.1 mm, RMS 3.6 ± 1.7; 1.1 ± 1.1 μm (p>0.05), years LASIK performed 13.2 ± 3.4; 10.8 ± 3.6 years; (p>0.05). Pre-LASIK sphere was -5.5 ± 2.2; 1.8 ± 0.6D and SE - 4.3 ± 3.0; 1.7 ± 0.5D, respectively; ($p \leq 0.05$).

Table 1 registers general mean pre and postoperative results. Overall, a mean of 5.4 ± 2 lines of distance UCVA and 5.9 ± 3.6 lines for near UCVA improvement were recorded ($p \leq 0.05$).

Mean general results (30 eyes)	Follow-up (y)	Spherical equivalent (diopters)	FAR uncorrected visual acuity (decimal scale)	NEAR uncorrected visual acuity (decimal scale)	Addition (diopters)	FAR best corrected visual acuity (decimal scale)	NEAR best corrected visual acuity (decimal scale)
PRE multifocal intraocular lens		-0.02 ± 2.3	0.34 ± 0.2	0.43 ± 0.4	1.4 ± 1.2	0.90 ± 0.2	0.99 ± 0.04
POST multifocal intraocular lens	1.4 ± 0.8	-0.09 ± 0.3	0.90 ± 0.1	1.0 ± 0.02	0.20 ± 0.6	0.95 ± 0.1	1.0 ± 0.0
p=paired t-student; $p \leq 0.002$; Statistical significance		p=0.9	P ≤ 0.00001	P ≤ 0.0001	p=0.08	p=0.2	p=0.9

Table 1: Mean pre-and postoperative general results. Significant improvement recorded for far and near uncorrected visual acuity (UCVA).

Postoperative mean results for segmented *vs.* trifocal IOL group, respectively, included SE -0.1 ± 0.27D; -0.1 ± 0.2, far UCVA 0.9 ± 0.1; 1.0 ± 0.1, near UCVA 0.99 ± 0.02; 1.0 ± 0, Add 0.26 ± 0.7; 0.0 ± 0.0, far BCVA 0.9 ± 0.1; 1.0 ± 0.0, and near BCVA 1.0 ± 0.0; 1.0 ± 0.0 (p>0.05). Mean postoperative follow-up was 1.4 ± 0.8 years.

Mean results clear lens multifocal IOL (MF-IOL)	Spherical equivalent (Diopters)	FAR uncorrected visual acuity (decimal scale)	NEAR uncorrected visual acuity (decimal scale)	Addition (Diopters)	FAR best corrected visual acuity (decimal scale)	NEAR best corrected visual acuity (decimal scale)
Segmented MF-IOL (+3.0 Add); (N=16); p ≤ 0.002 for significance	PRE 0.82 ± 2.8; POST 0.23 ± 0.21; p ≤ 0.00001	PRE 0.45 ± 0.09 POST 0.95 ± 0.09 p=0.002	PRE 0.28 ± 0.36 POST 0.99 ± 0.03 p=0.04	PRE 1.7 ± 0.90 POST 0.0 ± 0.0 p=0.11	PRE 0.95 ± 0.09 POST 0.95 ± 0.09 p=0.95	PRE 0.98 ± 0.60 POST 1.0 ± 0.0 p=0.34
Segmented MF-IOL (+1.5 Add); N=2; p ≤ 0.03 for significance	PRE -3.1 ± 1.6 POST 0.60 ± 0.60 p=0.4	PRE 0.18 ± 0.17	PRE 0.7 ± 0.42 POST 1.0 ± 0.0 p>0.05	PRE 0.0 ± 0.0 POST 0.0 ± 0.0 n/a	PRE 0.95 ± 0.07 POST 0.95 ± 0.07 n/a	PRE 1.0 ± 0.0 POST 1.0 ± 0.0 n/a
TRIFOCAL (MF-IOL) N= 6; p ≤ 0.002 for significance	PRE -0.1 ± 0.80 POST -0.13 ± 0.17 p=0.95	PRE 0.63 ± 0.11 POST 0.94 ± 0.13 p=0.04	PRE 0.22 ± 0.11 POST 1.0 ± 0.0 p≤0.0001	PRE 1.65 ± 0.65 POST 0.0 ± 0.0 p=0.005	PRE 0.88 ± 0.13 POST 1.0 ± 0.0 p=0.11	PRE 1.0 ± 0.0 POST 1.0 ± 0.0 n/a
+3.0 Add Segmented IOL *vs.* Trifocal IOL	p=0.17	p=0.92	p=0.52	n/a	p=0.35	n/a

Table 2: General mean results pre-and post MF-IOL implantation.

For all clear lens patients, postoperative results were significant for far UCVA, near UCVA, and Add (p<0.002), Significant results were recorded for near UCVA (p=0.03) and addition (p=0.005) in patients with trifocal intraocular lens. Data from +1.5 Add MF-IOL patients was included.

Table 2 displays mean MF-IOL results. Table 3 compares mean postoperative results for myopes *vs.* hyperopes, who underwent clear lens surgery. Table 4 shows cataract patients' pre and post-operative data. For the cataract group, the +3.0 Add segmented MF-IOL group gained a mean of 5.5 ± 1.8 far UCVA lines and the trifocal 3.7 ± 2.1 lines (p ≤ 0.05). The former gained a mean of 6.3 ± 3.5 near UCVA lines and trifocal group gained 6.5 ± 3.3 mean near UCVA lines (p ≥ 0.05).

Mean results clear lens (24 eyes)	Spherical equivalent (Diopters)	FAR uncorrected visual acuity (decimal scale)	NEAR uncorrected visual acuity (decimal scale)	Addition (Diopters)	FAR Best corrected visual acuity (decimal scale)	NEAR Best corrected visual acuity (decimal scale)
Hyperopic LASIK (N=14) p ≤ 0.01 for significance	PRE 1.6 ± 1.0 POST 0.0 ± 0.2	PRE 0.47 ± 0.1 POST 0.9 ± 0.1 p ≤ 0.0001	PRE 0.23 ± 0.3 POST 1.0 ± 0.0 p ≤ 0.0001	PRE 1.9 ± 0.6 POST 0.0 ± 0.0 p ≤ 0.0001	PRE 0.95 ± 0.0 POST 1.0 ± 0.1 p=0.95	PRE 1.0 ± 0.6 POST 1.0 ± 0.0 p=0.33
Myopic LASIK (N=10) p ≤ 0.01 for significance	PRE -1.2 ± 2.1 POST 0.2 ± 0.3 p=0.06	PRE 0.4 ± 0.3 POST 0.8 ± 0.1 p ≤ 0.0001	PRE 0.7 ± 0.3 POST 1.0 ± 0.0 p=0.005	PRE 1.0 ± 1.0 POST 0.0 ± 0.0 p=0.07	PRE 0.8 ± 0.2 POST 0.9 ± 0.1 p=0.06	PRE 1.0 ± 0.5 POST 1.0 ± 0.0 p=0.33
Postoperative results Hyperopic *vs.* Myopic p ≤ 0.01 for significance	p=0.03	p=0.0002	p=0.01	p=0.1	p=0.1	n/a

Table 3: Mean results for patients with previous hyperopic or myopic LASIK.

PRE/POSTOP results cataract	Spherical equivalent (SE)	FAR UCVA (DECIMAL)	NEAR UCVA (DECIMAL)	ADD (Diopters)	FAR BCVA (Decimal)	NEAR BCVA (Decimal)	Multifocal intraocular lens	Follow-up (years)	Years LASIK performed; (PRELASIK SE IN Diopters)
Patient 1 55-y-old									
PRE	-2.6	0.05	1	0	0.8	1	+1.5 ADD Segmented	2	9; (-6.25D)
POST	-0.25	0.8	1	0	0.8	1			
PRE	-1.25	0.5	1	0	0.8	1	+1.5 ADD Segmented	2	9; (-4.75D)
POST	-0.25	0.8	1	2.5	0.8	1			

Patient 2 47-y-old									
PRE	-1.25	0.2	1	0	0.3	1	+1.5 ADD Segmented	1	10; (-2.65D)
POST Single functional eye	0	0.7	0.4	2	0.7	1			
Patient 3 53-y-old									
PRE	0	0.7	0.3	1.75	0.7	1	TRIFOCAL	1.8	14; (-4.0D)
POST	0	0.8	1	0	1	1			
Patient 4 47-y-old									
PRE	-2	0.05	0.8	0	0.4	0.8	+3.0 ADD Segmented	2	10; (-2.75D)
POST	0	0.9	1	0	0.9	1			
PRE	0	0.4	1	0	0.7	1	TRIFOCAL	2	
POST	0	1	1	0	1	1			13; (-5.75D)
MEAN ± SD									
PRE	1.1 ± 1.3	0.2 ± 0.2	0.5 ± 0.5	1.3 ± 1.4	0.7 ± 0.2	1.0 ± 0.0		1.8 ± 0.4	10.7 ± 2.0
POST	0.2 ± 0.2	0.8 ± 0.1	0.9 ± 0.2	0.8 ± 1.2	0.8 ± 0.1	1.0 ± 0.0			(-4.4 ± 1.5D)
p=Paired t-student ≤ 0.01 significance	p=0.14	p=0.00	p=0.13	p=0.5	p=0.38	-			

Table 4: Cataract patients.

Hyperopic patients had significant improvement in SE and significantly in far UCVA, near UCVA, and Add; ($p \leq 0.005$). Myopic patients improved in postoperative SE, far UCVA, while significantly for near UCVA and Add ($p \leq 0.005$). Far UCVA was significantly better for hyperopes; ($p \leq 0.005$).

Post-operative complications included one eye with macular edema, after MF-IOL decentration and uneventful repositioning, which resolved after topical non-steroidal anti-inflammatory therapy (Nepafenac® Alcon laboratories Ltd., Surrey, UK).

Final postoperative far BCVA was 0.9 (0.7 preoperatively) and 1.0 for both near UCVA and BCVA. One eye (3%) with refractive surprise in a patient with previous myopic LASIK (-9.0D) Uneventful MF-IOL exchange resulted in final 1.0 far and near UCVA. Eight eyes (27%) underwent flap re-lift and laser re-enhancement for postoperative residual refraction. One developed dry eye syndrome and grade II Machat epithelial ingrowth but later stabilized at 0.9 final far and 1.0 near UCVA, with continued artificial tears use. One eye lost one line of far UCVA due to herpetic stromal keratitis and residual leukoma, 4 years post MF-IOL implantation.

Fifteen patients answered the questionnaire (14 underwent binocular and 1 monocular surgery), eight hyperopes and seven myopes, 11 with segmented and 4 with trifocal IOL. Two patients declined answering it.

Table 5 summarizes questionnaire difficulty scores for varying situations, in the general, trifocal, and segmented IOL groups. Figures 1 and 2 show satisfaction and difficulty mean scores for the general and trifocal *vs.* segmented IOL groups, respectively. Mean satisfaction scores for patients with previous hyperopic or myopic LASIK, respectively were: distance VA 8.0 ± 2.2 / 8.3 ± 1.2, near VA 7.7 ± 2.8 / 8.5 ± 1.8, intermediate VA 8.0 ± 2.4 / 8.3 ± 0.9; (p>0.003).

Visual acuity difficulty results questionnaire (N=16 patients) Score 0-4 points mean & standard deviation	General all patients	Trifocal intraocular lens N=4 patients	Segmented intraocular lens N=11 patients
Day driving	1.5 ± 1.5	0.75 ± 0.96	2.1 ± 1.4
Night driving	1.8 ± 1.6	1.5 ± 1.9	2.1 ± 1.5
Daylight	0.80 ± 0.9	0.25 ± 0.50	1.1 ± 0.83
Double vision	1.0 ± 1.4	0.25 ± 0.50	1.5 ± 1.5
Movies/theatre	0.60 ± 0.90	0.25 ± 0.50	0.90 ± 1.1
Reading white paper	0.9 ± 1.2	0.25 ± 0.50	1.4 ± 1.3
Halos	1.5 ± 1.6	0.75 ± 1.0	2.2 ± 1.5
Supermarket labels	1.0 ± 1.1	0.25 ± 0.50	1.5 ± 1.1
Parties	0.50 ± 1.0	0.25 ± 0.50	0.63 ± 1.2
Sports	0.62 ± 1.0	0.50 ± 1.0	0.75 ± 1.2
Do you wear glasses?	Yes: 25%	Yes: None	Yes: 50%

	No: 75%	No: 100%	No: 50%

Table 5: Questionnaire mean difficulty scores post MF-IOL implantation. Seventy-five percent reported not wearing glasses. All groups reported the greatest difficulty scores for halos and both day and night driving.

Figure 3 summarizes mean difficulty scores for hyperopic and myopic patients.

Mean difficulty scores for patients with either hyperopic *vs.* myopic LASIK, respectively were: distance VA 1.7 ± 1.6/1.0 ± 1.5 (50%), near VA 1.7 ± 1/1.3 ± 2 (38%), intermediate VA 0.3 ± 0.5/0.14 ± 0.4 (13%), halos 2.0 ± 1.1/0.9 ± 1.5 (63%), reading white paper 1.7 ± 1.4/0.3 ± 0.5 (44%), day driving 2.0 ± 1.4/1.1 ± 1.5 (56%), night driving 2.3 ± 1.6/1.3 ± 1.5 (63%), daylight 0.7 ± 0.82/0.9 ± 0.9 (44%), reading supermarket labels 1.0 ± 1.1/1.0 ± 1.5 (44%), double/distorted vision 1.5 ± 1.5/0.6 ± 1.1 (31%), at movies/theatre 0.7 ± 1.2/0.8 ± 0.8 (31%), parties 0.5 ± 1.2/0.4 ± 0.8 (19%), and performing sports 1.0 ± 1.3/0.3 ± 0.8 (25%); (p>0.003).

Two cataract patients (45 and 46 year old), with monocular +1.5 Add segmented IOL, and 1 clear lens patient, with bilateral +3.0 Add segmented IOL, needed additional glasses for reading or sewing (18%).
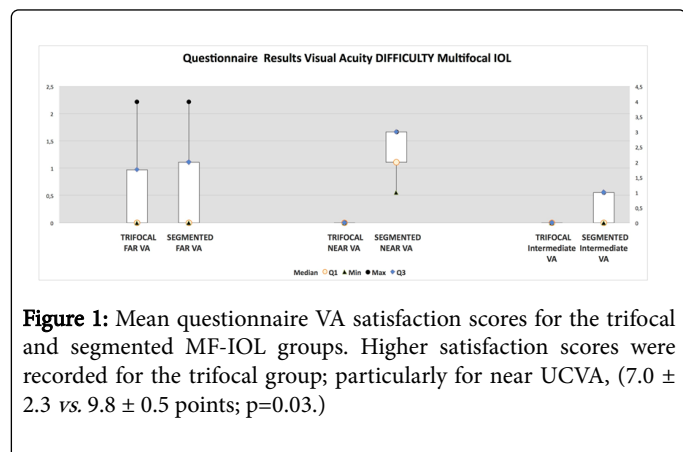

Figure 1: Mean questionnaire VA satisfaction scores for the trifocal and segmented MF-IOL groups. Higher satisfaction scores were recorded for the trifocal group; particularly for near UCVA, (7.0 ± 2.3 *vs.* 9.8 ± 0.5 points; p=0.03.)

Normal distribution was found for age (W=0.93), and in all 30 eyes for preoperative pachymetry (W=0.95), preoperative SE (W=0.90), far and near UCVA (W=0.74), Add (W=0.85), pupil (W=0.92), pachymetry (W=0.93). For hyperopic pre-LASIK sphere (W=0.90), pachymetry (W=0.92), pupil (W=0.87), postoperative SE (W=0.81), postoperative Add (W=0.50), postoperative far UCVA (W=0.72), post-operative near UCVA (W=0.34). For myopic eyes, normality was recorded for preoperative SE (W=0.84), preoperative sphere (W=0.87), Add (W=0.80), pupil (W=0.91), and pachymetry (W=0.95). Myopic postoperative SE (W=0.60), Add (W=0.50), far UCVA (W=0.90), near UCVA (W=0.50). Pearson correlation results for hyperopic pupil and questionnaire were: general satisfaction $R^2=0.40$, reading satisfaction $R^2=-0.40$, intermediate vision satisfaction $R^2=-0.40$, near vision difficulty $R^2=0.20$, far vision difficulty $R^2=-0.74$, halos difficulty $R^2=-0.85$, paper reading difficulty $R^2=0.43$, daylight driving $R^2=0.25$, night driving difficulty $R^2=0.35$, double vision difficulty $R^2=0.5$. Pearson correlation between pachymetry in hyperopic patients and questionnaire results were: general satisfaction $R^2=-0.34$, near vision satisfaction $R^2=-0.06$, intermediate vision satisfaction $R^2=-0.07$, far vision difficulty $R^2=0.40$, near vision difficulty $R^2=0.02$, paper reading difficulty $R^2=-0.14$, double vision $R^2=0.77$, daylight driving $R^2=0.50$,

night driving $R^2=0.45$, halos $R^2=0.97$. Linear regression analysis results are shown on Figures 2 and 3. No significant correlations recorded for other normally distributed nominal variables and survey scores.

Linear regression analysis for pupil in hyperopic patients and halos difficulty points was $R^2=0.51$, p=0.07 (Figure 4).
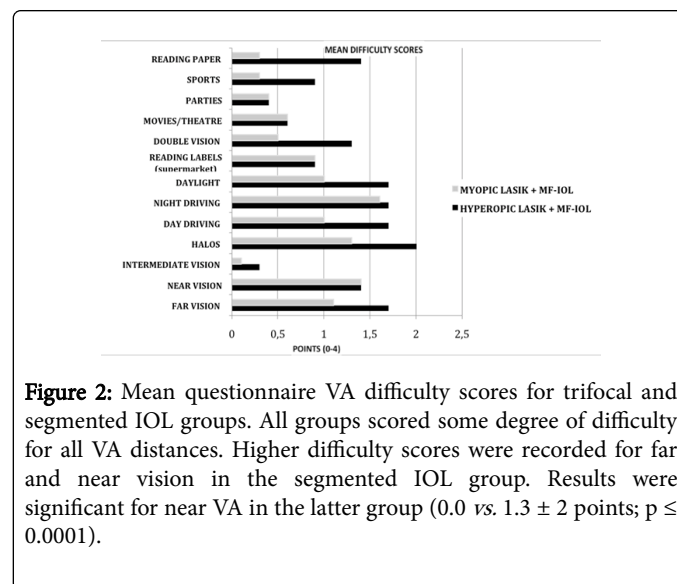

Figure 2: Mean questionnaire VA difficulty scores for trifocal and segmented IOL groups. All groups scored some degree of difficulty for all VA distances. Higher difficulty scores were recorded for far and near vision in the segmented IOL group. Results were significant for near VA in the latter group (0.0 *vs.* 1.3 ± 2 points; p ≤ 0.0001).
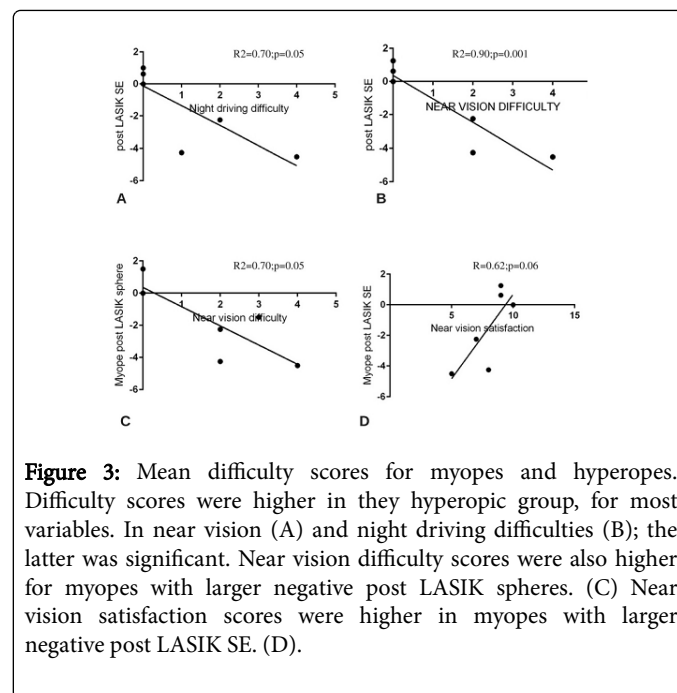

Figure 3: Mean difficulty scores for myopes and hyperopes. Difficulty scores were higher in they hyperopic group, for most variables. In near vision (A) and night driving difficulties (B); the latter was significant. Near vision difficulty scores were also higher for myopes with larger negative post LASIK spheres. (C) Near vision satisfaction scores were higher in myopes with larger negative post LASIK SE. (D).

Discussion

Premium IOL implantation improves UCVA in patients with previous refractive surgery but few reports address outcomes and satisfaction in this patient group [1-6]. LASIK patients usually have no differences in VA with controls but this patient group is more prone to postoperative refractive surprise, requiring further laser enhancement, halos, and degradation in contrast sensitivity [5,12,15-17].

Vega et al. provided evidence that implanting an aspheric multifocal IOL in eyes, after myopic LASIK, resulted in similar optical and visual quality to phakic myopic LASIK eyes [3]. They concluded that visual results and quality were superior to the use of a spherical MF-IOL [3].
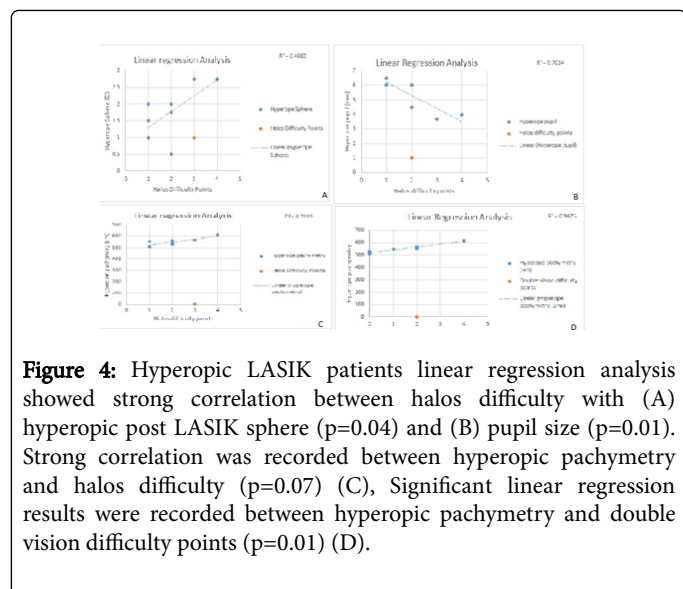

Figure 4: Hyperopic LASIK patients linear regression analysis showed strong correlation between halos difficulty with (A) hyperopic post LASIK sphere (p=0.04) and (B) pupil size (p=0.01). Strong correlation was recorded between hyperopic pachymetry and halos difficulty (p=0.07) (C), Significant linear regression results were recorded between hyperopic pachymetry and double vision difficulty points (p=0.01) (D).

Newer MF-IOLs, segmented and trifocal, implanted in this patient group, are effective in visual restoration, for specific cases [7-9,11-15,17].

Segmented MF-IOLs have one addition sector, which is the only area that directs light to a near focal point, thus allowing for the remainder of the optic to act as a monofocal IOL for distance vision [12]. They are more suitable for larger pupils and provides adequate VA and patient satisfaction [10,12].

Newer trifocal diffractive IOLs also provide general satisfactory UCVA for all distances and improved contrast sensitivity [7-9,11-15]. Khoramnia et al. bilaterally implanted toric-segmented MF-IOL in a patient with repeated LASIK who improved both far and near UCVA, and gained 6 lines of UCVA [8].

We analyzed post-operative results in patients with previous refractive surgery and post MF-IOL (segmented or trifocal) implantation for cataract or presbyopia with CL. Overall, post-operative far and near UCVA improved significantly, after MF-IOL implantation (p ≤ 0.002). In this small retrospective study, 97% of previous LASIK eyes had final SE within ± 0.50D, 90% at least 0.7 far UCVA, four eyes gained postoperative BCVA (13%), and no eyes lost BCVA. These results are similar or better than other reports with MF-IOL implantation in post refractive surgery patients [4,5, 15,17].

We also found no VA differences between all patients and those requiring subsequent enhancement (0.9 ± 0.12; 0.88 ± 0.13); (p>0.002). One eye (20%) lost one VA line due to herpetic leukoma, postoperatively, 4 eyes with cataract and 2 CL eyes gained VA lines. We also recorded refractive surprise on one eye (3%), which underwent uneventful MF-IOL exchange.

Patients implanted with segmented IOL (+3.00 Add) significantly improved post-operative far and near UCV (p<0.0001), while those with trifocal IOL improved postoperative near UCVA p<0.0001. Postoperative addition values also decreased in both groups (p>0.002). The trifocal IOL group gained higher far UCVA lines than the +3.00 Add segmented IOL group (p=0.1). Patients with clear lens surgery significantly improved postoperative Add and both near and far UCVA (p ≤ 0.002), while final mean SE was 0.03D. Alfonso et al. also reported -0.06 mean SE in CL LASIK patients implanted with diffractive IOL [4]. In this study, 98% were within ± 0.50D final SE, compared to reports ranging from 72%-84% [4,5]. Mean postoperative far UCVA results were better for hyperopes than myopes with clear lens surgery (0.94 ± 0.08 *vs.* 0.85 ± 0.16; p=0.03), but so were their preoperative values (0.47 ± 0.14 *vs.* 0.35 ± 0.28; p=0.3). Despite significant lower preoperative Add values for myopes (1.0 ± 1.1D) compared to hyperopes (2.1 ± 0.50; p=0.03), postoperative mean Add values were not significant (p=0.1).

All cataract eyes had previously undergone myopic LASIK and we recorded significant improvement for post-operative far UCVA, p=0.001. Their post-operative Add results were not significant, probably due to the inclusion of younger patients implanted with a +1.5 Add segmented IOL and the small sample case series. Mean postoperative SE was higher to that already reported by Miyajima et al. (0.22 ± 0.21D *vs.* -0.03 ± 0.38D) for cataract patients with previous LASIK [17].

Visual satisfaction and difficulty information are lacking for this patient group, post MF-IOL implantation for presbyopia or cataract. Satisfaction was high in patients with segmented IOLs but one point lower than patient reports with no previous corneal surgery, (>7 points for all distances *vs.* 8.1 points, respectively), as reported by Muñoz et al. [12]. Ninety percent of the segmented IOL group would recommend their MF-IOL choice compared to the 98% reported by Venter et al. in patients with no previous corneal surgery [9].

Gatinel et al. reported that diffractive IOL showed better near focal point resolution than segmented IOLs [16]. The trifocal group reported higher satisfaction for all VA distances compared to the segmented IOL group. We recorded higher, though non-significant, near VA satisfaction in the trifocal IOL group (p=0.04) and 100% answered they would repeat their MF-IOL selection. The fact that only 4 patients with trifocal and 11 with segmented IOL answered the questionnaire, could explain these non-significant findings, while final conclusions could be drawn when the former sample increases.

Regarding difficulty scores for daily activities, the trifocal group reported less difficulty, significant when reading supermarket labels. The latter finding may be an attributable to the superior near focus for the trifocal IOL, while segmented IOL provides less adequate near UCVA [12,16].

Halos has already been reported in 10.6% regular patients with segmented IOLs while Muñoz et al. concluded it should be expected, in a small number of patients, despite very good functional results [12,20]. In this study, sixty-three percent reported some degree of halos difficulty, particularly in patients with previous hyperopic LASIK or segmented IOL. Hyperopic patients reported higher halos difficulty scores (mean 2 ± 1.2 points) than myopes (1.3 ± 1.8 points); p=0.4, and could be explained by the fact that hyperopic LASIK correction induces greater changes in corneal asphericity, is associated to smaller effective optical zones, and slightly more third order aberrations than in myopes could explain this finding [21,22]. In addition, higher halos difficulty scores were associated to larger post LASIK pachymetry and smaller pupil size in hyperopic patients. Hyperopic LASIK treatment is peripheral and the further from the center of the cornea the more the ablation is having a different effect on each quadrant because it acts at different depths and with varying hydration along the surface [5].

A recent study concluded that, after phacoemulsification, unsatisfied patients reported worse OSDI scores and would need to determine, to what extent postoperative dry eye could also be responsible for these findings [23].

Regarding the negative correlation between pupil size and halos, Oshika et al. have reported the higher influence of coma-like aberrations on visual performance in LASIK patients with smaller pupils, and could also explain our findings [24]. This could also explain why myopic LASIK patients reported higher satisfaction, for all VA distances, and less difficulties than those with hyperopic laser treatment (p=0.08). In addition, the MF-IOL aspheric design might be contributing to improving visual quality in myopes and Alfonso et al. found no differences in corneal aberrations for patients with previous myopic LASIK implanted with diffractive IOL [2]. We found higher RMS in myopes than hyperopes (3.6 *vs.* 1.1 μm; p=0.3), which can be attributed to the small case sample, and aberrations will be accounted for in future studies with larger samples. Linear regression analysis concluded greater near vision difficulty was associated to higher post LASIK negative SE and sphere (R^2=0.60 and R^2=0.70), significant for the former (p ≤ 0.01). Bissen-Miyajima et al. concluded degradation in contrast sensitivity was greater for post-LASIK eyes with higher myopic corrections, after implantation of diffractive IOL for cataracts [17]. Although both hyperopic and myopic patients reported similar night driving difficulties (2 ± 1.8 and 1.6 ± 1.7 points, respectively; p=0.7), we can highlight that linear regression analysis showed significant association with greater post LASIK negative SE in myopes (R^2=0.90; p=0.001). This result is consistent with a previous report associating greater night difficulties on myopic patients with higher attempted degree of LASIK corrections [25]. Pop et al. also reported no association between pupil diameter and night driving difficulties in myopes after LASIK, as our study also showed, (R^2=0.14) [26,27].

It remains unclear whether these worsened after a MF-IOL implantation and a pre-operative questionnaire could help.

After at least 12 months, UCVA for all patients improved a mean of five lines, BCVA significantly improved in 20% of all eyes, patients are highly satisfied, 63% manifested halos or night driving difficulties, 38% near vision difficulties, and most are spectacle free. Despite scoring visual difficulties, 94% would repeat the procedure.

This study is limited due to its retrospective nature of a small sample case series, the inclusion of different MF-IOL models for clear lens and cataract patients, lack of objective intermediate VA data, no preoperative questionnaire, and need for longer post-operative follow-up. In addition, MF-IOLs were not chosen according to refractive error however another study reported results of implanting the same diffractive and segmental IOL in both hyperopes and myopes [28]. However, it provides us with information regarding a patient group, which will be seeking presbyopia correction with the latest premium IOLs.

Patients with previous refractive surgery and trifocal or segmented MF-IOL implantation were generally satisfied and significantly improved post-operative far and near UCVA. Post LASIK SE, in myopic patients with MF-IOL implantation, could determine postoperative visual difficulties, although further study and follow-up is required.

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