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Managing dissatisfaction after multifocal intraocular lens implantation through lens exchange using monofocal or alternative multifocal IOLs

Olena Al-Shymali¹ | Mario Cantó-Cerdán¹ | Jorge L. Alió del Barrio^{1,2} | Colm McAlinden^{3,4,5} | Pilar Yebana¹ | Jorge L. Alio^{1,2}

¹Cornea, Cataract and Refractive Surgery Unit, Vissum (Miranza Group), Alicante, Spain

²Division of Ophthalmology, School of Medicine, Universidad Miguel Hernández, Alicante, Spain

³Corneo Plastic Unit & Eye Bank, Queen Victoria Hospital, East Grinstead, UK

⁴Eye & ENT Hospital of Fudan University, Shanghai, China

⁵School of Optometry and Vision Sciences, Cardiff University, Cardiff, UK

Correspondence

Jorge L. Alio, Vissum Miranza Alicante, Cornea, Cataract and Refractive Surgery Unit, Vissum (Miranza Group), Universidad Miguel Hernandez, Alicante. Spain, Calle Cabañal 1, 03016 Alicante, Spain.

Email: jlalio@vissum.com

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Abstract

Purpose: To manage patient dissatisfaction following multifocal intraocular lens (MF-IOL) implantation by IOL exchange with either a monofocal or an alternative MF-IOL, and to compare outcomes in these two groups.

Methods: MF-IOL exchange was performed in 32 patients (64 eyes) with neuroadaptation failure. The MF-to-MF group involved patients who had a MF-IOL exchanged with another MF-IOL of a different optical profile and the MFto-MO group involved patients who had a MF-IOL exchanged to a monofocal IOL. Visual outcomes and complications were analysed. The Quality of Vision (QoV) questionnaire, Visual Function Index (VF-14) and its Rasch-revised version (VF-8R) were also used to assess outcomes.

Results: There were no significant differences (p > 0.05) in the QoV scores between the two groups, both preoperatively and postoperatively. Preoperatively, there were no significant differences in VF-14 scores between both groups (p > 0.05). Postoperatively, there were statistically significant differences in VF-14 (total score, intermediate vision and near vision) in favour of the MF-to-MF group (p < 0.05). The postoperative VF-8R score in the MF-to-MF group was significantly better than the MF-to-MO group ($p \le 0.001$). Uncorrected and corrected near as well as corrected distance visual acuities were significantly better (p < 0.05) in the MF-to-MF group compared to the MF-to-MO group at 3 months. **Conclusion:** Patient dissatisfaction and neuroadaptation failure following MF-IOL implantation can be managed by an IOL exchange with an alternative optical design of MF-IOL or a monofocal IOL. Although, in the current study, the MF-to-MF group showed some better postoperative results, both options are feasible solutions.

KEYWORDS

dissatisfaction after multifocal intraocular lens implantation, monofocal intraocular lens, multifocal intraocular lens explantation, multifocal intraocular lenses, neuroadaptation failure, patient satisfaction, quality of vision

1 | INTRODUCTION

Multifocal intraocular lenses (MF-IOLs) are expected to ensure good vision and spectacle independence at all distances. In general, patients are satisfied after MF-IOL implantation (Rosen et al., 2017; Venter et al., 2013). However, in some cases, MF-IOLs have been associated with adverse effects leading to patient dissatisfaction (de Vries et al., 2011; Woodward et al., 2009). When the cause of dissatisfaction is residual ametropia, posterior capsular opacification (PCO) or dry eye syndrome, it can be treated accordingly (Alio et al., 2007, 2017; de Vries et al., 2011; Gibbons et al., 2016; Woodward et al., 2009). Nevertheless, when it comes to be a real

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neuroadaptation failure, IOL explantation may be the only solution available for such dissatisfied patients (Al-Shymali, Alió Del Barrio, et al., 2022, Al-Shymali, McAlinden, et al., 2022).

The common practice following explanation of a MF-IOL is to exchange it with a monofocal IOL (Alsetri et al., 2022; Al-Shymali, Alió Del Barrio, et al., 2022; Al-Shymali, McAlinden, et al., 2022; Davies & Pineda 2nd, 2016; Fernández-Buenaga et al., 2012; Galor et al., 2009; Jones et al., 2014; Kamiya et al., 2014; Kim et al., 2017; Mamalis et al., 2008; Naujokaitis et al., 2022; Tassignon et al., 2014). Although this option provides good visual function for distance, and a significant improvement in subjective photic phenomena (Al-Shymali, Alió Del Barrio, et al., 2022; Al-Shymali, McAlinden, et al., 2022), a recent study by our group suggested that explanted MF-IOLs (due to neuroadaptation failure) can be exchanged with an alternative MF-IOL with a different optical profile (Al-Shymali, Alió Del Barrio, et al., 2022; Al-Shymali, McAlinden, et al., 2022). This treatment option was shown to be feasible, while keeping a satisfactory unaided near visual function, which is the primary motivation why a multifocal IOL was initially selected. According to this previous evidence, in the current study we aimed to compare the visual outcomes and patient satisfaction between patients that underwent exchange of a MF-IOL with another MF-IOL (of different optical profile) and patients that underwent an exchange of a MF-IOL with a monofocal IOL, to help determine the best approach to neuroadaptation failure after MF-IOL implantation.

2 | MATERIAL

This consecutive case series obtained approval from the Institutional Ethical Board Committee and was conducted in accordance with the Declaration of Helsinki (64th WMA General Assembly, Fortaleza, Brazil, October 2013). All patients signed informed consent.

2.1 | Patient selection

Patients who developed real neuroadaptation failure, following the exclusion of other causes of postoperative dissatisfaction, after bilateral implantation of MF-IOLs with their further explantation were included in the study. Patients were divided into two groups: MF-to-MF group included patients who had bilateral MF-IOLs explantation followed by the implantation of other MF-IOLs of a different optical profile, and MF-to-MO group included patients who had bilateral MF-IOLs exchange with monofocal IOLs. In the MF-to-MF group, the selection of the new MF-IOL was performed as follows: Cases implanted with any type of diffractive technology were exchanged by a refractive optical design. Those implanted with a refractive multifocal optic were exchanged with a diffractive MF-IOL. EDOF lenses were exchanged with either a diffractive or refractive MF-IOL. Such a decision was made under the hypothesis that different optical designs activate e1041

and follow different neuroadaptation mechanisms. The decision of implanting a MF-IOL in the first place and afterwards choosing the next IOL whether monofocal, MF or EDOF for exchange is very individualized. We dedicated extensive chair time to the patients to inform them conveniently about the procedures and to study their personality, lifestyle and expectations. The IOL models explanted and implanted in each patient of both groups are presented as (Table S1). Patients with anatomical causes for the exchange, such as lens decentration, were excluded.

Selection of the explanted cases was performed in the framework of the Iberia Biobank database of explanted ophthalmic devices (UMH, Alicante, Spain). All exchange procedures were performed by the same surgeon (JLA) at Vissum (Miranza Group; Alicante, Spain). Exchange surgery was considered after at least 3 months of neuroadaptation failure presumed to have been caused by the implanted lens, in the absence of any residual ametropia or anatomical findings that could justify the dissatisfaction. This study includes cases used in our previous papers concerning this topic, (Al-Shymali, Alió Del Barrio, et al., 2022; Al-Shymali, McAlinden, et al., 2022) with a greater sample size.

2.2 | Definition of neuroadaptation failure

Neuroadaptation is a gradual adjustment process of the nervous system to neural input changes (Alió & Pikkel, 2019). Such changes include the implantation of a MF-IOL which creates a different distribution of light and creates a superimposition of images that makes the brain accept different images located at different focal distances. As neuroadaptation is an acquired learning process, our brains need time to adapt to the superimposition of images and the decreased contrast sensitivity caused by the implanted MF-IOL (Alió & Pikkel, 2019). Hence, when the brain fails to percept a well-detailed image, neuroadaptation failure occurs (Al-Shymali, Alió Del Barrio, et al., 2022; Al-Shymali, McAlinden, et al., 2022). In this study, we considered that patients had neuroadaptation failure when they reported poor quality of vision, sometimes with loss of best corrected visual acuity, not associated to residual refractive error or any organic reason within 6 months after the implantation of the first MF-IOL. In order to rule out the potential participation of residual refractive error as a cause of the dissatisfaction, a 1 month trial of wearing glasses was prescribed, following which the patients were still not satisfied with their vision. We tried to delay the exchange surgery at least 6 months after MF-IOL implantation in order to give the patient a sufficient amount of time to neuroadapt to the MF-IOL. However, in some very dissatisfied cases, the exchange was performed earlier but not less than 3 months after MF-IOL implantation.

2.3 | Surgical technique

The aim was to preserve the capsular bag in order to re-implant the new IOL into it in both groups. The optic cut technique was used to explant the MF-IOL a Ophthalmologic

(Doctor Jorge Alió YouTube Channel, n.d.; Al-Shymali & Alio, 2019). Intravenous sedation and local peribulbar anaesthesia were used in all cases; two paracentesis of 1.0 mm and a 3.0 mm main incision were made. Intracameral injection of a mixture of tropicamide, phenylephrine and lidocaine (Fydrane, Théa) was used to dilate the pupil. After filling the anterior chamber with a dispersive viscoelastic (Viscoat, Alcon), the IOL was dissected from the capsular bag, especially the rim of the anterior capsule using a cohesive viscoelastic (ProVisc OVD, Alcon) with a 30G cannula. The IOL was loosened from the capsular bag using a Sinskey hook and a Lester hook (Katena) by pressing and moving the lens especially in cases with significant capsular adhesion with IOL. Then, the IOL was placed on the anterior capsular rim and was cut radially to its centre using IOL cutting microscissors (Katena). Then, the IOL was extracted through the main incision using two forceps that were alternated in grasping the IOL while eliminating it from the anterior chamber. Subsequently, the capsular bag was filled with cohesive viscoelastic (ProVisc OVD, Alcon) and the new IOL, either a MF-IOL or a monofocal IOL, was implanted into the capsular bag. The procedure was finalized routinely with intracameral antibiotics (Cefuroxime 10 mg/mL, Normon). If a 10/0 nylon interrupted suture was required for incision sealing, this was then removed 3 weeks post-operatively. Post-operative treatment consisted of topical tobramycin combined with dexame hasone four times a day for 1 week and a non-steroidal anti-inflammatory three times a day for a month.

The group of MF-to-MF had all the second MF-IOLs implanted into the capsular bag. In the MF-to-MO group, the monofocal IOL was implanted into the capsular bag in 19 eyes and the surgeon considered the capsular bag as unsuitable for the new IOL implantation (in relation to the integrity of the posterior capsule) in nine eyes, where a three-piece monofocal IOL was implanted in the sulcus.

The group of MF-to-MF had all the second MF-IOLs implanted into the capsular bag. In the MF-to-MO group, the monofocal IOL was implanted into the capsular bag in 19 eyes and the surgeon considered the capsular bag as unsuitable for the new IOL implantation (in relation to the integrity of the posterior capsule) in eyes, where a three-piece monofocal IOL was implanted in the sulcus.

2.4 | Main outcome measures

Post-operative outcomes between both groups were compared at 3 and 12 months following the exchange. The following parameters were evaluated:

2.4.1 | Visual and refractive outcomes

Uncorrected (UDVA) and corrected distance (CDVA) visual acuity (5 m), uncorrected (UNVA) and corrected (CNVA) near visual acuity (40 cm), as well as refractive

outcomes, were measured and compared between the MF-to-MF and MF-to-MO groups.

2.4.2 | Quality of vision evaluation

The validated Quality of Vision (QoV) questionnaire was administered pre-IOL exchange and 3months post-IOL exchange (McAlinden et al., 2013). The QoV questionnaire includes 10 visual symptoms (glare, halos, starbursts, hazy vision, blurred vision, distortion, double/multiple images, fluctuation in vision, focusing difficulties and difficulties in judging distance or depth perception) and asks patients to respond based on symptom frequency, severity and bothersomeness. Raw data were Rasch-scaled into a 0–100 scale, with one score for each subscale (frequency, severity and bothersome), with lower scores indicating better quality of vision (McAlinden et al., 2010).

2.4.3 | Subjective visual function Index-14 evaluation

Subjective visual function was evaluated using the VF-14 questionnaire. The VF-14 consists of 14 questions describing difficulties encountered by patients even when wearing glasses in their daily life activities. The respondents chose one of five ability levels that range from 'no difficulties' to 'unable to do'. The total score was calculated using a previously described method (Kishimoto & Ohtsuki, 2012). Higher scores indicate better visual function. Additionally, we divided the questions into three groups in order to study visual function in daily activities at different distances. The first contained six questions that best described far vision, the second had three questions for intermediate vision and the third included five questions relating to near vision activities. Scores for each distance were calculated using the same method. Moreover, due to concerns raised over the scoring of the original VF-14, we performed Rasch analysis (using WINSTEPS, Version 3.93.2) to score the eight items of the refined version. This version is known as the VF-8R (Gothwal et al., 2010).

2.4.4 | Satisfaction evaluation

Patients were asked about their overall satisfaction with their near, intermediate and far vision, their spectacle independence for these distances, and if the patient would repeat the surgery again with either the MF-IOL or the monofocal IOL.

2.5 | Statistical analysis

The SPSS software version 20.0 for Windows (SPSS Inc.) was used in this study. Normality was assessed using the Kolmogorov–Smirnov test. The Wilcoxon signed-rank test and Mann–Whitney *U*-test were used for non-normally distributed data. Data were expressed as the

mean \pm standard deviation (SD) and a *p*-value <0.05 was considered statistically significant.

3 | RESULTS

The present study included 64 eyes of 32 patients (48 females; 16 males) that underwent MF-IOL exchange. Mean patient age at the time of IOL exchange was 57.16 ± 6.63 years (range: 42–70 years). Mean time between the implantation of the first IOL and the implantation of the second IOL was 12.28 ± 17.24 months (range: 3-89 months) in both groups. For the MF-to-MF group that time was 10.69 ± 20.04 months while for the MF-to-MO group, the mean time between the two surgeries was 14.32 ± 12.85 months (p=0.002).

3.1 | Visual and refractive outcomes

The analysis of visual outcomes was performed 3 and 12 months post-operatively. Patients had neuroadaptation failure associated with different photic phenomena and visual dissatisfaction despite spectacle correction of residual refractive error if there were any.

Table 1 shows visual and refractive outcomes for both the MF-to-MF group. For the MF-to-MF group, the mean UDVA changed from 0.29 ± 0.31 logMAR preexchange to 0.14 ± 0.12 logMAR 12 months post-exchange (p=0.001). The CDVA improved significantly (p=0.001) from 0.17 ± 0.31 logMAR to 0.03 ± 0.07 logMAR at 12 months post-exchange. Mean UNVA changed from 0.41 ± 0.27 logMAR pre-exchange to 0.37 ± 0.24 log-MAR 12 months post-exchange (p=0.150). The CNVA improved significantly from 0.29 ± 0.28 logMAR to 0.13 ± 0.11 logMAR at 12 months post-operatively (p=0.003). The spherical refractive error changed from e1043

 0.17 ± 0.63 D to 0.32 ± 0.70 D (p=0.270). Cylindrical refractive error changed from -0.41 ± 0.40 D to -0.55 ± 0.47 D (p=0.609). The spherical equivalent (SE) refraction changed from 0.00 ± 0.55 D to 0.01 ± 0.56 D (p=0.529).

Table 2 shows visual and refractive outcomes for the MF-to-MO group. For the MF-to-MO group, the mean UDVA changed from 0.29±0.20 logMAR preexchange to 0.23±0.19 logMAR 12months following exchange (p=0.280). The CDVA improved (p=0.092) from $0.13\pm0.12 \log MAR$ to $0.06\pm0.07 \log MAR$. Mean UNVA changed from $0.36 \pm 0.20 \log MAR$ pre-exchange 0.49 ± 0.21 logMAR 12 months post-exchange to (p=0.002). The CNVA improved from 0.24 ± 0.17 log-MAR to $0.17 \pm 0.15 \log$ MAR (p=0.013). The spherical refractive error changed from 0.23 ± 0.88 D to -0.31 ± 0.63 D (p=0.022). Cylindrical refractive error changed from -0.68 ± 0.51 D to -0.43 ± 0.51 D (p=0.080), and the SE refraction changed from -0.08 ± 0.81 D to -0.44 ± 0.60 D (p=0.041).

Table 3 shows comparative visual and refractive outcomes between the two groups. Before the exchange, there were statistically significant differences (p < 0.05) only in the cylinder. Post-operatively, at 3 months, significant differences appeared in the sphere and SE. In addition UNVA, CDVA and CNVA were significantly better (p < 0.05) in MF-to-MF group compared to MFto-MO group. Post-exchange, at 12 months, significant differences appeared in the sphere and SE, as well as in the UNVA in favour of the MF-to-MF group. At 3 months, efficacy and safety indexes reached 1.04 and 1.38 respectively for the group of MF-to-MF. For the MF-to-MO group, efficacy and safety indexes were 0.85 and 1.22 respectively. There were no significant differences between groups in safety (p=0.296) or efficacy (p=0.561). At 12 months post-exchange, efficacy and safety indexes reached 0.99 and 1.23 respectively for the MF-to-MF group. For the MF-to-MO group,

TABLE 1Refractive and visual outcomes following the first multifocal intraocular lens and the second multifocal intraocular lensimplantation at 3 and 12months postoperative.

	Multifocal to M	ultifocal		p			
	Pre expl	Post 3M	Post 12M	Pre-3M	Pre-12M	3M-12M	
UDVA	$0.29\!\pm\!0.31$	0.18 ± 0.18	0.14 ± 0.12	0.020	0.001	< 0.001	
(logMAR)							
UNVA	$0.41\!\pm\!0.28$	0.28 ± 0.17	$0.37 \!\pm\! 0.24$	< 0.001	0.150	0.003	
(logMAR)							
CDVA	0.17 ± 0.31	0.03 ± 0.05	0.03 ± 0.07	< 0.001	0.001	0.940	
(logMAR)							
CNVA	$0.29\!\pm\!0.28$	0.01 ± 0.05	0.13 ± 0.11	0.001	0.003	0.003	
(logMAR)							
SPHERE	0.17 ± 0.63	$0.36 {\pm} 0.47$	0.32 ± 0.70	0.077	0.270	0.830	
(D)							
CYLINDER	-0.41 ± 0.40	-0.72 ± 0.48	-0.55 ± 0.47	0.007	0.609	0.133	
(D)							
SE	0.00 ± 0.55	0.00 ± 0.52	0.01 ± 0.56	0.929	0.529	0.660	
(D)							

Abbreviations: CDVA, Corrected distance visual acuity; CNVA, Corrected near visual acuity; D, Diopters; M, Months; PRE EXPL, Before explantation of the first multifocal intraocular lens; POST, After the exchange of the first multifocal intraocular lens with another multifocal intraocular lens; SE, Spherical Equivalent; UDVA, Uncorrected distance visual acuity; UNVA, Uncorrected near visual acuity.

TABLE 2 Refractive and visual outcomes following the multifocal intraocular lens and the monofocal intraocular lens implantation at 3 and 12 months postoperative.

	Multifocal to Mo	onofocal		р			
	Pre Expl	Post 3M	Post 12M	Pre-3M	Pre-12M	3M-12M	
UDVA	0.29 ± 0.20	0.25 ± 0.22	0.23 ± 0.19	0.328	0.280	< 0.001	
(logMAR)							
UNVA	$0.36 {\pm} 0.20$	$0.46 {\pm} 0.19$	0.49 ± 0.21	0.008	0.002	0.017	
(logMAR)							
CDVA	0.13 ± 0.12	$0.06 \!\pm\! 0.07$	$0.06 \!\pm\! 0.07$	0.022	0.092	0.946	
(logMAR)							
CNVA	0.24 ± 0.17	0.12 ± 0.14	0.17 ± 0.15	0.002	0.013	0.778	
(logMAR)							
SPHERE	0.23 ± 0.88	-0.35 ± 0.50	-0.31 ± 0.63	0.001	0.022	0.713	
(D)							
CYLINDER	-0.68 ± 0.51	-0.60 ± 0.65	-0.43 ± 0.51	0.532	0.080	0.205	
(D)							
SE	-0.08 ± 0.81	-0.65 ± 0.60	-0.44 ± 0.60	0.002	0.041	0.801	
(D)							

Abbreviations: CDVA, Corrected distance visual acuity; CNVA, Corrected near visual acuity; D, Diopters; M, Months; PRE EXPL, Before explantation of the multifocal intraocular lens; POST, After the exchange of multifocal intraocular lens with monofocal intraocular lens; SE, Spherical Equivalent UDVA, Uncorrected distance visual acuity; UNVA, Uncorrected near visual acuity.

efficacy and safety indexes were 0.84 and 1.14 respectively. Once again, there were no significant differences between groups in safety (p=0.099) and efficacy (p=0.320). Over time, no statistically significant differences were found between the 3-month and 12month post-operative indexes for either the MF-to-MF or MF-to-MO groups (p>0.05).

3.2 | Subjective QoV

When preoperative and postoperative scores were compared in each of the groups separately, a statistically significant improvement was found after the MF-IOL exchange in the frequency, severity and bothersome subscales in both MF-to-MF and MF-to-MO groups (p < 0.05). However, as shown in Table 4, when comparing groups with each other, there were no statistically significant differences (p > 0.05) in all three subscales pre-operatively or post-operatively.

3.3 | Visual function index-14

When comparing the pre-operative and post-operative VF-14 scores in the MF-to-MF group, a statistically significant improvement was seen in all scores (p < 0.05). This indicates an improvement in the visual function in general, for far, intermediate and near vision in patients after the exchange of a MF-IOL to another MF-IOL. On the contrary, in the MF-to-MO group, far and intermediate vision scores improved, but only the improvement in the far vision was statistically significant (p=0.013). The total and the near vision scores worsened, although not significantly (p>0.05), in the MF-to-MO group after the exchange of the MF-IOL with a monofocal IOL. Table 5 shows the results comparing VF-14 scores between both

groups. Pre-operatively, no statistically significant differences existed in any of the scores between the two groups (p > 0.050). Post-operatively, there were statistically significant differences in the total score, intermediate vision and near vision, in favour of the MF-to-MF group (p < 0.05).

The Rasch version of the VF-14, the VF-8R, showed that the mean (\pm SD) post-operative score of the MF-to-MF group (-2.89 ± 1.87) was significantly better than the post-operative score of the MF-to-MO group (-0.25 ± 0.99) ($p \le 0.001$).

3.4 | Patient satisfaction

Tables 6 and 7 show the results of patient satisfaction for the MF-to-MF and MF-to-MO groups respectively. Percentage of patients with 'very good' or 'good' overall post-operative satisfaction with far vision consisted of 83.4% in the MF-to-MF group versus 64.3% in the MFto-MO group. Regarding near vision, 55.6% of patients had 'very good' or 'good' satisfaction in the MF-to-MF group versus 14.3% in the MF-to-MO group. When patients were asked if they would repeat the surgery again, 66.7% answered 'yes' in the MF-to-MF group versus 28.6% in the MF-to-MO group.

3.5 | Complications

In the MF-to-MF group the following complications occurred. Zonular dehiscence occurred in both eyes of one patient that had the initial MF-IOL implantation 89 months previously. The IOL-exchange was performed with placement of the IOL, in both eyes, into the capsular bag after the implantation of a capsular tension ring. Post-operative complications included: PCO requiring

cta Ophthalmologica

e1045

TABLE 3 Comparative refractive and visual outcomes following the first multifocal intraocular lens and the second intraocular lens implantation at 3 and 12months postoperative.

	Preoperative			Postoperative 3 months			Postoperative 12 months		
	Multifocal to Multifocal	Multifocal to Monofocal	р	Multifocal to Multifocal	Multifocal to Monofocal	р	Multifocal to Multifocal	Multifocal to Monofocal	р
UDVA	$0.29\!\pm\!0.31$	0.29 ± 0.20	0.444	0.18 ± 0.18	0.25 ± 0.22	0.142	0.14 ± 0.12	0.23 ± 0.19	0.115
(logMAR)									
UNVA	$0.41\!\pm\!0.28$	0.36 ± 0.20	0.854	0.28 ± 0.17	0.46 ± 0.19	0.006	0.37 ± 0.24	0.49 ± 0.21	0.006
(logMAR)									
CDVA	0.17 ± 0.31	0.13 ± 0.12	0.545	0.03 ± 0.05	0.06 ± 0.07	0.044	0.03 ± 0.07	0.06 ± 0.07	0.318
(logMAR)									
CNVA	0.29 ± 0.28	0.24 ± 0.17	0.859	$0.01\!\pm\!0.05$	0.12 ± 0.14	0.001	0.13 ± 0.11	0.17 ± 0.15	0.592
(logMAR)									
SPHERE	$0.17 {\pm} 0.63$	0.23 ± 0.88	0.493	$0.36 {\pm} 0.47$	-0.35 ± 0.50	< 0.001	0.32 ± 0.70	-0.31 ± 0.63	0.001
(D)									
CYLINDER	-0.41 ± 0.40	-0.68 ± 0.51	0.037	-0.72 ± 0.48	-0.60 ± 0.65	0.187	-0.55 ± 0.47	-0.43 ± 0.51	0.341
(D)									
SE	0.00 ± 0.55	-0.08 ± 0.81	0.897	0.00 ± 0.52	-0.65 ± 0.60	< 0.001	0.01 ± 0.56	-0.44 ± 0.60	0.011
(D)									

Abbreviations: CDVA, Corrected distance visual acuity; CNVA, Corrected near visual acuity; D, Diopters; SE, Spherical Equivalent; UDVA, Uncorrected distance visual acuity; UNVA, Uncorrected near visual acuity.

TABLE 4 Quality of Vision questionnaire Rasch score. Scores of the patients before the exchange of a multifocal intraocular lens and after the exchange with another multifocal intraocular lens or with a monofocal intraocular lens.

	Preoperative			Postoperative		
	Multifocal to Multifocal	Multifocal to Monofocal	р	Multifocal to Multifocal	Multifocal to Monofocal	p
Frequency	61.26 ± 16.42	69.77 ± 14.36	0.091	35.87 ± 29.40	34.46 ± 16.33	0.561
Severity	54.20 ± 17.83	$61.08 \!\pm\! 13.58$	0.157	34.20 ± 32.26	28.46 ± 14.09	0.640
Bothersome	$59.66 \!\pm\! 18.12$	67.92 ± 14.46	0.127	32.33 ± 35.97	28.85 ± 16.22	0.514

Note: The greater the score (maximum 100), the worse is the quality of vision.

 TABLE 5
 Visual Function Index-14 questionnaire score and Visual Functioning Index-8R questionnaire score.

		Preoperative			Postoperative		
		Multifocal to Multifocal	Multifocal to Monofocal	р	Multifocal to Multifocal	Multifocal to Monofocal	р
VF-14	Total Score	58.73 ± 23.06	67.61 ± 25.50	0.342	87.41 ± 13.81	$63.79 \!\pm\! 10.86$	< 0.001
	Far	61.62 ± 22.80	73.65 ± 23.95	0.116	87.94 ± 14.39	90.95 ± 8.78	0.905
	Intermediate	66.90 ± 25.01	$78.87 \!\pm\! 23.71$	0.141	$94.21 \!\pm\! 10.80$	$79.44 \!\pm\! 19.29$	0.005
	Near	53.89 ± 29.13	52.88 ± 36.04	0.834	82.50 ± 18.96	25.00 ± 29.22	< 0.001
VF-8R	Total score	-0.49 ± 1.27	-1.30 ± 2.40	0.639	-2.89 ± 1.87	-0.25 ± 0.99	< 0.001

Note: Mean scores of the patients before the exchange of a multifocal intraocular lens and after the exchange with another multifocal intraocular lens or with a monofocal intraocular lens. The greater the score (maximum 100), the better is the visual function.

a laser posterior capsulotomy in two eyes. Two eyes of a patient showed a moderate decentration following the IOL exchange (a diffractive model), with no impact on the visual outcome.

In the MF-to-MO group the following complications occurred: one eye that had a vertical tear along a previous posterior capsulotomy, with vitreous loss, requiring anterior vitrectomy (the IOL was implanted within the bag eventually). Post-operative complications included mild anterior uveitis post-exchange in one eye that was medically treated successfully. In addition, a decentred IOL was observed in another eye post-operatively. The decentration was approximately 0.7 mm and was caused by the inadequate location of the lens inside the capsular bag that was partially retracted. Despite the dislocation, the QoV scores still improved in this patient with stable visual acuity before and after the exchange. **TABLE 6** The percentage of patients answering four questions regarding their overall satisfaction with their vision for different distances, their willingness to repeat the surgery, their spectacle independency and the frequency of spectacle use, all with the first multifocal intraocular lens versus the second multifocal intraocular lens.

	What wa	as your overall satisfaction with	the vision?			
	With firs	st Multifocal		With second Mu	ltifocal	
	Far	Intermediate	Near	Far	Intermediate	Near
Very good	5.6	0.0	0.0	16.7	38.9	27.8
Good	16.7	27.8	22.2	66.7	27.8	27.8
Average	33.3	44.4	38.9	0.0	16.7	16.6
Bad	5.6	5.6	11.1	11.1	11.1	27.8
Very bad	38.9	22.2	27.8	5.5	5.5	0.0
			Would you re	epeat the surgery?		
			With first M	ultifocal		With second Multifocal
Yes			11.1			66.7
No			88.9			33.3
	Were you s	spectacle independent?				
	With first 1	Multifocal		With second M	ultifocal	
	Far	Intermediate	Near	Far	Intermediate	Near
Yes	83.3	72.2	61.1	88.9	83.3	66.7
No	16.7	27.8	38.9	11.1	16.7	33.3
	Ho	w often you used spectacles?				
	Wit	th first Multifocal		With secon	d Multifocal	
	Far	r Intermediate	Near	Far	Intermediate	Near
Never	94.4	4 88.8	66.7	100.0	94.4	66.7
Almost never	5.	6 5.6	5.6	0.0	0.0	5.5
Sometimes	0.0	0 0.0	5.6	0.0	5.6	0.0
Almost always	0.0	0 5.6	5.6	0.0	0.0	27.8
Always	0.0	0 0.0	16.7	0.0	0.0	0.0

4 | DISCUSSION

In this study, we considered that patients had real neuroadaptation failure when they were dissatisfied with their vision even after we ruled out or treated any possible cause for this dissatisfaction. Such causes may include residual ametropia, posterior capsular opacification, dry eye syndrome or IOL decentration. Residual refractive error has been demonstrated to interfere significantly with subjective satisfaction following MF-IOL surgery (Seiler et al., 2019). In cases of neuroadaptation failure, an IOL exchange may be required. Two separate previous reports from our group showed that exchanging a MF-IOL with either another MF-IOL of a different optical profile or a monofocal IOL are feasible solutions for neuroadaptation failure (Al-Shymali, Alió Del Barrio, et al., 2022; Al-Shymali, McAlinden, et al., 2022). In the current study, we aimed to compare the outcomes of both treatment solutions along with expanding the sample size.

MF-IOL exchange is a complex procedure that can be influenced by various challenges, such as capsular bag retraction or disruption, zonular dehiscence and posterior capsular rupture. Taking into consideration the complications that happened in this consecutives case series, MF-IOL exchange may be considered a safe approach but with meeting certain conditions such as an experienced surgeon and maintaining the capsular bag intact before and during the procedure. In some cases, with dissatisfaction due to neuroadaptation failure that develop PCO, it is important to postpone the Nd: YAG-capsulotomy if the final decision will be MF-IOL exchange.

When evaluating the QoV questionnaire scores, we saw a statistically significant improvement between pre-operative and post-operative values in each group independently. However, no statistically significant difference was found in the quality of vision after the exchange between both groups. On the other hand, there was a statistical significant difference post-operatively in all VF-14 scores except for far vision between both groups. This brings us to the conclusion that the MFto-MF group had a better total, intermediate and near visual function postoperatively compared to the MFto-MO group. When preoperative and postoperative VF-14 scores were compared in each of the groups separately, there was a significant improvement post-exchange in the MF-to-MF group. In the MF-to-MO group, far vision improved significantly while the near vision scores

Acta Ophthalmologica

e1047

TABLE 7 The percentage of patients answering four questions regarding their overall satisfaction with their vision for different distances, their willingness to repeat the surgery, their spectacle independency and the frequency of spectacle use, all with the first multifocal intraocular lens versus the second monofocal intraocular lens.

	What was	your overall satisfaction with	the vision?			
	With Mul	tifocal		With Monof	ocal	
	Far	Intermediate	Near	Far	Intermediate	Near
Very good	0.0	0.0	0.0	21.4	0.0	0.0
Good	0.0	0.0	21.4	42.9	35.7	14.3
Average	50.0	57.2	35.8	35.7	57.2	21.4
Bad	28.6	21.4	21.4	0.0	7.1	7.1
Very bad	21.4	21.4	21.4	0.0	0.0	57.2
			Would you re	epeat the surgery?		
			With Multifo	ocal		With Monofocal
Yes			0.0			28.6
No			100.0			71.4
	Were you spee	ctacle independent?				
	With Multifo	cal		With Monofoc	al	
	Far	Intermediate	Near	Far	Intermediate	Near
Yes	57.1	50.0	35.7	78.6	35.7	0.0
No	42.9	50.0	64.3	21.4	64.3	100.0
	How	often you used spectacles?				·
	With	Multifocal		With Mon	ofocal	
	Far	Intermediate	Near	Far	Intermediate	Near
Never	78.6	71.4	64.3	64.3	21.4	0.0
Almost never	7.1	7.1	0.0	14.3	28.6	0.0
Sometimes	0.0	14.4	0.0	14.3	28.6	21.4
Almost always	14.3	7.1	28.6	7.1	21.4	14.3
Always	0.0	0.0	7.1	0.0	0.0	64.3

decreased, although not significantly, after the exchange. Yet, this non-significant deterioration of the near vision score can be explained by the fact that the patients were asked about their daily activities even with glasses.

Nevertheless, we shall take into account that in the MF-to-MO group, a more myopic refractive outcome was observed (significant difference in sphere and SE compared to the MF-to-MF group). Probably, this is due to bias introduced by the surgeon by ensuring a more myopic outcome when exchanging by a monofocal IOL, while targeting an outcome closer to full emmetropia when a new MF-IOL was planned. This difference in postoperative SE and sphere is likely justifying the non-significant change in UDVA observed in the MF-to-MO group (compared to MF-to-MF group where it was significant), as well as the slightly better efficacy index in the MF-to-MF group, being the safety index equal in both groups.

Previous studies reported that the main cause behind patient dissatisfaction with MF-IOLs was blurred vision. Although most cases improved after Nd: YAGcapsulotomy, spectacles or refractive surgery, some cases required the explantation of the MF-IOL (Woodward et al., 2009) (de Vries et al., 2011). IOL exchange should be carefully considered and must be selected as the last treatment option. Some patients remain dissatisfied after the exchange surgery despite careful selection and good visual acuity obtained after surgery. This may explain the high percentage of patients that answered they would not repeat the surgery again in both groups of this study, especially the MF-to-MO group (71.4%).

When it comes to the satisfaction questionnaire, in the MF-to-MF group, spectacle independence after the exchange for far, intermediate and near vision was 88.9%, 83.3% and 66.7% respectively. While in the MF-to-MO group, the percentages of spectacle independent patients were 78.6%, 35.7% and 0% for far, intermediate and near vision respectively. These findings correlate with previous publications that compared outcomes after the implantation of MF-IOLs and monofocal IOLs, where most of them favoured MF-IOLs in terms of spectacle independency (de Silva et al., 2016; Rosen et al., 2017). This fact was confirmed as well with the UNVA outcome that was significantly better in the MF-to-MF group $(0.37\pm0.24 \text{ logMAR})$ than in the MF-to-MO group $(0.49 \pm 0.21 \log MAR)$ (*p*=0.006) at 12-months follow-up. In regard to the postoperative overall satisfaction with far vision, none of the patients (0%) in the MF-to-MO group graded their vision as 'bad' or 'very bad' while 16.6% of the patients in the MF-to-MF group graded their far vision as 'bad' or 'very bad'.

Taking into consideration all the above mentioned, before the implantation of any MF-IOL it is crucial to explain to the patient the trade-offs of MF-IOLs. The patient should understand the concessions to be made such as decreased quality of vision and contrast sensitivity or some photic phenomena in exchange for convenience of having good visual acuity in all distances. Besides, it is critical that the patient learns about all probable outcomes and complications of the surgery, including the inadequate neuroadaptation process, and their possible solutions. Although MF-IOL exchange is one of those solutions, it is a complicated decision and should be individualized to each patient.

The advantage of this study is the presence of a second group where patients had their MF-IOLs exchanged with monofocal IOLs. This gave us the opportunity to compare the outcomes of both groups and extract the pros and cons of exchanging a MF-IOL to either another MF-IOL or a monofocal IOL. However, the limitations of this study include that it was a consecutive case series and not a randomized controlled trial. Even though the total sample size is not small, it would be preferable to increase the sample size of each group. Part of the outcomes were based on subjective questionnaires answered by the patients; therefore, the study may carry a certain amount of patient expectation bias.

In conclusion, patient dissatisfaction and real neuroadaptation failure are a serious complications following MF-IOL implantation that may force the surgeon to exchange the IOL. This decision should be made carefully since some relevant intraoperative complications may occur, but definitely not skipped as the quality of life of such patients is deeply affected. In addition time runs against the surgeon since the longer the time between the implantation and the exchange, the more is the fibrosis and retraction that may be expected in the capsular bag, and the higher the intraoperative risks or the chances of having an unsuitable capsular bag to keep the lens within it. According to the present study, neuroadaptation failure can be managed by MF-IOL exchange with either a different MF-IOL optical profile or a monofocal IOL. The MF-to-MF group showed better post-operative patient satisfaction thanks to the preservation of the near visual function without glasses, which in the end was the original expectation of the patient when selecting a MF-IOL.

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CONFLICT OF INTEREST STATEMENT

Jorge L. Alio: Akkolens: Consultant/Advisor, Grant Consultant/Advisor; BlueGreen: Support; Biotic: Consultant/Advisor; C.S.O. Srl: Grant Support; Capsulaser: Consultant/Advisor, Grant Support; Carl Zeiss Meditec: Consultant/Advisor, Grant Support; Dompe: Grant Support; Hanita Lenses: Consultant/ Advisor, Grant Support; International Ophthalmology Consultants: Jaypee Highlights Medical Publishers, Inc.: Patents/Royalty; Magrabi: Consultant/Advisor; Mediphacos: Grant Support; Novagali: Grant Support; Oculentis: Consultant/Advisor, Grant Support; Oftalcare Nutravision:; Omeros Corporation: Consultant/Advisor; OPHTEC: Lecture Fees/Speakers Bureau; Presbia: Consultant/Advisor; Santen, Inc.: Consultant/Advisor; SCHWIND Eye-tech-Solutions GmbH: Lecture Fees/ Speakers Bureau, Grant Support; SLACK: Consultant/ Advisor; Springer: Patents/Royalty; Tekia, Inc.: Consultant/Advisor; Teleon: Patents/Royalty; Topcon Medical Systems Inc.: Consultant/Advisor. Colm McAlinden: Dr McAlinden has received consultancy fees/honorarium (past 36 months) from: Acufocus (Irvine, California, USA), Atia Vision (Campbell, California, USA), Bausch and Lomb (Bridgewater, New Jersey, USA), BVI (Liège, Belgium), Coopervision (Pleasanton, California, USA), Cutting Edge (Labége, France), Fudan University (Fudan, China), Hoya (Frankfurt, Germany), Knowledge Gate Group (Copenhagen, Denmark), Johnson & Johnson Surgical Vision (Santa Ana, California, USA), Keio University (Tokyo, Japan), Ludwig-Maximilians-University (München, Germany), MedeviseConsultingSAS(Strasbourg, France), OphtecBV (Groningen, The Netherlands), SightGlass vision (Menlo Park, California, USA), Science in Vision (Bend, Oregan, USA), Scope (Crawley, UK), SpyGlass (Aliso Viejo, California, USA), Sun Yat-sen University (Guangzhou, China), Targomed GmbH (Bruchsal, Germany), Thea pharmaceuticals (Clemont-Ferrand, France), University of São Paulo (São Paulo, Brazil), Vold Vision (Arkansas, USA). Dr McAlinden has received travel expenses from (past 36months): Bayer (Leverkusen, Germany), British Society of Refractive Surgery (Oxford, UK), Portuguese Society of Ophthalmology (Coimbra, Portugal), Royal College of Ophthalmologists (London, UK), Scope (Crawley, UK), Thea pharmaceuticals (Clemont-Ferrand, France). Dr McAlinden developed the Quality of Vision (QoV) questionnaire and the Orthokeratology and Contact Lens Quality of Life Questionnaire (OCL-QoL), and has a financial interest in these tools. He also consults on topics including Rasch analysis, questionnaires, statistical analyses and clinical/surgical ophthalmology topics. Dr McAlinden is a co-applicant on an awarded Welsh Government research grant related to diabetic eve disease (unpaid role), council member of the British Society for Refractive Surgery (unpaid role) and a PROM advisor to the Royal College of Ophthalmologists (unpaid role). Dr McAlinden has undertaken paid peer reviews for Research Square (Durham, North Carolina, USA). Dr McAlinden is an editorial board member for Graefe's Archive for Clinical and Experimental Ophthalmology, Eye and Vision, Archives of Medical Science, Journal of Clinical Medicine, Journal of Ophthalmology, and Journal of Clinical and Experimental Ophthalmology. Dr McAlinden is an Associate Editor for Frontiers in Medicine – Ophthalmology. Jorge L. Alió del Barrio: consultant for Teleon, and has received research and travel grants from CSO. Olena Al-Shymali: No financial disclosures. Mario Cantó-Cerdán: No financial disclosures. Pilar Yebana: No financial disclosures.

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ORCID

Colm McAlinden https://orcid. org/0000-0002-4517-4616 *Jorge L. Alio* https://orcid.org/0000-0002-8082-1751

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SUPPORTING INFORMATION

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