16 Multifocal Intraocular Lenses: The Hanita Family of Lenses

Jorge L. Alió, Alfredo Vega-Estrada, and Ana B. Plaza-Puche

16.1 Background

Using multifocal (MF) intraocular lenses for improving refractive and optical quality outcomes to fulfil high visual expectations for intermediate near and distance vision has become the main target after cataract surgery with the aim of improving quality of life of the patients [1–4].

In the current chapter we present a model of apodized diffractive IOL, with an asymmetrical light distribution: the SeeLens MF (Hanita Lenses R.C.A Ltd., Kibbutz Hanita, Israel). The SeeLens MF is an aspheric apodized diffractive multifocal IOL with an optic diameter of 6.0 mm and an overall length of 13.0 mm. The incident light is distributed with 65% to distance focus and 35% to near focus for a 3 mm diameter pupil. This IOL generate +3.00D addition power for near vision equivalent to 2.4D in the spectacle plane.

Many studies [5–8] have reported visual outcomes and optical quality with several models of diffractive IOLs, including a clinical trial where analysis of patients who underwent cataract surgery and were implanted bilaterally with The SeeLens MF was performed.

In the present chapter we summarized the clinical outcomes of this multifocal diffractive IOL evaluating the visual and optical quality, and quality of life in patients who underwent cataract surgery and were implanted with the SeeLens apodized diffractive multifocal IOL. Additionally, we present the main features of the new BunnyLens MF IO which is design with four points haptics that provides excellent centration within the capsular bag and that together with the SeeLens MF comprises what the Hanita company defines as the Full Range Multifocal IOL.

16.2 SeeLens MF IOL

In order to provide a perspective of this IOL we summarizes the clinical investigations conducted by our research group that was performed to analyse the clinical results of this multifocal intraocular lens.

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16.2.1 Patients

In a clinical study performed by our research team it was included 20 eyes of 10 bilateral cataract surgery patients ages ranging from 58 to 71 years old and that underwent phacoemulsification cataract procedure with SeeLens IOL implantation. The inclusion criteria for the study was the following: bilateral cataract, patients older than 50 years, corneal astigmatism of less than 1D. The exclusion criteria were patients with active ocular diseases, visually significant corneal scars, and known retinal disorders.

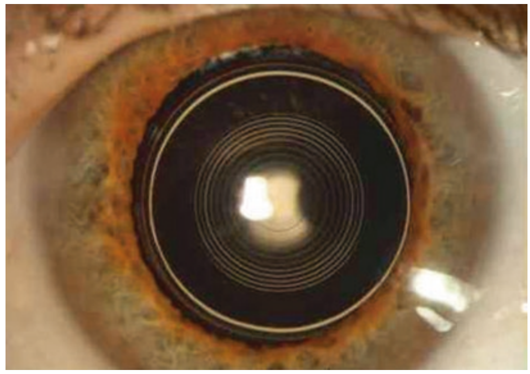


Fig. 16.2 Slit lamp view of the eye from a patient implanted with the SeeLens MF IOL

16.2.2 The Intraocular Lens

The SeeLens (Figs. 16.1 and 16.2) has an optimized optic that is aimed to provide optimal energy distribution in different light conditions, minimize spherical aberrations, and generate +3.0D addition power for near vision, equivalent to +2.4D at the spectacle plane. The IOL introduces diffractive steps that are located in the 4 mm central zone, suiting pupil sizes in various lighting conditions. The steps follow an apodization function, meaning they reduce in height according to an algorithm designed so the patient can function comfortably all day long. The aspheric surface integrated with the diffractive profile is the SeeLens AF aberration free optic, which has been clinically proven to provide excellent vision in all conditions. In photopic conditions, when the pupil is small, the SeeLens MF distributes 65% of the light for far vision and 35% for near vision, providing light for all daytime activities. In mesopic and scotopic conditions, distance vision gets most of the light energy, enabling night vision, and driving in the dark, when the pupil is enlarged.

Fig. 16.1 Schematic view of the SeeLens multifocal intraocular lens

This lens has concentric rings located at 4 mm from the middle, allowing a good adaptation to any pupil size. With this design an optimal distribution of energy is produced in different light conditions, minimizing spherical aberrations. Apodization concept refers to a property of the diffractive steps, such that the height of these is gradually reduced from the center to the periphery, providing a distribution of light energy dependent pupil. Therefore, to increase the pupil diameter in mesopic conditions, the proportion of light to a distance focus increases. This principle provides increased image quality decreasing halos and glare, improving contrast sensitivity.

16.2.3 Surgical Technique

Cataract procedures can be performed using a standard technique of sutureless microincision (MICS) phacoemulsification. All patients received topical anesthesia during surgery. The main incision is placed on the axis of the positive corneal meridian. The IOL is implanted in the capsular bag through a corneal incision of 1.8 mm. Postoperative topical therapy included a combination of topical antibiotic and steroid agents (Tobradex® Alcon Cusí Inc., Barcelona) that are administered during 1 week. In addition nonsteroides anti-inflammatory drops (Diclofenaco Alcon Cusí Inc, Barcelona) are administered during 6 weeks.

16.2.4 Preoperative and Postoperative Examination

Before cataract surgery all patients underwent a complete ophthalmic examination, including the evaluation of the refractive status, the distance and near visual acuities, slit lamp examination, tonometry, and funduscopy. Distance and near visual acuity was measured with the ETDRS charts. Other important clinical measures were corneal topography with the CSO (Costruzione Strumenti Oftalmici), ocular aberrometry with KR1W (Topcon Corp), and biometry with IOL Master (Zeiss). In the postoperative examination, patients were evaluated during the follow-up at 1st day, 1st week, and 1st, 3rd, and 6th month after surgery. At 3rd and 6th months, contrast sensitivity function in photopic (85 cd/m^2) and scotopic (3 cd/m^2) conditions with CST 1800 (Vision Sciences Research Corp) and the defocus curve were also evaluated. In order to perform the defocus curves, the visual acuity was measured with the ETDRS charts at 4 m.

At 6th month after surgery, functional visual impairment and quality of life was assessed by performing the Visual Functioning Index (VF-14) questionnaire. Each question had five possible responses graded (0–4: 0, no difficulty; 1, a little difficulty; 2, moderate difficulty; 3, quite difficulty; 4, impossible performed).

16.3 Clinical Outcomes After SeeLens MF IOL Implantation

16.3.1 Visual and Refractive Results

Table 16.1 shows the visual and refractive results from preoperative to 6 months after surgery with the SeeLens MF. A significant improvement was observed at 6 months in the uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), uncorrected near visual acuity (UNVA), and corrected near visual acuity (CNVA).

Table 16.1 Comparative table showing the preoperative and postoperative visual condition of patients included in this study

Mean Range	Preoperative	3 Months	6 Months
UDVA	0.19 0.05 to 0.50	0.60 0.10 to 1.00	0.60 0.10 to 1.00
Sphere (D)	−0.41 −5.00 to +3.50	0.16 −0.75 to +2.00	0.10 −3.00 to +2.00
Cylinder (D)	−0.78 −1.75 to 0.00	−0.70 −1.50 to 0.00	−0.81 −2.25 to 0.00
CDVA	0.46 0.10 to 1.00	0.86 0.20 to 1.00	0.91 0.64 to 1.00
UNVA	0.24 0.40 to 1.00	0.48 0.10 to 1.00	0.56 0.24 to 1.00
CNVA	0.44 0.10 to 1.0	0.71 0.24 to 1.00	0.92 0.50 to 1.00
Addition	2.73 2.50 to +3.00	0.88 0.00 to 2.50	0.81 0.00 to +1.50

Abbreviations: *D* diopters, *UDVA* uncorrected distance visual acuity, *CDVA* corrected distance visual acuity, *UCNVA* uncorrected near visual acuity, *CNVA* corrected near visual acuity

Regarding manifest refraction no significant changes were found in the sphere and cylinder during the follow up period.

These results are similar to those reported by other authors, which also observed a significant improvement in the different ranges of vision that were evaluated using MF IOL. Although most patients achieved a functional visual acuity for distance and for near with different models of diffractive IOLs, a main limitation is the poor intermediate vision that this technology provides [7]. In the design of the SeeLens MF IOL, however, an aspheric surface together with an optimized diffractive optic may improve the intermediate vision of patients as clinical results showed [8].

16.3.2 Defocus Curve Results

The mean defocus curve for eyes implanted with the SeeLens MF is reported in Fig. 16.3.

This multifocal IOL provides two peaks of maximum vision, one at far distance (around 0 defocus level) and one at near vision (around −2.5 D defocus level). Between these two peaks, defocus of approximately −1.5 D was observed which provides adequate intermediate vision (better than 0.3 in LogMAR scale). This slight slope between these two peaks means that patients can achieve adequate and functional intermediate visual acuity. One of the reasons that could explain these findings may be related to the fact that the new design of this IOL is based on an aspheric refractive–diffractive apodized profile.

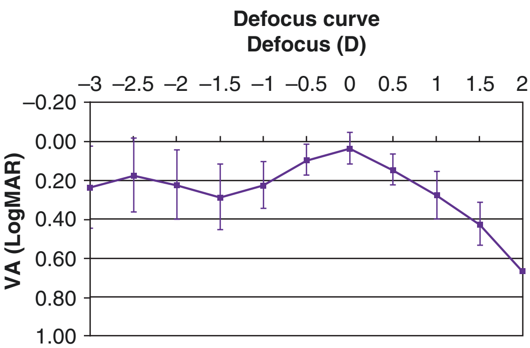


Fig. 16.3 Mean defocus curve of the patients implanted with the SeeLens MF IOL. It can be observed two peaks of maximum vision, one at distance (around 0 defocus level) and one at near (around −2.5 D defocus level). Between these two peaks, defocus of approximately −1.5 D provides adequate intermediate vision

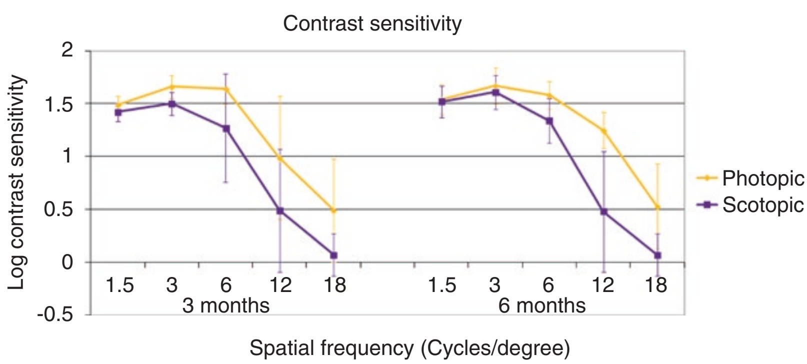
16.3.3 Contrast Sensitivity Function Results

In relation to contrast sensitivity function (CSF), results after SeeLens MF implantation are shown in Fig. 16.4. A significant increase in scotopic contrast sensitivity for 6 cycles/° spatial frequency during follow-up ($p = 0.04$) was found, but no significant changes were observed for the rest of spatial frequencies ($p \geq 0.06$). Regarding the photopic CSF, when compared with the normal population of the same age, the results obtained with the SeeLens MF are within physiological levels. Nevertheless in scotopic conditions a reduction in CSF after surgery was found when compared with normal population of the same age. This reduction in the contrast sensitivity function might be due to dispersion of energy (light) that occurs and is more pronounced in low light conditions [9, 10]. However and despite this reduction, there is a trend to get a better perception in the contrast of the image between the 3rd and 6th month after surgery which most probably is related to neuroadaptation process observed in patients implanted with multifocal IOLs [11].

16.3.4 Ocular Aberrometric Results

Figure 16.5 shows the internal aberrometric outcomes as measure with the KR1W (Topcon Corp.). Six months after SeeLens MF implantation, there

Fig. 16.4 It shows the mean postoperative contrast sensitivity function (CSF) in logarithmic scale under photopic and scotopic conditions at 3rd and 6th months after surgery



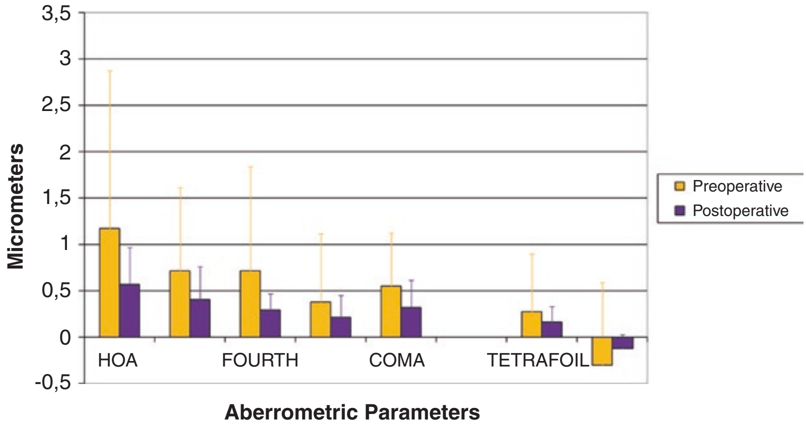


Fig. 16.5 Evolution of the internal aberrations throughout the follow up period. As shown in the graphic, there is a significant reduction for the RMS (root mean square) of the internal high-order aberrations 6 months after implantation of the SeeLens MF IOL

was a significant reduction for the RMS of the internal high-order aberrations and in the coma aberration ($p \leq 0.04$). Also, a significant reduction for the RMS for the third and fourth order aberrations was detected (both $p = 0.03$). However, in other Zernike coefficients as the internal trefoil, tetrafoil, and spherical aberrations, no significant changes were observed in ($p \geq 0.41$).

Regarding optical quality analysis, a significant increase of the ocular Strehl ratio was observed from 0.11 ± 0.06 preoperative to 0.19 ± 0.11 at 6 months after surgery ($p = 0.02$). In addition, the mean postoperative Strehl ratio was better than those observed in a normal population of the same age and was comparable to values obtained in young, healthy patients. These results were better than those published previously with other types of diffractive IOLs [12, 13]. One fact that it has to be have in mind is that optical quality analysis was performed with the KR1W ocular aberrometer that based its assessment in Hartmann–Shack technology which might induce some limitations when evaluating diffractive optics.

Table 16.2 Mean values of the VF-14 QOL Questionnaire items at 6 months postoperatively

Items	Punctuation
1. Reading small print, such as medicine bottle labels, a telephone book, or food labels	1.00 ± 0.93
2. Reading a newspaper or a book	0.50 ± 0.53
3. Reading a large-print book or large-print newspaper or numbers on a telephone	0.13 ± 0.35
4. Recognizing people when they are close to you	0.33 ± 0.71
5. Seeing steps, stairs, or curbs	0.11 ± 0.33
6. Reading traffic signs, street signs, or store signs	0.11 ± 0.33
7. Doing fine handwork like sewing, knitting, crocheting, carpentry	0.75 ± 0.89
8. Writing checks or filling out forms	0.63 ± 0.74
9. Playing games such as bingo, dominos, card games, or mahjong	0.00 ± 0.00
10. Taking part in sports like bowling, handball, tennis, golf	0.00 ± 0.00
11. Cooking	0.00 ± 0.00
12. Watching television	0.22 ± 0.44
13. Driving during the day	0.20 ± 0.45
14. Driving at night	1.20 ± 0.45

Grading scale: 0, no difficulty; 1, little difficulty; 2, moderate difficulty; 3, quite difficulty; 4, impossible performed

16.3.5 Quality of Life Questionnaire Results

Quality of life after cataract surgery and SeeLens MF IOL implantation was evaluated with the Visual Functioning Index (VF-14) questionnaire at 6th month after surgery. Table 16.2 shows the responses of the patients to this questionnaire.

Patients found more difficulty reading small print, such as medicine bottle labels, a telephone book, or food labels and for driving at night. In despite of finding more difficulty in reading small prints letter, most of the responses to the questionnaire showed high levels of satisfaction when doing the tasks that often take place in their daily life.

16.4 The BunnyLens MF

In the recent years, Hanita lenses launch a new multifocal IOL with four point haptics defined as the BunnyLens MF IOL (Fig. 16.6).

This lens is manufactured in a hydrophilic acrylic HEMA/OEMA copolymer with an UV blocker and violet light filter. It has an overall diameter of 11 mm and optic diameter of 6 mm, and it comes in a power range from 10 to 35 diopters. The lens has a multifocal diffractive apodized aspheric optic with a 360° continuous square edge that significantly reduces the rate of posterior capsular opacification. The aspheric diffractive optic of the BunnyLens distributes the light energy in different focis, which generates a + 300 diopters addition equivalent to +2.4 in the spectacle plane. The diffractive steps are located within the 4 mm central zone suiting pupil size in different light conditions. The lens can be placed within the capsular bag through a small corneal incision of 1.8 mm. Another new characteristic of this multifocal IOL is that has four point haptics design with provides an excellent centration within the eye a feature of a major relevance when implanting MF IOL.

Fig. 16.6 Schematic view of the BunnyLens multifocal intraocular lens

Together the BunnyLens and the SeeLens MF IOLs belongs to what the Hanita company defines as the Full Range Optics IOL designs to provide spectacle free independence in different distance conditions in patients operated of cataract surgery.

16.5 Conclusion

The SeeLens MF IOL can restore distance and near vision in presbyopic patients undergoing cataract surgery. Additionally, this IOL provides functional intermediate vision with an adequate intraocular optical quality performance which places this IOL as a suitable choice within the different alternatives of diffractive multifocal IOL. The SeeLens MF IOL provides a high level of satisfaction in patients with most of them reporting spectacle independence for most of their daily activities. Finally, the SeeLens and the BunnyLens belongs to the Hanita family MF IOL and are what the company defines as the Full Range Optic IOLs which are lenses design to provide a solution for presbyopia while reducing known complications associated with most diffractive lenses.

What is the best of the Hanita Family Lenses

The main advantages of these lenses are the following:

- High level of patient's satisfaction
- Good near and far vision
- Low rate of posterior capsular opacification
- Can be implanted through 1.8 mm corneal incision
- Good optical quality with an adequate contrast sensitivity function

The main pitfalls of these lenses are:

- Poor intermediate vision
- Presence of halos and glare

Compliance with Ethical Requirements Jorge L. Alió, Alfredo Vega-Estrada, and Ana B. Plaza-Puche declare that they have no conflict of interest. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all patients for being included in the study. No animal studies were carried out by the authors for this chapter.

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